



**PRESCRIPTION DRUG DIVERSION  
AND COUNTERFEITING—Part 1**

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**HEARINGS**  
BEFORE THE  
SUBCOMMITTEE ON  
OVERSIGHT AND INVESTIGATIONS  
OF THE  
COMMITTEE ON  
ENERGY AND COMMERCE  
HOUSE OF REPRESENTATIVES  
NINETY-NINTH CONGRESS  
FIRST SESSION

JULY 10, AUGUST 7, SEPTEMBER 19,  
OCTOBER 31, AND DECEMBER 6, 1985

**Serial No. 99-61**

for the use of the Committee on Energy and Commerce

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# PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING

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WEDNESDAY, JULY 10, 1985

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:07 a.m., in room 2322, Rayburn House Office Building, Hon. Gerry Sikorski, presiding (Hon. John D. Dingell, chairman).

Mr. SIKORSKI. The subcommittee will come to order. I will begin by reading the opening statement of the Chairman Dingell.

Today's hearing on the diversion of prescription drugs and other products is the first in what is anticipated to be a series of hearings into this serious and complex problem. This morning, we are releasing a preliminary report on drug diversion prepared by the subcommittee staff.

The staff report summarizes the publicly available portion of the information developed through several months of investigation and is intended to define the problem. The subcommittee intends to convene further hearings this fall at which time all elements of the pharmaceutical industry will be invited to present their views. This investigation, which grew out of the subcommittee's inquiry into product counterfeiting in the last Congress, was unanimously approved by the members of the current subcommittee in March 1985.

The subcommittee had hoped to take testimony from industry and Government personnel familiar with recent drug diversion cases, such as the introduction into the U.S. domestic market of counterfeit Ovulen-21 birth control pills. However, because this and other cases remain the subject of active criminal investigation, the subcommittee has deferred public exploration of these matters. We have been assured that several criminal cases will have been completed, or at least entered the public stage, by this fall.

Now, despite the need to defer public comment on certain open criminal cases, there is more than enough information available to demonstrate that American consumers and legitimate American businessmen and women face serious problems because of prescription drug diversion. As the staff report explains, consumers cannot be certain that the pharmaceuticals they purchase are safe and effective. Moreover, wholesale distributors and retail pharmacists suffer unfair and apparently illegal competition as a result of drug diversion.

Finally, the ability of the Food and Drug Administration or the manufacturers to recall pharmaceuticals is seriously undermined by the operation of the diversion market.

The subcommittee intends to investigate this problem carefully and fully, so that appropriate solutions can be developed before the serious potential danger posed by wide-scale drug diversion becomes a sad reality.

This concludes Chairman Dingell's opening statement.

I would like to, for the record, introduce, with unanimous consent, my opening statement without objection.

[The prepared statement of Mr. Sikorski follows:]

STATEMENT OF HON. GERRY SIKORSKI

Mr. Chairman, I would like to commend you for bringing this topic out of the shadows and into the light of investigation. People in the pharmaceutical industry have spoken about this problem, in whispers for many years. But it has taken unfortunate circumstances like the Tylenol murders and the "Ovulen 21" disaster to focus national attention on the source and quality of the drugs we use. Congress and industry have acted by making product tampering a Federal crime and produce packaging tamper-proof, hoping to prevent more deaths and relieve consumer anxiety.

However, now the problem of drug diversion poses a serious threat to the lawful distribution and maintenance of top quality drug merchandise—a threat which has the capacity to undermine the quality of America's drugs and the public's confidence in the drugs that they need and buy.

In the "Ovulen 21" case last fall, nearly 2 million bogus birth control pills were imported from Panama and distributed through legitimate channels. The effectiveness of these pills was zero. What do we tell the thousands of women who were trying to be responsible about birth control?

Through this illegal subterranean "diversion market", bargain price drugs which have been mislabeled, improperly stored, or are outright counterfeits, get into the retail chain and make their way to the public. These drugs are bad for business. They damage the reputations of manufacturers, retailers, and wholesalers alike. They tilt the economic playing field away from legitimate businesses and toward those out for a quick kill. They can harm the public and they undermine an important component of the Nation's health delivery system.

I'm certainly not against a bargain. Manufacturers, distributors and retailers are entitled to negotiate the best sale price and, in good faith, meet or beat the competitor's price. There's nothing wrong with that. It's just that I want to be sure of what my family and I are getting. When I bought my ticket from Minnesota to Washington this week, I expected to go on a jet, not a balsa wood model airplane with a rubber band.

There are several techniques used for diverting drugs, involving reportedly hundreds of millions of dollars in this illegal or quasi-legal market. There is the classic U-boat diversion, the sale of "surplus" pharmaceuticals by hospitals, the marketing of relabeled counterfeit or spoiled drugs and the diversion through non-profit institutions in unfair and illegal competition with private pharmacies.

Drug diversion is bad for manufacturers, bad for retailers, bad for distributors, and bad for the American public. Through these hearings we hope to learn exactly what is at stake; how much trade there is in counterfeit pharmaceuticals; how much capital is being diverted out of legitimate trade channels along with these drugs; whether there is a connection to organized criminal elements and money laundering; and what exactly is the threat to the health of the American public both from the goods themselves and from the corresponding loss of integrity suffered by industry?

Mr. WYDEN. Mr. Chairman.

Mr. SIKORSKI. The gentleman from Oregon.

Mr. WYDEN. Thank you very much, Mr. Chairman.

I just have a brief opening statement. I want to commend the subcommittee staff in particular for developing a very excellent

report, because I think what we have here is a public health disaster that's waiting to happen.

Ripoff artists and con men have developed a pipeline for foisting off ineffective pharmaceuticals on the American consumer. We have got to move quickly to shut this pipeline down. If we don't, a lot of innocent consumers in this country could get hurt.

There is a role for the Federal Government through two agencies, the Food and Drug Administration and the Federal Trade Commission, to help us deal with this problem. Also at the State level, pharmacists are obligated to be trained to make sure that medications come from reputable pharmacies. But between these two points of control lies a vast and hazy area, an area that is populated by wholesale distributors who transport and sell prescription medicine without adequate controls or adequate oversight.

This is where diversion of drugs is taking place, and it is creating a situation where consumer safety could be jeopardized through the mingling of drugs that are authentic and counterfeit, effective and ineffective, potent and impotent.

The last point that I would make, Mr. Chairman, is that it seems to me that this drug market, the diversion market, creates a fertile environment for the safety of dangerous and unregulated prescription drugs, and could also serve as an instrument for unfair competition among retailers. We know that the vast majority of retailers in this country are honest, scrupulous people. But certainly we now know that there are some who want to take advantage of an illegal, yet profitable, market.

Again, Mr. Chairman, I commend you and the subcommittee staff for putting together an excellent hearing, and I look forward to the testimony.

Mr. SIKORSKI. Thank you. The time of the gentleman has expired.

The gentleman from Florida.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

I, too, would like to thank you for calling this hearing today to examine the staff report on the critical issue of drug diversion.

Let me say that, like the rest of us, I am deeply concerned by the findings in the report. Even though I try to approach each issue which comes before this subcommittee with an open mind, I have to admit, after reading the report, a deep concern for the health of my constituents, most of whom are elderly, and any other individual who must have a prescription filled.

There is no doubt, Mr. Chairman, that we have a responsibility, a responsibility to protect the American public from bogus and/or dangerous drugs. This is one area where average citizens cannot protect themselves, and it is incumbent upon us to find an appropriate remedy to the serious problem of drug diversion and the marketing of counterfeit drugs.

As you may or may not be aware, Mr. Chairman, I represent one of the most elderly populated districts in the United States. Unfortunately, along with advancing age comes illness. My 87-year-old father is in Morton Plant Hospital in Clearwater, FL right now. And this means an extraordinary amount of prescription drugs.



We have all been brought up with the maxim that the buyer must beware. However, in the case of prescription drugs, I don't know how this can be exercised.

Mr. Chairman, I look forward to this morning's hearing and hope that before this session of Congress ends, we will have a solution to these problems.

Thank you.

Mr. SIKORSKI. I thank the gentleman.

Does the gentleman from Ohio have an opening statement?

Mr. LUKEN. I don't have an opening statement, Mr. Chairman.

Mr. SIKORSKI. It is important that we understand that the problem of drug diversion does pose a serious threat to the lawful distribution and the maintenance of quality drug merchandise.

Through the illegal subterranean diversion market, as explained in the staff report, bargain price drugs have been mislabeled, improperly stored, or counterfeited then put into the retail chain to make their way to the public. These drugs are bad for business as they damage the reputations of manufacturers, retailers and wholesalers alike. They tilt the economic playing field away from legitimate businesses and toward those out for a quick kill. They can harm the public and undermine an important component of the Nation's health delivery system.

Our witnesses this morning are Stephen Sims and David Nelson from the subcommittee staff.

Gentlemen, you know the precautions prior to testimony here at the Oversight and Investigations Subcommittee. The rules are before you, and you are familiar with those.

Do you have any objections to being sworn in?

Mr. SIMS. No.

Mr. NELSON. No.

Mr. SIKORSKI. If not, raise your right hands.

[Witnesses sworn.]

Mr. SIKORSKI. Please proceed.

#### TESTIMONY OF STEPHEN F. SIMS, SPECIAL ASSISTANT, AND DAVID W. NELSON, STAFF ECONOMIST, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Mr. SIMS. Good morning.

Mr. Chairman, a preliminary report by the staff of the Oversight Subcommittee is being released this morning. The report describes serious potential problems resulting from the diversion and counterfeiting of prescription drugs. With your permission, I would like to summarize the study at this time.

On my right, as you noted, Mr. Chairman, is David Nelson, and I am Steve Sims. We are both professional staff members of the subcommittee. And I might add that Russell Smith, the associate minority counsel, is also a contributor to this report and should have equal credit.

Mr. SIKORSKI. The subcommittee thanks him as well.

Mr. SIMS. Thank you.

Mr. Chairman, American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective. It is the principal finding of the study that the integrity of the

U.S. distribution system is insufficient to prevent the introduction of substandard, ineffective, or counterfeit pharmaceuticals.

Specifically, the existence and method of operation of a wholesale submarket, which is referred to in the report as "the diversion market," prevents effective control over, or even routine knowledge of, the true source of merchandise in a significant number of cases. As a result, pharmaceuticals which have been mislabeled, improperly stored, have exceeded their expiration dates, or are bald counterfeits are injected into the national distribution system for ultimate sale to consumers. Fortunately, while diversion is commonplace, instances of harmful or ineffective merchandise reaching consumers through normal retail outlets are few.

The staff investigation was triggered by the discovery last fall by G.D. Searle & Co. that its Ovulen-21 birth control pills had been counterfeited. Nearly 2 million of the bogus Ovulen pills were imported from Panama and distributed throughout the United States.

I have examples of the counterfeit and the real Ovulen-21. These were seized by the Food and Drug Administration. As you can see, they are virtually indistinguishable.

I would say, because they are labeled—I can say, because they are labeled, this is the counterfeit, and this is the authentic version [indicating]. And when you open the packages up and compare the packets inside, it is equally difficult to tell the difference.

Mr. SIKORSKI. Would you bring those up Mr. Sims?

[The members examine the sample drugs.]

Mr. SIKORSKI. Both say they were made in San Juan, PR.

Mr. SIMS. Yes; the packaging is an exact counterfeit of the original Searle packaging. And, in fact, we are informed that the packaging was produced in the United States.

Because this matter is the subject of an open criminal investigation, there is very little more that we are able to say in this open session, Mr. Chairman.

It was the speed and ease with which the counterfeit pills were funneled through the wholesale system that drew the attention of the staff. If pills from Panama, selling at a fraction of their normal cost, could move through the system and on to retailer shelves, what was to prevent a similar attempt to market other foreign or domestic counterfeits? The preliminary finding of the staff is that there is nothing to prevent this.

The primary reason that counterfeits like Ovulen-21 could easily be introduced into the distribution system is the existence of what is referred to as the diversion market. As used in the report, diverted merchandise is generally any brand name product that is not obtained directly from the manufacturer or an authorized distributor.

The diversion market is supplied from a range of sources. They include nonprofit institutions that buy in excess of their needs and illegally resell the surplus; companies or individuals that obtain pharmaceuticals from manufacturers through false or fraudulent pretenses; samples that are intended for use in health care institutions or by doctors that are sold to wholesalers instead; pharmaceuticals that are produced in the United States, sold to foreign buyers, and then reexported back to the United States; foreign produced goods that are relabeled and/or repackaged prior to sale in

the United States; stolen merchandise; and counterfeits, both foreign and domestic.

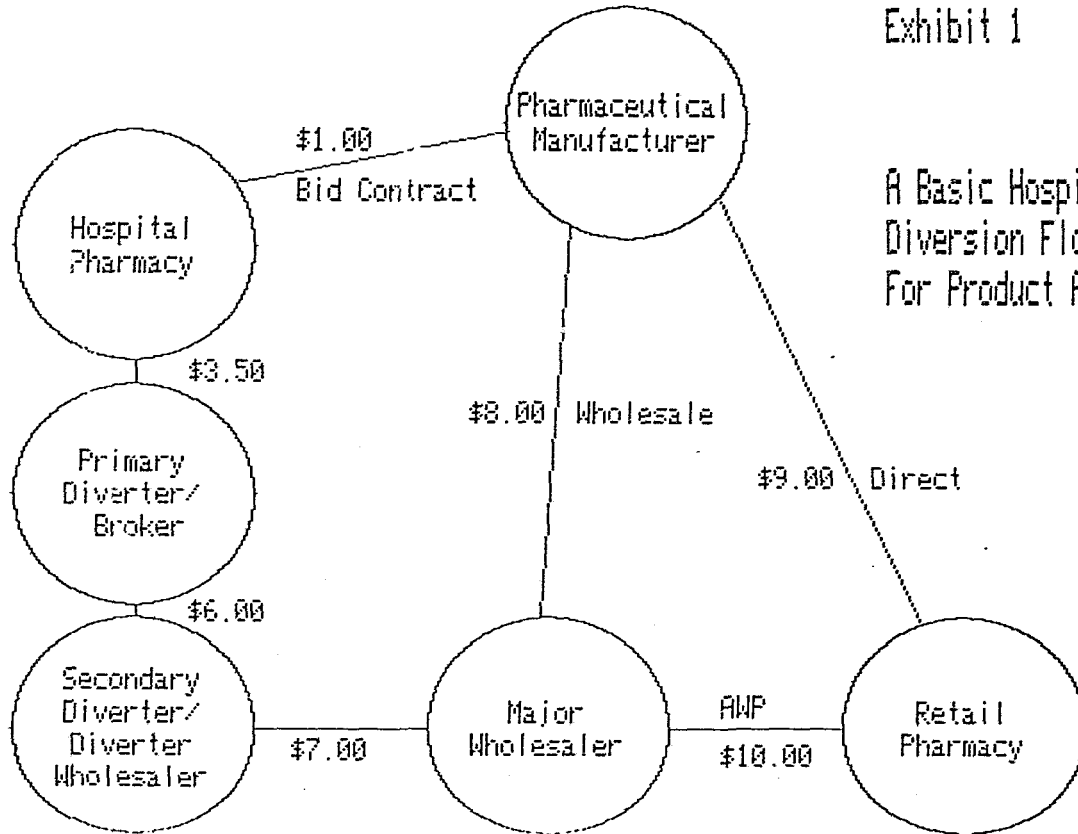
Nonprofit institutions have purchased pharmaceuticals beyond their needs and diverted the excess to the wholesale market for many years. Recently, the volume of merchandise and the number of diversions from nonprofit institutions appears to have increased dramatically. The practice appears to violate the Robinson-Patman Act, which prohibits a drug manufacturer from discriminating in price between purchasers of the same drug, where the effect will injure competition, but confers an important exemption for purchases, quote, "for their own use," unquote, by hospitals and other charitable institutions not operated for profit.

Under this exemption, drug manufacturers have consistently sold pharmaceuticals to nonprofit hospitals at substantially greater discounts than those offered to the wholesale and retail drug trade. This process is depicted in exhibit 1.

Could we have the staff please show the large chart?

[The chart referred to follows:]

Exhibit 1



A Basic Hospital-Type  
Diversion Flow Chart  
For Product A

Mr. SIMS. As you can see, the pharmaceutical manufacturer, in the normal course of events, would sell directly to the wholesaler or directly to the retail pharmacy, and the prices you see in the exhibit are representative of a kind of sale.

The diversion occurs on the left-hand side of the chart, where you can see the red line. The manufacturer might sell for only \$1 dollar a unit a pharmaceutical to a hospital pharmacy. Once the pharmacy resells that, it is a violation of the Robinson-Patman Act, and you can see the large disparity in price that is available to the diverters, to these wholesalers, and you can also easily understand how the legitimate businessmen who do not have access to this cheap supply can be unfairly competed against;

This is happening in increasing volume throughout the United States, and we have a discussion of it, including various documents, in the staff report that I will not try to summarize here.

Mr. SIKORSKI. Steve, they can actually undersell the wholesaler that the manufacturer is selling to as well?

Mr. SIMS. That's correct. You can have any number of parties in this daisy-chain operation, so long as the final sale is at or less than the average wholesale price.

Mr. WYDEN. Steve, excuse me. Did you say how often the problem at that first part of the daisy-chain took place?

Mr. SIMS. The evidence that we've obtained from the industry is that it's increasing in volume. We have identified in the staff report by name several companies, most of which happen to operate out of California and have a certain amount of interlocking directorates and many of whom have the same law firm, that have made these representations in writing, guaranteeing certain levels of profit to nonprofit hospitals around the country, and this seems to be escalating.

We cannot give any precise estimate as to the volume of product involved, but it does appear to be significant. The effect on competition is quite obvious.

Mr. LUKEN. You say competition. These are actual charges, costs? Not costs, but the pharmaceutical manufacturer charges the big hospital \$1?

Mr. SIMS. In some cases, yes. The primary purpose is as a marketing tool by the manufacturer. This may be a teaching hospital or—

Mr. LUKEN. In large quantities?

Mr. SIMS. Yes, in quantity. This may be a teaching hospital, for example, and they wanted to get the doctors familiar with their product.

Mr. LUKEN. And comparably, the same pill or unit would be sold to a retail pharmacy by that manufacturer for \$9, nine times the charge?

Mr. SIMS. Yes; this is designed to show the disparities that can occur in product.

Mr. LUKEN. Now if the FTC had jurisdiction over such matters, that would be a violation of Robinson-Patman on the fact of it, would it not?

Mr. SIMS. Yes; the resale by the hospital—

Mr. LUKEN. No, not the resale.

Mr. SIMS [continuing]. Is the violation.

Mr. LUKEN. Not the resale, but the difference between \$1 to the hospital pharmacy and \$9 to the retail pharmacy, that couldn't be countenanced under Robinson-Patman, could it?

Mr. SIMS. Yes; it is, because of a part of the Robinson-Patman Act called the Non-profit Institution Act.

Mr. LUKEN. No, that wasn't my question.

If it were covered under Robinson-Patman, except for the exemption—

Mr. SIMS. Oh, yes, of course.

Mr. LUKEN. It would not be countenanced—it could not possibly be, if it were a for-profit situation, the hospital, it couldn't possible be—that wide nine times couldn't possibly be approved by the FTC under Robinson-Patman.

Mr. SIMS. I would think not. The Robinson-Patman Act, as I understand it—

Mr. LUKEN. They could have a wholesale discount, a volume discount, but not nine times.

Mr. SIMS. It says that you cannot differentiate between different classes of trade. Now you would have to answer the questions as to whether a hospital was a different class of trade than a retail pharmacy or a wholesaler. So it's an important legal question you raise, and I really don't know what the answer is.

Mr. LUKEN. It would have to relate to the costs. What I'm saying is, the cost could not be nine times as much, despite the volume, I wouldn't think.

Mr. SIMS. Well, yes, I wouldn't think so. But the way the law stands now—and that's one of the reasons why we have raised this question—is that this committee may want to take a look at the Robinson-Patman Act and take a look at what the Federal Trade Commission jurisdiction is.

Mr. SIKORSKI. Steve, it might help if you go through the companies—in through the whole process here, explaining that kind of situation where you have nonprofits.

Mr. BILIRAKIS. Mr. Chairman, to back up a moment, what would be the cost of that drug, the cost to the manufacturer? Something less than \$1, I would assume; is that right?

Mr. SIMS. That's my assumption.

Mr. BILIRAKIS. So we're talking about something less than \$1 being conceivably sold to the retail pharmacy for—

Mr. SIKORSKI. Wait a minute, wait a minute. The gentleman doesn't have the time.

At this point, why don't you proceed through this discussion, as you've highlighted it in your report, and I think some of the answers will come from that.

It's my understanding that \$1 may or may not reflect the true cost. It certainly—or it's unlikely to represent the kind of goodwill and marketing costs associated with the buildup of that product. But because of the attempt to market it through the hospital, they're willing to reduce on that in some instances.

Mr. SIMS. That's correct.

Mr. SIKORSKI. Do you want to proceed?

Mr. SIMS. Mr. Luken, is that clear now?

Mr. LUKEN. I'll follow the chairman's wishes.

Mr. BILIRAKIS. We don't have any choice, but hopefully you will answer our question in the process.

Mr. SIMS. OK.

Mr. SIKORSKI. Is the answer, then, in some cases, it may or may not exceed the—

Mr. SIMS. Yes; it depends on the marketing strategy of the company and the substance in question. I picked this not to be definitive on the issue of what drug companies sell their products for, but merely to illustrate what kind of price differential can exist between sales to hospitals and sales to other institutions and what kind of profit motive, therefore, results, which is the basis for this kind of activity.

Mr. SIKORSKI. You wouldn't want anyone to conclude from your chart that every sale is one-tenth of the sale to the legitimate wholesaler, but that in the instances you've looked at, the charge to the hospital pharmacy is dramatically under the charge to the wholesaler or the retailer—so much so that when it runs through the daisy-chain, it arrives at the retail or wholesale markets.

Mr. SIMS. That's correct. The hospital has to be able to resell the product at less than the wholesaler can get it to make the transaction economic.

Mr. SIKORSKI. Mr. Nelson.

Mr. NELSON. I think one way that you might look at this is that the sale to the nonprofit institution essentially has a large component of it which is market development cost for the pharmaceutical firm. They are willing, in many cases, to sell it at below any economic measure of average variable cost to a nonprofit hospital, because what they are trying to do is to develop an awareness on the part of the residents and the interns in those hospitals of the uses of their drugs, so when they go out in private practice, they will continue to prescribe them. These are loss leaders, largely, for pharmaceutical houses.

Mr. SIKORSKI. Gentlemen, can I suggest we finish this, the nonprofit diversion aspect.

Mr. SIMS. I think we have finished it, and unless there are—we can come back to it in questions, if you wish.

I would like to talk about the false representation schemes, if I could, now, Mr. Chairman.

Mr. SIKORSKI. You do not want to talk about the companies and particular States?

Mr. SIMS. They are listed in the report and are available to everyone. You know, time is short.

Mr. SIKORSKI. OK. Go ahead.

Mr. SIMS. I would like to move through this before we start running into votes and things.

A significant volume of pharmaceuticals end up in the domestic market as a result of false representations by purchasers. In March 1983, two Americans and one Haitian were indicted in Federal Court in Newark, NJ, for fraud and conspiracy in conjunction with a 1980 scheme that bilked Johnson & Johnson out of more than \$1 million worth of pharmaceutical products.

The deception involved sales by Johnson & Johnson of birth control pills at prices well below wholesale to dummy companies in Haiti, established to supply nonexistent family planning clinics. A

Haitian official was paid over \$100,000 in bribes to certify that the clinic plan was sponsored by the Haitian Government. In fact, title to the pills was routed through the Antilles Trading Co., a Haitian firm, to I&E International, Inc., a Tennessee import/export firm.

The merchandise was shipped to Haiti, but remained in that country for less than 12 hours before it was returned to the United States. The pills eventually were sold to an Indiana-based distributor, Bindley Western Drug Co., Inc., and from there were sold to retail customers.

Johnson & Johnson's Ortho Pharmaceutical Corp. was also defrauded by a Washington, DC, drug wholesaler, who engineering a scheme in the fall of 1978 to supply nonexistent Nigerian birth control clinics. According to a complaint filed by Ortho, goods with a domestic wholesale value of \$1.9 million were sold to a London trading company for \$535,000. Instead of forwarding the drugs to Nigeria, the company shipped them back to the United States, where they were discovered in the possession of the Washington Wholesale Drug Exchange, Inc.

Ortho charged Washington Wholesale Drug Exchange and several of its officers of conspiring with the London and a related Nigerian firm to divert the shipments. The case was highlighted by the involvement of a Nigerian tribal chief and a trade official in the Nigerian embassy.

Yet another variation on this scam, this time involving a phony Bulgarian trading company, was perpetrated in 1977 and 1978 against Stuart Pharmaceuticals, a division of ICI Americas. A Canadian businessman, posing as an agent of the Bulgarian company, purchased a variety of pharmaceutical products at large discounts. Instead of being distributed in Eastern Europe, the \$800,000 worth of merchandise was diverted to a warehouse on the eastern seaboard and from there to the retail market, according to an indictment returned in Federal District Court in Wilmington, DE, in March 1982.

The warehouse in New Castle, DE, was owned by Baylin Co., a large wholesale drug distributor. The president of Baylin pled guilty to tax evasion and went to prison. The Canadian pled guilty to charges in Canada and paid a criminal fine.

There are several other of these schemes listed which illustrate the same point, which I will not describe at this time.

I do want to describe some domestic scams that are quite notable. Particularly, there was an elaborate scam that conned drug manufacturers into selling or even donating millions of dollars worth of pharmaceuticals to bogus charities between 1975 and 1978. The goods were supposed to go to needy people in Third World countries. Instead, they were resold at retail for a substantial profit in south Florida.

Following a jury trial in the District Court for the Southern District of Florida, five persons, including Mr. Solomon Richman, who is a rather famous figure in the diversion market, were found guilty of conspiring to conduct an enterprise through a pattern of racketeering activity, as well as several counts of mail and wire fraud.

On June 12, 1985, the appeals court affirmed most of these convictions. According to a statement of the case prepared by the U.S.



attorney, large pharmaceutical companies sold the conspirators about \$2.5 million worth of merchandise at significantly reduced prices. The firms victimized the scheme included Parke, Davis, Ortho, and Wyeth.

Initially, the conspirators established a branch in Washington, DC, of a legitimate charity, Opus Christi, based in Rome with offices in several other European cities. The bogus charity in Washington, DC, bought pharmaceuticals from manufacturers and resold them to American Medicinal International, Ltd., of Miami, FL, and various other companies that were part of the conspiracy, including a company known as Majestic Sales.

The conspirators had the drug companies deliver the merchandise to a freight forwarder at Washington Dulles Airport to support the deception that the goods would be shipped overseas. Instead, the merchandise was trucked to Florida where the shipping labels, as well as the numbers and letters on the bottles, were removed prior to resale.

To further conceal their fraudulent activities, the conspirators arranged to procure pharmaceuticals through another legitimate charity, Inter-Church Medical Assistance. By corrupting IMA's director, the conspirators used IMA as a purchasing agent for Opus Christi. The use of IMA became necessary because manufacturers were becoming aware of Opus Christi's diversion activities and were refusing to sell to this organization.

The conspirators created yet another front organization, in this case a branch of the Church of God World Missions, in Alexandria, VA, to further their fraudulent diversion scheme. The general manager of AMI, Mr. Philip Weinstein, used the fictitious name of Dr. Philip Adamelli in conjunction with the bogus Church of God branch. Mr. Weinstein even used the Dr. Adamelli alias in a visit to the Upjohn plant in Kalamazoo, MI.

By 1977, the drug companies had discovered that the alleged Church of God operation was also a front for drug diversion and ceased sales to that entity.

During the time of this domestic scam, the coconspirators also did business with Mr. Solomon Richman's firm in Brussels, Belgium.

The testimony in the Florida case involving the bogus charities also revealed significant information regarding the operation of the diversion market in the United States. As part of their case, the defendants called witnesses to testify that diversion was a standard practice and a time-honored method by which at least some pharmaceutical retailers obtained supplies. As indicated in the previous section, drug companies' salespersons were claimed to knowingly sell to diverters to meet quota, to move an oversupply of a certain product, or for various other reasons that were approved or tolerated by the companies.

One witness, Robert Brewer, had been director of purchasing and distribution of pharmaceuticals for Revco Drug Stores, a large chain. Mr. Brewer testified that between 1975 and 1977, Revco purchased about \$150 million a year worth of pharmaceuticals, about 20 percent of which were from diverters, and that this was a standard way of conducting business during his employment with the company.

Mr. Brewer also said that Revco had established subsidiary companies which specialized in the purchase and resale of diverted pharmaceuticals, and that periodic reports on the practice were submitted to the company's top management.

When asked how pharmaceuticals entered the diversion market, Mr. Brewer identified nonprofit associations, hospitals, clinics, and nursing homes as among the sources. International Christian Relief in Washington, DC was said to have sold several million dollars worth of pharmaceuticals to Revco.

While purchases from diverters were attractive, because they gave Revco a price advantage against its competitors, such purchases raised questions as to the quality of the merchandise. Mr. Brewer testified that it made no difference to Revco where the initial diverters purchased the merchandise, as long as they were licensed. He added, and I quote: "All the people that we dealt with were duly licensed under their State, and if they were duly licensed under their State, the product was legitimate, and that is what our main goal was, to make sure that everybody was licensed," unquote.

The problem, of course, is that possessing a State license, which is quite easy to obtain, is no guarantee of quality. The importer and the primary distributors of the counterfeit Ovulen-21 birth control pills were all licensed. This is certainly not to say that companies like Revco would knowingly purchase substandard pharmaceuticals.

Rather, the testimony of Mr. Brewer and others in this case illustrate the dilemma that continues to exist in the marketplace today. In reference to quality, what risks should a prudent businessman take in order to obtain goods at favorable prices?

The apparent widespread practice of buying diverted goods raises the related question of what risks a businessman needs to take in order to remain competitive.

These questions cannot be answered by the staff in this report, but I believe they should be very carefully addressed in our subsequent hearings.

In any event, Revco appears to have continued its practice of buying from diverters. In the case where pharmaceuticals were diverted back to the United States while allegedly on their way to Zaire, the goods ended up in Revco's possession in Tennessee. Revco reportedly advanced the funds to the diverter, including the firm operated by Solomon Richman, prior to the purchase of the merchandise from the manufacturer.

In this regard, one other part of Mr. Brewer's testimony is instructive. The following is a line of questioning of Mr. Brewer by the prosecutor in the Florida case:

*Question by the prosecutor.* Now, sir, had you known that International Christian Relief, Opus Christi, or the Church of God was making false representations to manufacturers to get those products, would you then have purchased those products?

*Answer.* I would have probably taken it up with our counsel.

*Question.* You would have taken it up with your counsel?

*Answer.* Yes, I think I would have. Yes.

*Question.* And you don't know what, if any—

*Answer.* We would have probably purchased the merchandise.

Stanley Kowitt, owner and president of SK Enterprises, which did business with the other defendants in the case as Majestic Sales Company and American Drug Brokers, testified that his firm sold diverted merchandise to many major drugstore chains in the United States, including Revco, Eckerd, Drug Fair, Rite-Aid, Adams, and Thrifty. Mr. Kowitt went on to confirm that pharmaceutical products are traded freely in the marketplace to diverters and that he had never attempted to conceal from his customers the fact that he was dealing in diverted product.

One problem with buying from diverters, even though they are licensed, is that the retailer really has no guarantee that the product is genuine or effective. Eckerd Corporation, for example, discovered it had counterfeit Ovulen-21 in Dallas, TX and Largo, FL.

Another witness, Gerald Rome, president of the the H.L. Moore Drug Exchange of New Britain, CT, said that the diversion market had existed throughout his 23 years of experience in the wholesale pharmaceutical industry. Mr. Rome said that his firm got calls on a daily basis from suppliers offering diverted merchandise. Mr. Rome testified that he does not know where his suppliers get their merchandise, adding that he would never knowingly buy stolen goods, but since no questions are asked, it is unlikely that Mr. Rome's company would know whether the goods were stolen or not. Mr. Rome also stated that it would be no concern of his if he were offered goods that were purchased based on the representation that they would be used for charitable purposes.

Thus, at least one diverter seems to be saying that stolen merchandise, if identified as such, would be rejected, but pharmaceuticals obtained through false representations or fraud are perfectly acceptable.

I would like to turn now to the counterfeiting aspect. On November 15, 1984, the subcommittee sent letters to the large brand name pharmaceutical manufacturers in the United States. The survey, which was completed by the end of January 1985, sought information on counterfeit or intentionally mislabeled pharmaceuticals. Generic look-alikes and so-called gray market equivalents were not covered in this survey.

The results confirmed earlier indications that a significant volume and range of pharmaceuticals are being counterfeited by foreign pirates for sale overseas. Of the 25 manufacturers responding to the questionnaire, 9 or 36 percent had experienced serious counterfeiting problems abroad in the last 5 years. A number of the respondents had seen their products copied in several countries or even several continents.

Several companies whose experience did not fit under the rather restrictive definition of counterfeiting in the subcommittee's survey have had their patents violated by local companies and foreign countries, such as Brazil and Taiwan, who produce and market copies of their pharmaceuticals.

All of these products threaten the health and safety of consumers in the foreign countries where they are marketed. Like the bogus Ovulen, they are also potential sources of supply to American wholesalers.

We have deleted, for the public portion of this testimony, the actual names of the companies, and I have substituted letters.

Company A reported that some distribution of counterfeit product had been discovered in a few countries in Latin America, the Far East, Nigeria, and Italy. A spokesman for Company A told the subcommittee staff that one of their best-selling pharmaceuticals was widely available in drugstores in Columbia in a perfectly copied package. However, the product inside the package was composed of dried milk and sugar.

The company hired private investigators in an attempt to track down the counterfeiters but received no assistance from Columbian authorities. According to the company spokesman, many leading American brand name drugs are counterfeited and offered for sale in Columbia.

Company B reported that an Indian company is selling counterfeits of its anti-inflammatory compounds in Nigeria, and that a bogus anti-infective agent, containing only talc and cornstarch, has been sold in Columbia.

Moreover, Company B has moved criminally and civilly against another Indian company for counterfeiting an antibiotic, and also has had its products illegally copied in Malaysia and Italy.

Company B concluded that, and I quote:

These examples of international counterfeit activities are certainly not an exhaustive list of the cases that can be documented or of the problems that we and other pioneer research pharmaceutical companies encounter. They do, however, indicate that the international counterfeiting problem is real, complex, and, to the extent that foreign laws do not adequately protect American corporate trademarks and proprietary rights, amounts to expropriation of American technology and intellectual property rights.

Company C told the subcommittee that they have experienced problems in Brazil where, for the last 2 years, their intrauterine device has been copied. A brand name cough syrup has also been copied in Brazil, but that problem apparently has been brought under control.

Company D has had its antimalarial agent copied in Thailand and its sedative pirated in Indonesia, Malaysia, and Singapore.

Criminal actions were also brought against several individuals in Germany who counterfeited several pharmaceutical products, including one of Company D's.

Brazil has been a source of problems for Company E, which discovered that one of its injectable antibiotics had been copied, including the packaging. The counterfeit product exhibited no antibiotic activity in laboratory tests and was thought to be composed of flour. The counterfeiter, when arrested by the police, had enough printers, ampules, vials, and related materials to manufacture an estimate 20,000 units. The company also found bottles of its liquid antibiotic in bogus packaging for sale in a Rio de Janeiro suburb. The antibiotic had been diluted to about one-tenth normal strength.

Company F has suffered from counterfeiting of a dermatological product in Hong Kong. The counterfeit pharmaceutical has also been sold in Taiwan and in the Philippines where it has been distributed in stolen genuine packaging.

Company G found that bogus polio vaccine was being distributed to schools and institutions in the Philippines. The counterfeiters were reclaiming the small disposable vials in which the genuine vaccine was packaged and refilling them with water. According to the company, "The investigation ended abruptly when our lawyers advised us that our witnesses refused to cooperate, since they had apparently been intimidated."

Company I had a similar experience in Mexico where its antifungal tablets were being counterfeited. The fake tablets, composed of wheat paste, are being found in several Mexican provinces. The private investigators for this company were also intimidated.

Fortunately, there is very little domestic counterfeiting. I have described in the report one case from the mid-seventies involving a firm called Jamieson-McKames Pharmaceuticals of Missouri. That case has been prosecuted, and that is the only major case of domestic counterfeiting of which we are aware in the last several years.

I would like to return now to the Ovulen-21 case. The potential that foreign counterfeit products could be introduced into the U.S. wholesale market and distributed by diverters poses an obvious threat to the health and safety of Americans. The reimportation of genuine pharmaceuticals in the United States and foreign purchases also raises questions. There is no guarantee that they have been properly stored or handled so as to preserve potency. Labeling may also be deficient. The true source of the drugs may be altered by repackaging or poor recordkeeping, which could make it very difficult to trace the goods in the event of a recall.

Moreover, pharmaceuticals that are declared to customs and sold to customers as American-produced goods may really be produced abroad.

Issues of quality control and recallability are even more pronounced in such instances.

Finally, the U.S. Customs Service has discovered foreign-produced medical devices that are falsely represented as U.S. goods.

Because of the significant volume of pharmaceuticals reimported to the United States as American goods returned, many of which shipments originate from or near countries with known counterfeiting problems, there is a real danger that more counterfeit pharmaceuticals could enter the U.S. distribution system.

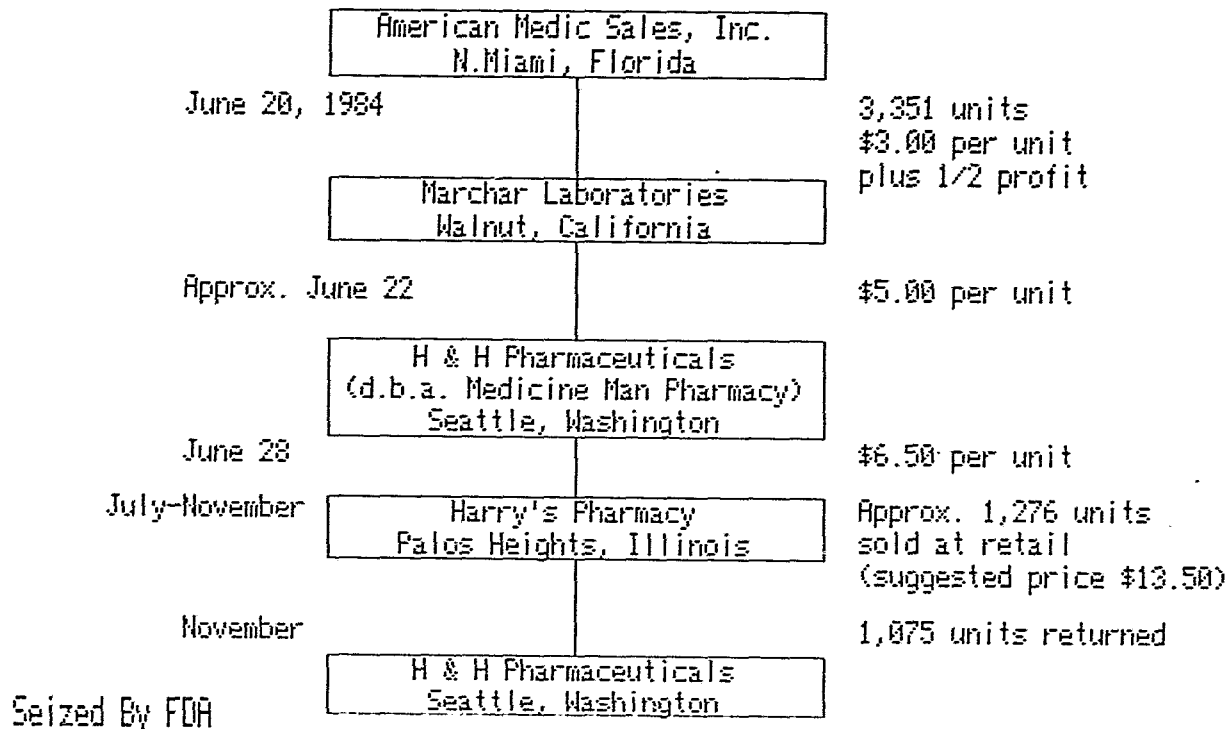
Moreover, it is the impression of the staff that American goods returned receive minimum scrutiny from the Customs Service of the Food and Drug Administration. Recent interviews with the Food and Drug Administration and Customs officials in the New York area indicate reimportation of pharmaceuticals from foreign areas such as Belize, Panama, Hong Kong, the British West Indies, the United Arab Emirates, the Philippines, and Jamaica. It is unknown to the staff how U.S. wholesalers such as Interstate Cigar Corp. or Quality King that import significant quantities of pharmaceuticals can be certain that the products are safe and effective.

The subcommittee has pieced together one example of how the counterfeit Ovulen-21 was quickly moved through the diversion market after its introduction into the United States.

If we could have the second and last exhibit.

[The chart referred to follows:]

Exhibit 2  
Diversion Of Counterfeit Ovulen-21



Mr. Sims. Mr. Chairman, because of the open criminal case, we have not been able to fill in the top portion of the chart, so we simply will have to finesse the question of who sold American Medic Sales of North Miami, FL, the Ovulen.

But starting with this firm, on June 20, 1984, American Medic Sales sold 3,351 units, and each of those boxes that you have before you there is one unit, at \$3 a unit plus half the profit of the next sale. On June 22, the company that bought the material from American Medic Sales, Marchar Laboratories in California, sold the entire lot for \$5 a unit to H&H Pharmaceuticals in Seattle, WA. H&H does business as Medicine Man Pharmacy. On June 28, H&H sold the entire lot at \$6.50 a unit to Harry's Pharmacy in a suburb of Chicago, IL.

So you can see, in the space of a little more than a week, this large quantity of counterfeit product moved from coast to coast and halfway back again, and the product did physically move.

Harry's sold the goods at retail, and until November when word that the product was counterfeit became widespread, sold approximately 1,276 boxes of counterfeit product to its customers. The suggested retail price is about \$13.50 a box. I really don't know what Harry's sold it for.

So you can see the very large profit potential. This is a typical example, not only of the Ovulen, but we believe typical of the way this diversion market works.

One other obvious source of goods for the diversion market is stolen merchandise. Since there are a number of wholesalers who buy pharmaceuticals with no questions asked, disposing of the stolen merchandise does not appear to be a problem.

On April 5, 1984, Pedro Malave, pharmaceutical manager of the Thuna Manufacturing Co. in Manati, PR was indicted for warehousing \$900,000 worth of stolen pharmaceuticals. The merchandise, used to treat high blood pressure, ulcers, and anxiety, was part of an entire truckload that was hijacked at gunpoint in November 1983, from a Smith, Kline & Beckman subsidiary in Puerto Rico. Mr. Malave was arrested in New York on March 30, 1984, when he was attempting to sell the drugs which had been moved to a Bronx, NY warehouse.

Mr. Malave pled guilty, was fined \$5,000 and sentenced to 5 years of probation. Pedro Malave's employer in Puerto Rico, Mr. Martin Thuna, was himself indicted for trafficking in stolen goods in March 1984. Unlike the New York case, Mr. Thuna used his own outlets to dispose of the goods. According to the indictment in Federal District Court in Puerto Rico, Mr. Thuna used a drugstore in Puerto Rico and Farmedic, Inc., a Chattsworth, CA wholesaler of drugs and sundries, to move the merchandise. Mr. Thuna owned both businesses. The stolen property was an entire container load of Tic-Tac candies valued at \$180,000.

On May 31, 1985, Mr. Thuna was one of six persons indicted in connection with the May 1983, theft of \$330,000 worth of Tagamet from Eastern Airlines' shipping facilities in PR. The pharmaceuticals were shipped from Thuna's pharmacy in PR to his wholesale pharmaceutical company in California for resale. Mr. Thuna is presently in jail in Rio Piedras, Puerto Rico in lieu of bail.

The last source of supply to the diversion market is samples. Many pharmaceutical manufacturers promote their products by giving free samples to doctors, clinics, and hospitals. The samples are normally dispensed by the sales representatives of the companies.

When questioned by the staff, representatives from several manufacturers explained the practice as an important and valuable sales tool. If residents in a teaching hospital become familiar with a drug product, it is hoped that they will continue to prescribe it in their subsequent practice. The practice of providing samples has been used for a number of years, but it has been abused by sales representatives, doctors, and pharmacists throughout its history.

A salesman can falsely claim that his samples were dispensed when, in fact, they were sold to a druggist or wholesalers. Doctors can do the same thing. The resale of drug samples was said to be a multimillion dollar a year business nationwide, according to a series of Newsday articles in 1981, reporting various arrests in the Long Island area resulting from a police crackdown on the practice.

Samples are a traditional source of product for the diversion market, and various suggestions have been advanced regarding reform or elimination of the practice.

This concludes the prepared testimony, Mr. Chairman, and to the extent we're able, we'd be glad to entertain any of the questions that you may have.

Mr. DINGELL. Mr. Sims, the committee comments you for an excellent report and for an excellent statement. We also commend your colleague, Mr. Nelson, who is also a very valuable member of the staff, for his assistance to us in this important matter.

Mr. Nelson, did you have some comments you wished to add to those made by Mr. Sims?

Mr. NELSON. No.

Mr. DINGELL. Then the Chair will commence recognizing members in order of their appearance in accordance with the rules.

The Chair recognizes first the distinguished gentleman from Oregon, Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

I, too, gentlemen, want to commend you for an excellent job.

My first question to you is that it doesn't seem to me that the Customs Service or the Food and Drug Administration are doing much of a job to check out these imported pharmaceuticals. Is that correct?

Mr. NELSON. Mr. Wyden, there is probably no less attention paid to pharmaceuticals than to other goods entering the United States, unfortunately, but there is certainly not enough attention being paid.

I think you may have in your folder the entry documents associated with two of the counterfeit Ovulen shipments.

Mr. WYDEN. Mr. Chairman, I would ask unanimous consent that they be put in the record at this point.

Mr. DINGELL. Without objection, so ordered. And without objection, the exhibits to the statement of Mr. Sims and the submissions made in connection with his statement will be inserted in the record at the appropriate place.

[The entry forms referred to follow:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

TAKEN FROM 84 215 942 3		DATE OF THIS FORM IS PREPARED AFTER JANUARY 1, 1974	
8/6/84		APR 27 1 03 PM '84	
007-8605 4990		MIAMI, FLA.	
COUNTRY OF ORIGIN U. S. A.	PORT OF UNLOADING MIAMI, FLA.	ENTRY NO AND DATE	PLATFORM NO.
VALUE OF ENTRY IN U.S. \$ 26,880 00	CONTAINER NO.	IMPORTING VESSEL EASTERN AIRLINES	ARRIVAL DATE 8/1/84
IMPORTER OF RECORD SAME	MANUFACTURER/SHIPPER DARO S. A. ZONA LIBRE DE COLON COLON, PANAMA	DATE OF ANALYSIS	
BROKER (if not same as above) IMPERIAL FREIGHT BROKERS INC.		LOCATION OF ENTRY For FDA examination only MIAMI, FLA.	PHONE NO.

THIS IMPORTATION  
MAY PROCEED  
Without FDA Examination

This notice does not preclude action should the merchandise later be found violative.

VALID ONLY IF SIGNED

*[Signature]*  
FDA Representative

(FOR BROKER'S USE)

GENERAL DESCRIPTION OF SHIPMENT		
QTY.	PACKAGED	ITEMS CONTAINED AND NET GROSS WEIGHTS (SEE INSTRUCTIONS FOR USE)
2	CTNS.	OVULEN 21 COMPACT REFILL

1. Entry and the shipment will be available for sampling.
2. Location in local area of the shipment on that date.
3. Breakdown as shown on the invoice number and size of units each lot, and \$ value each lot.

0 8 1 8 4 1 38

Ovulen-21 Investigation  
Imperial Freight Brokers Inc.  
11/25/84  
for/bcs  
attachment 2 pg 1 of 1

MAY PROCEED NOTICE 98

Use of this form is prohibited after January 31, 1986.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Aug 10 1 13 PM '84

0814122

DATA TAKEN FROM Advance Number 24-215 264 3 Man's Est. Date 8/9/84 IT Advance Notice Commercial Invoice attached		ENTRY NO. AND DATE			
BILL OF LADING NO. 007-8555 6015	PORT OF LADING CCLON	COUNTRY OR ORIGIN EX U.S. A.	PORT OF UNLOADING MIAMI, FLA.	PORT OF ENTRY MIAMI, FLA.	
BROKER'S REF NO. 4772A	SHIP NO. 268	VALUE OF ENTRY IN U.S. 9 57 120.00	CONTAINER NO.	IMPORTING VESSEL EASTERN	ARRIVAL DATE 8/8/84
FOR THE ACCOUNT OF Consignee LANTOR CORP. 780 N. E. 65TH ST. MIAMI, FLA. 33118	Name & Address Importer of Record SAME	Name & Address Manufacturer/Shipper DARO S. A. ZONA LIBRE DE COLON COLON, PANAMA	MANUFACTURER/SHIPPER (Name & Address)		DATE 8/8/84
BROKER (If not same as above) IMPERIAL FREIGHT BROKERS		LOCATION OF LOT (For FDA examination) LANTOR CORP.		DATE NOW	
LEAD SAMPLE		PHONE NO.			

THIS IMPORTATION  
MAY PROCEED  
Without FDA Examination

This notice does not preclude action should the information is later be found to be false.

VALID ONLY IF SIGNED

SIGNER: *[Signature]*  
FDA Representative Date: *5/1/84*

IF FOR BROKER'S USE

GENERAL DESCRIPTION OF SHIPMENT		
QTY.	PACKAGED	ITEMS
4	CXNS.	OVULEN 21 COMPACT TABLETS

IMPORTANT NOTICE: This shipment must be examined by the FDA either prior to or from FDA. With the exception of the Broker, the Broker or Importer must inform the FDA of the following:

1. Earliest date the shipment will be available for sampling.
2. Location in local area of the shipment on that date.
3. Breakdown as shown on the invoice number and size of units each lot, and \$ value each lot.

*Order 21 Investigation  
Imperial Freight Brokers Inc  
8/13/84  
JWB/DCB  
ATTACHMENT 10 1/1*

Mr. NELSON. As you can see on these documents, the FDA stamp of approval was applied, and it shouldn't be surprising that neither FDA nor Customs pays much attention to these entries. They are agencies that are overwhelmed, particularly in south Florida.

For example, the Southeast Regional Headquarters of the Customs Service last year issued instructions to their ports that 80 percent of all merchandise had to be bypassed. That is to say, there is to be no inspection of the paperwork at all.

Mr. WYDEN. Excuse me. I want to understand that. Basically, what you're talking about is a rubberstamp, then.

Mr. NELSON. Exactly.

Mr. WYDEN. For approving these drugs.

Mr. NELSON. Right. In New York, an Ovulen-21 shipment was caught by a fluke, and it was kind of the exception that proves the rule with regard to the situation with the Customs Service.

The entries were on a bypass system, and they do periodic quality control checks. This is not a routine checking of the entry documents. Occasionally they'll go in and try and figure out how much they're missing by bypassing all of these entries.

The entry that happened to contain Ovulen going to a Long Island wholesaler, was part of this kind of sample when the import specialist, an alert import specialist, very typical of the quality of Customs personnel when they're allowed to do their jobs in the field, saw the invoice. The next day or shortly thereafter, the Ovulen-21 case broke in the papers, and she recalled that in that spotcheck there had been an Ovulen-21 entry which she had just passed on, because she didn't have time to do any real detailed work with it.

She recalled the entry, and Customs was able to seize the goods on the premises of the Long Island importer. That's the situation with Customs in New York and Florida.

Mr. DINGELL. Were these stamps, in fact, put on by FDA or Customs, or were they put on by some other goodhearted soul in the absence of sufficient numbers of employees.

Mr. NELSON. They are supposed to be put on by FDA, and this is the required statutory review that FDA is supposed to make of documentation and to pull entries that would appear curious.

Now why Ovulen-21 should be coming in from Panama might make most of us curious, but it doesn't interest, apparently, this FDA inspector.

When we were in New York at JFK Airport, for example, we found that the person applying these stamps to the customs documents—and the stamp has to be there for certain kinds of merchandise, pharmaceuticals and food to be allowed into the country by Customs—was a very low-level clerical employee at FDA. And one of the Customs inspectors told me that from time to time, apparently significant periods of time, there's been no one there from FDA, and the stamp is just routinely turned over to the Customs inspector, who is told to just check off every entry.

Mr. WYDEN. Gentlemen, I understand that a significant volume of pharmaceuticals comes into the country duty-free, what's called "American goods returned," and that this is a special category assigned to products that are manufactured and exported from this country and then reimported.

Mr. DINGELL. Would the gentleman forgive the Chair.

Mr. NELSON. I'd be happy to yield.

Mr. DINGELL. The Chair has got to observe that 11:03, there is a vote on the House floor with regard to a motion by Mr. Foley to lay on the table a resolution raising the question of the privileges of the House, H. Res. 17. For that reason, it will be necessary for the committee to recess. We will return in approximately 20 minutes and reconvene.

The Chair apologizes to the gentlemen.

[Brief recess.]

Mr. SIKORSKI. We will continue. The gentleman from Oregon.

Mr. WYDEN. Thank you very much, Mr. Chairman. I want to return to the question of American goods returned, Mr. Nelson and Mr. Sims. As we said this was a category assigned products that were manufactured and exported from this country and then were reimported.

Now Customs used to police these kinds of American goods returned. They would require proof that no refunds or drawbacks were paid upon exportation and I understand now that that is not done any more because of a recent ruling by Customs Headquarters.

So my question to you is, given that that is the case, isn't it true that now, the shipment of American goods returned will come from places like the Philippines and Panama and other countries and be coming right into this country for resale to American consumers?

Mr. NELSON. That is correct, Mr. Wyden. This decision by Customs Headquarters to place the burden of proof on their own employees to show that no drawback had been taken, no refunds had been made, has made it virtually impossible for the people in the ports to do any substantial checking at all.

Mr. WYDEN. These are the places where the drugs are counterfeited?

Mr. NELSON. That is right.

Mr. WYDEN. Those specific countries. So we are not checking any more when we know that these are the countries where drugs are counterfeited?

Mr. NELSON. Yes; even when there are very strange things on Customs entry documents, for example, many of the drugs are returned from countries, Arab countries in the Middle East, using Jewish wholesalers and Jewish shipping agents. One would think there might be a little bit of a problem in the country of export with those kinds of commercial arrangements if in fact they were coming from those countries.

Mr. WYDEN. Gentlemen, I know I am running out of time and I only want to ask one other quick question.

Here we have the two products, the Ovulen-21. One is authentic. One is counterfeit. Clearly people of reasonable intelligence, American consumers, myself included, wouldn't have any idea how to tell the difference. I couldn't except that on the back you have marked which one is authentic and which one is counterfeit.

My question is, is there any evidence, gentlemen, that women in this country have gotten pregnant as a result of these counterfeit Ovulen-21 pills and if there is any evidence, could you describe it to the subcommittee?

Mr. SIMS. Yes; I called counsel for Searle & Co. on Monday and made inquiry along those lines. Counsel for Searle advised me that they had received approximately 25 complaints from women allegedly who had taken counterfeit birth control pills, counterfeit Ovulen-21 birth control pills.

They also advised me that they had been informed of at least five pregnancies which have allegedly resulted from taking counterfeit birth control pills and one abortion.

Mr. WYDEN. There was an abortion in addition?

Mr. SIMS. Yes.

Mr. WYDEN. You said that there were five pregnancies and one abortion from those who allegedly have taken the counterfeit?

Mr. SIMS. Yes, sir.

Mr. WYDEN. Mr. Chairman, I thank you for the chance to ask those questions.

Mr. SIKORSKI. The time of the gentleman has expired. You have described theft. You described the U-boat kind of diversion, and similar kinds of diversion situations, the counterfeiting, the samples and the nonprofit.

It seems to me that almost all of these use the wholesale part of the system to make entry into the market. Is that correct, and is that the problem area and why isn't it in retail or in manufacturing?

Mr. NELSON. Mr. Chairman, it appears to be almost exclusively a wholesale level problem. We very early in the investigation, the chairman sent out letters of inquiry to the members of the Wholesale Drug Trade Association.

We queried almost 140 companies. We got less than 10 responses. Throughout the travels that we have done and the places that we have gone and the folks that we have talked to, the problem seems to be centered in terms of the diverters themselves in the wholesale trade but there are other folks that are party to this, the nonprofit institutions.

According to a member of the Pharmacy Board in the State of California about 90 percent of this market is sustained from sales from the nonprofit institutions and these folks are very definitely a part of that problem.

Mr. SIKORSKI. So it is in the wholesaling process that this kind of stuff gets into the system.

Mr. SIMS. Mr. Chairman, I would point out that the Food and Drug Administration very carefully polices the manufacturers. The pharmacies by in large are watched very closely by the State boards. In the middle about the only thing you need is a business license from your State and therein lies the problem.

Mr. SIKORSKI. Before we look at that nonprofit aspect, can you attach numbers in terms of dollars to this problem? I know I saw one figure in the report back in 1975 or 1978 of \$100 million.

Mr. SIMS. That was just one company, I think.

Mr. SIKORSKI. Yes.

Mr. SIMS. It is my impression that the volume or the value of merchandise in the diversion market in a given year would be in the hundreds of millions of dollars easily.

Mr. SIKORSKI. Would it be an exaggeration to say that we are talking about a \$1 billion problem?

Mr. SIMS. I would not think so.

Mr. SIKORSKI. The effects on public health of the kinds of diversion mechanisms you have pinpointed seem to be raised most by those that are counterfeit drugs where you have just bogus ingredients, isn't that correct?

Mr. NELSON. There are other problems.

Mr. SIKORSKI. Sure. Do you want to list in order of descending importance the other kinds of problems?

Mr. NELSON. People that trade in pharmaceuticals in this country are required by FDA regulations to maintain certain kinds of storage facilities. Obviously, if pills get too hot or too cold or too damp, they can lose their efficacy rather quickly.

When goods are shipped out of the United States and returned, all that quality control is lost. The condition of a container load of drugs that has been sent to the United Arab Emirates, God only knows, stored under what conditions over there, and then returned in a container on the top of a ship, it seems to me to be very obvious that there is a likelihood of some damage to those drugs.

This market also contains a number of people who are willing to purchase drugs that are just about to expire. Whether they get sold before their expiration dates or whether there is any great damage if it is a few months after their expiration dates, we don't know.

Because there is so much repackaging involved here, the potential danger is rather substantial.

I think part of the problem, too, is that people tend not to question, even doctors tend not to question whether or not there might be a bad drug at fault when a treatment fails.

We are just becoming aware of the extent of the problem. If antibiotics, for example, don't work, you try another antibiotic, you don't question whether or not the antibiotic might be wheat paste brought in from Mexico.

Mr. SIKORSKI. So there is the public health threat. There are the dollar figures.

Mr. SIMS. One other thing that I would point out that could be very significant is given the manipulation of this product in the market, in the event of a recall it would be almost impossible to trace a certain percentage of these products if they had gotten into the diversionary market.

So in case a company did make a mistake which can happen from time to time, and a lot of their product got into the diversion market, they would realistically have no way of being able to trace it and the Food and Drug Administration would have a very, very difficult time trying to find this in a timely fashion.

Mr. WYDEN. Would the gentleman yield?

Mr. SIKORSKI. Of course.

Mr. WYDEN. I appreciate the gentleman yielding. How would we know whether or not counterfeit, ineffective or substandard drugs were being sold to somebody in Washington, DC today?

Mr. SIMS. After the fact, I would presume, Mr. Wyden.

Mr. SIKORSKI. If we ever did know.

Mr. NELSON. If you ever did.

Mr. SIKORSKI. The point is that no drug is effective across the universe and ineffective reduction of fever means you move on to

something else. There is no running to the labs to do an analysis of what actually was taken.

My last question is on the nonprofit diversion which I have looked at somewhat extensively. You have included in your report a letter that I have looked at which focuses on this kind of inventory enhancement, hospital/pharmacy enhancement program described by Healthcare Marketing Services, Inc. and then a letter of nine pages from the law firm of Hirschtick, Chenen and Cavanaugh signed by Arthur Chenen or rather Arthur Chenen's name appears on it.

Its legal basis is severely undercut by the attached Congressional Research Service Library of Congress analysis of it. What has bothered me for some time with this letter is this provision dictated but not read. What the heck does that mean?

Mr. SIMS. I was puzzled by that myself, Mr. Chairman, and I really think that perhaps the subcommittee should make inquiry of the author himself as to his legal opinions. I don't think I could characterize exactly why they would do that kind of practice. I don't think that would excuse the author in any way from what the words on the page mean.

Mr. WYDEN. Would the gentleman yield?

Mr. SIKORSKI. Sure.

Mr. WYDEN. I think the gentleman's question is a very important one and I would ask unanimous consent the committee staff look into the author of that document, why it was handled in that fashion.

Mr. SIKORSKI. Without objection, we will do that. My time has expired.

[Note: During a telephone interview, the author of the legal opinion, Mr. Chenen, defended its validity and indicated that he was perfectly willing to sign it as he had signed others.]

Mr. SIKORSKI. The gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I, too, want to add my very sincere commendation to the committee staff for the great investigative job that they have done here.

Of course, we all realize here that we are talking about something awfully criminal. We are not talking necessarily criminal in terms of violating an antitrust law or bilking people of money. We are talking about hurting people, hurting people's health and keeping them from getting well and that is just as criminal as could be.

The bottom line, as I see it, and I may be wrong, seems to be the distribution network. Is that basically what it comes down to?

Mr. NELSON. That is the problem.

Mr. BILIRAKIS. In both areas, the distribution of the counterfeit drugs as well as the other. So that has to be improved. Mr. Wyden referred to the Customs people and the FDA and I suppose there is always room for improvement there although I don't think we are ever going to have improvement if we don't increase the number of personnel—particularly in the Customs area.

Earlier, I raised the question of the manufacturers' costs and that is not really directly related here although I do think it is something that this subcommittee might look into. However, I think that there is room for doctors' samples, hospitals and clinics' samples and we certainly cannot come up with any sort of an idea

that would get us away from the discount sales of drugs or sales of drugs on a discount basis to nonprofit organizations; but therein, I think, lies really much of the problem.

It seems to me that the law is much too broad in terms of definition of charitable institutions and nonprofits and maybe sale to Third World countries, or whatever the case may be, which is just a wide open type of a thing and it encourages this sort of thing.

I know I spoke with my colleague here, Mr. Eckert, who by the way says the Eckert that is referred to in the report is not he and I said, "My gosh, there are so many ways to make money in this world, they are practically all illegal and that is certainly one of them."

Do you agree with those statements?

Mr. SIMS. Yes; I would simply add that in the nonprofit diversion area, there does not seem to be a problem in the law so much as a problem in enforcement. As best as the staff can determine—

Mr. BILIRAKIS. How about definition there? Definition of who qualifies?

Mr. SIMS. No; that does not appear to be so much of a problem either. The Supreme Court in the leading case ruled very clearly that a hospital could purchase these products under the exemption for its own use and reselling them to a wholesaler is very clearly not for its own use.

The problem lies, so far as we can determine, with the fact that the primary Federal agency that enforces this law is the Federal Trade Commission and that in section 4 of the Federal Trade Commission Act, they are denied jurisdiction over nonprofit institutions.

So you have the situation where their authority can reach the transactions but they can't directly reach the key institution in the transaction. So it complicates their ability to enforce the law.

Mr. BILIRAKIS. I see. But that is an area that we can possibly explore.

Mr. SIMS. Yes, sir.

Mr. BILIRAKIS. How about the law requiring purchase from a manufacturer or an authorized distributor? How about if we had a law that required that and then possibly really with more definitiveness defined what an authorized distributor might be? Would that be of some help?

Mr. SIMS. I think we should certainly consider those ideas just as we should seriously consider how to increase the accountability of the distribution system. But if you tried to draw a law that required people in the free market to purchase only from designated persons, you would have created yet another set of problems.

So it is a very complex area and I think we are going to need to bring all of the industry in and very carefully look at all these matters.

Mr. BILIRAKIS. All right. So, if we can basically limit the problem, or isolate the problem, I suppose is a better term, to the distribution network, then what we have to do is come up with suggestions or laws to improve that distribution network in some way that it would discourage that sort of thing from continuing to happen. Is that right?

Mr. SIMS. I would agree completely with your characterization.



Mr. BILIRAKIS. Has the committee come up with any suggestions in the process of all your investigations with what changes can be made?

Mr. SIMS. We are starting that process right now.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Chairman.

Mr. SIKORSKI. I thank the gentleman. The gentleman's time has expired. The gentleman from Ohio, Mr. Luken.

Mr. LUKEN. We are not talking about prescription drugs, are we? These are all over-the-counter drugs?

Mr. NELSON. These are all prescription drugs except controlled substances.

Mr. LUKEN. They are all prescription drugs?

Mr. SIMS. Our report focuses on prescription drugs. The same kind of activity takes place with over-the-counter drugs and health and beauty aids and other products, I would add.

Mr. LUKEN. Then clearly the jurisdiction of the Federal Government and the State government is there so that as you have indicated if we want to bring up the standards of the industry in handling the matter, there is no question that we have the jurisdiction; isn't that right?

Mr. SIMS. I would think so, sir.

Mr. LUKEN. What bothers me about all this and where I think you are really onto something in terms of the importance of it, the overriding importance of it, is we are not talking about clothing or hardware or even ordinary food products where it is a question of quality and the public being cheated. We are well beyond that.

But we are into an area, prescription drugs, where a positive therapeutic effect is usually anticipated in the use of these drugs and the failure of that therapeutic effect if we have a bogus or counterfeit item can be very deleterious to the health of the individual.

Mr. SIMS. That is absolutely correct.

Mr. LUKEN. So we are in an industry, for example, the medical doctors and nurses, we are in an industry where trust, where reputation, where integrity is so vital and yet you have just described here whole networks of operation of sale and resale of counterfeit products from one hand to the next where there appears to be lack of trust, the lack of reputability. Would you agree with that?

Mr. SIMS. I would agree with that and I would say that the reputable elements in the industry which, of course, make up the overwhelming majority, are hoping against hope that they don't have another Tylenol in the near future.

Mr. LUKEN. There seems to be almost a criminally callous approach on the part of such a broad segment of the industry. Do we have a lot of complaints from the industry? There must be a pretty broad awareness of this?

Mr. SIMS. Most of the major manufacturers have very active security programs.

Mr. LUKEN. Are they telling us about the others? They must be aware of what is going on outside their own particular shop.

Mr. SIMS. The major manufacturers have been very helpful to the staff and have provided us with whatever information we required and are obviously very concerned about this because it af-

fects their goodwill and their future sales in addition to their obvious concern about the health of their fellow Americans.

Mr. LUKEN. So it is going to be difficult as you have indicated to issue Federal licenses and restrict the handling and the resale of these products. It is going to be difficult. But as I understand from what you are saying you both would anticipate that some kind of Federal legislation or regulation would be helpful.

Mr. SIMS. I think that is our task, to see if we can define ways to increase the accountability, particularly at the wholesale market.

Mr. LUKEN. Such as putting a special burden on these resellers.

Mr. SIMS. If that is considered necessary, perhaps the subcommittee would want to consider that.

Mr. LUKEN. We would certainly want to look at what the FDA has been doing with this rubberstamp kind of operation, for example. They might be brought up to speed.

What I am getting from the whole description as I listen to it is that we are probably going to need more than that in setting forth stricter regulations and requirements.

Mr. SIMS. I would agree absolutely with what you said.

Mr. LUKEN. Incidentally, something has been bobbing around as you have been talking about it, are these only nonprofit hospitals that have been involved? What about the big profit hospitals?

Mr. NELSON. The law that gives the discounts—

Mr. LUKEN. I am not asking about the law. Who is involved in your investigation?

Mr. NELSON. For-profit hospitals get their drugs at the same cost as wholesalers so they have no resell incentive.

Mr. LUKEN. Is that right?

Mr. NELSON. That is my understanding.

Mr. SIMS. It may get complicated where for-profit and not-for-profit institutions are part of the same buying group, but by and large to the best of my knowledge the majority of the problem, the overwhelming majority of this particular problem, comes from the nonprofit institutions.

Mr. LUKEN. I guess the profit hospitals are not teaching institutions. I have never heard of one, but then I am from a section of the country where we don't have many for-profit hospitals. I would just think that in places like California, where the for-profit hospitals are large and sometimes predominate that you would find this practice extended to the for-profit hospitals, too, because of the very volume that they deal in and the fact that if they are large and they predominate, they are leading the industry there. They have the doctors who are the ones that the drug industry wants to influence and so on.

Mr. SIMS. I presume, Mr. Luken, that if a drug company wanted to sell to a class of purchasers which class would be made up of for-profit hospitals and as long as they did not discriminate between the different for-profit hospitals in the class of purchaser, that they could certainly sell to this class at a price below the average wholesale price.

Mr. SIKORSKI. Would the gentleman yield on that point?

Mr. LUKEN. I would be glad to yield.

Mr. SIKORSKI. In the report the letter from the lawyer attempts to use the fact that there was no discrimination in price between

the nonprofit and the for-profit to justify his opinion and the response from the Congressional Research Service so the point is that the cut is made and is applied apparently across the board or at least there is some evidence of it, the response from the Congressional Research Service. It doesn't still get you out from under the real enforcement problems.

Mr. LUKEN. I bring it up partially as an aside because the for-profit hospitals would be covered under the Federal Trade Commission.

Mr. SIMS. That is my understanding.

Mr. LUKEN. Maybe as we get into this further we will find that there is a problem also in the profit hospitals and it also might give us a peg or give the enforcement people a peg into getting into the matter in the for-profit areas where the exemption may apply.

What about that exemption? Does that prevent us from enforcement completely?

Mr. SIMS. No.

Mr. LUKEN. The exemption for nonprofit hospitals?

Mr. SIMS. The Federal Trade Commission has—

Mr. LUKEN. It makes it more difficult but not impossible; right?

Mr. SIMS. It makes it more difficult but not impossible. That is correct. They have jurisdiction over the transactions but they don't have jurisdiction over one of the parties in the transaction.

Mr. LUKEN. So they can still investigate fully?

Mr. SIMS. They are, in fact, investigating the matter.

Mr. LUKEN. We might consider the question ultimately of whether the exemption should apply in this case.

Mr. SIMS. I presume that we would want to call the Federal Trade Commission as one of the future witnesses and get them to tell us what their thought process was.

Mr. LUKEN. We would certainly want to call these hospitals as we get into the matter, at least the offending ones, that are involved. Has the FTC indicated that they want to investigate? What reaction have we gotten?

Mr. SIMS. The staff of the subcommittee has provided the staff of the FTC with all of these materials and the staff of the FTC is looking into the question.

On May 17 of this year, the materials were provided to the FTC. In early June they were referred to a deputy or an assistant director for litigation and since that time this individual and his staff have been studying the matter.

Mr. LUKEN. As we go along, I hope that the staff will advise the subcommittee as to the apparent vigor with which the FTC is proceeding. I think that the hearing this morning has indicated that the members would like to see that investigation vigorously prosecuted.

Mr. SIKORSKI. Good point. The time of the gentleman has expired. The gentleman from New York now has the time and then we will get to Mr. Robinson who will provide us with some helpful testimony. The gentleman from New York, Mr. Eckert.

Mr. ECKERT. Mr. Chairman, I just want to commend Mr. Sims and Mr. Nelson for a very fine report on a very interesting subject and for your testimony here this morning.

The only question I want to ask at this point, I do very much look forward to the hearings this fall but are there not criminal investigation actions going on right now against the middlemen?

Mr. SIMS. Yes. There are a number of open criminal cases.

Mr. NELSON. There are several sitting Federal grand juries.

Mr. SIMS. That is one reason why we are here before you today rather than some of the middlemen because of the constitutional problems and our desire not to possibly taint an ongoing criminal process.

Mr. ECKERT. Those actions are being taken not by the Federal Trade Commission?

Mr. SIMS. No. By the Department of Justice, the U.S. Attorney's Office, the FBI people.

Mr. ECKERT. Thank you.

Mr. SIKORSKI. I thank the gentleman. One last question, the gentleman from Oregon.

Mr. WYDEN. Thank you very much, Mr. Chairman. Gentlemen, I understand in the report that you document counterfeit polio vaccine being administered in the Philippines. Could this sort of thing possibly happen here in the United States due to our diversion drug market?

Mr. NELSON. One thing that we have seen and have documented in testimony and in reports is that counterfeiting itself of whatever product is a growing problem and the pattern evolves in certain parts of the world and ultimately those counterfeit products find their way here.

We have now had the first large-scale incident with the Ovulen 21. From everything we know about counterfeiting and everything we know about gray or diversion markets of this kind, I think it is reasonable to anticipate more counterfeit pharmaceuticals coming into the United States and the health problems that could result therefrom.

Mr. WYDEN. Would you like to add to that, Mr. Sims? That really leaped out at me. You document that problem in the Philippines and based on what you have described here, I think we need to know whether it could happen here.

Mr. SIMS. I would agree very definitely with my colleague that it not only could happen but we would be surprised if it didn't happen unless and until we make some changes in the process.

Mr. WYDEN. I thank the chairman.

Mr. SIKORSKI. I thank the gentleman from Oregon. The Chair now calls Mr. Philip Robinson, president of Robinson Associates, Inc. Once again, the subcommittee thanks the staff for their report and their testimony today and look forward to more in the future. Mr. Robinson, the rules of the subcommittee and the House are before you on the table. Do you have any objection to being sworn in as is the tradition of this subcommittee?

Mr. ROBINSON. No, I do not.

[Witness sworn.]

Mr. SIKORSKI. Mr. Robinson, please proceed.

TESTIMONY OF PHILIP ROBINSON, PRESIDENT, ROBINSON  
ASSOCIATES, INC.

Mr. ROBINSON. I am a licensed private investigator in New York State and president of Robinson Associates, Inc., a consulting firm that specializes in legal investigative work and management consulting.

As a result of 32 years of law enforcement experience with the New York County District Attorney's Office, I have developed considerable knowledge regarding the identities and techniques of companies that specialize in the diversion of pharmaceuticals and other products.

My involvement in the Randell case, which I will summarize, is particularly relevant to the subject of drug diversion. I will describe the general operation of the diversion market, but I must reserve many of my specific comments for the executive session.

On May 3, 1984, Jack Randell, president and sole shareholder of Audit Data, Inc., was indicted as the prime mover of a scheme that defrauded pharmaceutical manufacturers of approximately \$3,400,000. Randell and three coconspirators purchased pharmaceuticals through the United Cancer Institute [UCI], a previously existing nonprofit cancer research body, for the alleged treatment of cancer patients at UCI medical clinics.

Using the not-for-profit organization exemption to Federal anti-trust laws, discounts of up to 80 percent off regular wholesale price were obtained. No such clinics existed.

Randell also conspired with Louis Garruto, manager of the pharmacy advisory group, procurement department of the New York City Health and Hospitals Corporation, a nonprofit organization to purchase discounted pharmaceuticals for fictitious health care centers through the New York City organization.

The pharmaceuticals were diverted to wholesale and retail merchants. The schemes were carried out between June 1978 and May 1982. The sales personnel of the pharmaceutical companies became suspicious when the volume of sales to Randell increased significantly.

After a few months, a company would refuse to make discounted sales. Randell would then switch companies. During the period of the conspiracy, Randell purchased discounted products from no less than 17 different drug companies.

One of the principal purchasers of the diverted goods was Med Sales, a Hollywood, FL, wholesaler. Med Sales was one of the wholesale pharmaceutical companies that were known to deal in diverted merchandise, according to the testimony of Stanley Kowitt in the Florida bogus charity case described in the staff testimony earlier today.

Randell and his coconspirators were convicted of racketeering, mail, and wire fraud. Randell, his father and Garruto were also convicted of income tax evasion. The case was prosecuted in the Southern District of New York under a joint agreement between Federal and State prosecutors. Sentence was imposed on April 19 of this year. The total fines, forfeitures, back taxes, and penalties exceeded \$4.8 million.

Based on my experience in the Randell case and subsequent investigations, I have several general observations regarding the diversion market.

First, while there are several hundred diverters in the marketplace, a few large companies appear to handle the majority of the product and seem to have developed the diversion process to the highest art. These companies are primarily located in the New York metropolitan area and in Florida. There is a pattern of close cooperation between the various diverters. In some cases, the diverters have established shell companies through which they buy and sell.

After obtaining the merchandise, the diverters usually sell to other large wholesalers, whom I call receivers. The goods are resold, perhaps several times, for ultimate sale at retail. Large chain drugstores and large wholesale distributors are among the frequent customers of diverters.

For example, in the Randell case, the vice president for purchasing of Bindley Western Drug Co., a large Indianapolis, IN, distributor, testified that the company purchases \$600 million a year in pharmaceuticals, often from diverters.

These large companies tend to operate in cooperation with freight forwarders and trucking companies, which firms help conceal the involvement of the diverter. For example, the merchandise would be received by the freight forwarder for shipment overseas. Instead, the company would pass the shipment to a trucking company that would haul the goods to a destination designated by the diverter.

In some cases, false bills of lading or other records are prepared. The diverter would mastermind the entire transaction and bankroll the scheme from one of many banks, separate accounts or letters of credit, also designed to conceal the role of the diverting company.

The financial arrangements in the diversion process can be very complex. In one case I investigated one large diverter obtained 87 separate letters of credit from one bank and this was only one of about a dozen banks used by the diverter. In some of the schemes described in the staff report where pharmaceuticals were allegedly purchased for shipment to foreign countries, letters of credit were obtained from foreign banks. Diverters also use cashier's checks, some of which are made out to fictitious persons, to cover their financial trail.

The staff report mentioned several different methods of diversion, all of which are familiar to me. One variation the staff omitted is the promotional distribution scheme in which companies that are supposedly distributing promotional samples of over-the-counter products divert some or all the goods to the wholesale market instead. There are several open cases involving this type of activity.

Mr. SIKORSKI. Thank you, Mr. Robinson, for your public testimony. In order to not endanger lives or livelihoods or to undermine ongoing criminal investigations, we are going to ask that the questions and further testimony be conducted in execution session if there is no objection.

[No response.]

Mr. SIKORSKI. Hearing no objection, we will then convene in executive session in the offices of the counsel of the subcommittee and ask the reporter and Mr. Robinson to come with us.

[Whereupon, at 11:59 a.m., the subcommittee adjourned, to reconvene at the call of the Chair.]

## PREScription DRUG DIVERSION AND CONTERFEITING

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WEDNESDAY, AUGUST 7, 1985

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. Gerry Sikorski, presiding (Hon. John D. Dingell, chairman).

Mr. SIKORSKI. Today's hearing deals with the dangers of prescription drug diversion, and sources of the scheme. At our hearing last July 10, the subcommittee released a preliminary staff report, entitled "Prescription Drug Diversion and the American Consumer, What You Think You See May Not Be What You Get." This report outlines the potential dangers to the health and safety of unsuspecting American consumers from the operation of an illegal, subterranean diversion market.

In today's news, the FBI sting operation in Georgia further emphasizes the problem. The counterfeiting and illegal distribution of prescription drugs is a serious threat to the public health. It undermines the quality of America's pharmaceuticals and the public's confidence in them. It is shocking, but we have concluded that American consumers can no longer casually assume that the prescription drugs we receive at our local drugstores are safe or effective.

As one example, nearly 2 million counterfeit birth control pills have already reached our shores and gone into our distribution scheme, and an infinite number of dangerous fakes are available in the world market, awaiting only the greed of another drug diverter, a criminal, to enter the U.S. distribution system.

Drug diversion has grown to great proportions. Some have indicated it is an over \$1 billion a year business. It is a new black market, where the more than 2,000 suppliers include hospitals and clinics, sales representatives and doctors, pharmacies and relief groups, as well as wholesalers.

The result is a potentially dangerous drug supply. As an executive of one drug chain described it, there is so much counterfeit merchandise out there, that is what scares me. Well, the problem is one of big bucks, lax Government regulation and a too frequent hear-no-evil, see-no-evil, speak-no-evil attitude of industry.

Today, the subcommittee has called only one witness, Mr. Richard Allen, a senior agent with the Drugs and Narcotics Agency of



the State of Georgia. In a 2-year undercover operation, Mr. Allen, in conjunction with the FBI and U.S. attorney in Atlanta, found widespread fraud, mislabeling and misbranding and adulteration of drugs.

The Justice Department, through the offices of the U.S. attorney in Atlanta and elsewhere, took action that will likely result in some 46 guilty pleas by individuals and firms operating in the United States and abroad. There are at least 40 more targets of this investigation. The charges range from mislabeling and misbranding drugs to mail and wire fraud and conspiracy. Those charged include 14 pharmacists, 12 doctors and 20 businessmen, sales representatives and corporate executives.

Mr. Allen must be somewhat constrained in his testimony today, because the criminal investigation is far from over. He cannot discuss details of the investigation which have not been revealed publicly. The Chair intends to insure that these constraints are respected. We greatly appreciate his appearance and his unheralded efforts on behalf of the public. We are certain that his testimony today will help us grapple with this growing threat to public health.

It is clear from his testimony and that of others that the distribution system itself is a central problem. If we have learned anything from our 3-year investigation of foreign counterfeiting of American products, it is that we cannot rely on the U.S. Customs Service to keep dangerous products out of our marketplace.

Nor can consumers protect themselves from phony pharmaceuticals. Anyone who saw a box of the counterfeited Ovulen 21 held up against the real thing at our last hearing could plainly see that even pharmacists and health professionals cannot positively distinguish counterfeit drugs from the legitimate products.

The Food and Drug Administration, the FDA, does a relatively good job of regulating American manufacturers of pharmaceuticals. States keep pretty close tabs on the retail pharmacies, but nobody, nobody is really watching the wholesale distributors of prescription drugs that are not controlled substances. Yet, these products are essential to human health. They can save or they can take human lives.

While no one can protect us completely from dangerous counterfeits coming from abroad, Customs and FDA can do far more than they have today to eliminate the menacing threat of drug diversion.

Chairman Dingell is unable to attend this hearing today, and has asked me to enter into the record a copy of his prepared statement, as well as copies of letters to William von Raab, Commissioner of the U.S. Customs Service, and Dr. Frank Young, Commissioner of the Food and Drug Administration. In these letters, the chairman has requested that all pharmaceuticals entering this country as American goods returned be detained until they can be tested to assure that they are what they say they are.

Without objection, these documents will be entered in the record, and the record will be left open for the replies of the Customs Service and the FDA.

I wish to add that I have joined the chairman in making this request. Based on the hearing record and the information, we will

work to develop comprehensive legislation to eliminate this health threat.

In the meantime, the least the Government can do is to test the pharmaceuticals which present the most clear and present danger to American consumers. We intend to make sure that responsible agencies do just that.

Mr. Allen, do you want to step forward? Are there any opening statements that we want to insert in the record at this point? Without objection, the statement by Larry D. Thompson, the U.S. attorney, Northern District of Georgia, will also be entered into the record.

[Testimony resumes on p. 49.]

[The statements and letters referred to follow:]

STATEMENT OF HON. JOHN D. DINGELL

Investigation by the Subcommittee has revealed that a major source of prescription drug diversion is the import of pharmaceuticals designated, "American goods returned." As Chairman of the Subcommittee, I have requested today that the U.S. Customs Service and the Food and Drug Administration, the agencies responsible for policing pharmaceutical imports, embargo all imports of pharmaceuticals marked "American goods returned," until each entry can be tested to assure the drugs pose no danger to the health of American consumers.

Over one million counterfeit Ovulen 21 birth control pills were entered into the United States last year from Panama labeled "American goods returned." The entries received routine approval from the Customs Service and the Food and Drug Administration.

This situation occurred because of the addepleted policies of both agencies, who are attempting to cope with budget cuts by reducing inspections of imports, at the same time that imports are growing exponentially. In particular, the U.S. Customs Service "By-pass" procedure, which exempts whole classes of imports not only from inspection but also meaningful paperwork review, practically assures the easy import of fraudulent and dangerous products.

The paperwork review of entries by import specialists is vital to the detection and interdiction of counterfeit and substandard pharmaceuticals, as well as other commercial contraband. Yet, the Administration appears irrationally determined to reduce this vital force of import specialists.

American consumers might still be unaware of the danger posed by diverted pharmaceuticals were it not for the work of such a Customs Service employee, who prevented the entry of even more fake birth control pills. During a random spot check of the by-pass system, a New York import specialist happened to come across an Ovulen 21 entry after reading press accounts about the earlier Florida entry of counterfeit pills. The import specialist was able to order redelivery of the phony pills, which were subsequently seized at a Long Island wholesaler before they could be disbursed into drugstores throughout the United States.

It is important to note that even legitimate pharmaceuticals marked "American goods returned" pose significant health and safety problems to American consumers. The export and reimport process contains inherent dangers, including lack of proper storage and handling controls. Drugs destined for foreign markets may be labelled differently than those designed for sale in our market. Thus, these prescription drugs may be expired, mislabelled or damaged from excessive heat, cold or moisture. There is simply no assurance that they are safe.

The Subcommittee's investigation to date indicates that legislation may be necessary to control this dangerous market in diverted drugs. However, until the Subcommittee has had time to consider all the dimensions of this market and recommend appropriate change in the law or its administration, the least we can do for the American consumer is have the Government test the most suspicious drugs before they enter the marketplace.

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PRESS CONFERENCE STATEMENT OF LARRY D. THOMPSON, U.S. ATTORNEY, NORTHERN DISTRICT OF GEORGIA, AUGUST 6, 1985

We are here this morning to announce the culmination of a 2 year nationwide FBI undercover operation and the prosecution of 46 individuals and corporations for

engaging in a variety of illegal practices which are sometimes broadly referred to as drug diversion and drug adulteration and misbranding.

However, before we begin we would like to publicly acknowledge our sorrow in the passing of our colleague Phil Peters. Mr. Peters, as many of you know, was the Director of the Georgia Bureau of Investigation. Phil was a dedicated law enforcement professional. I know I speak for the entire federal law enforcement community when I say that we lost a friend and valued colleague in Phil. I also know that Phil and the GBI have been keenly interested in the problems posed by illegal drug diversionary practices, and I believe Phil would have been extremely pleased with the results of the investigation we are announcing today. Our prayers go out to Mrs. Peters, Phil's three sons, and the rest of the Peters family.

The undercover operation and prosecutions we announce today are significant for two primary reasons. They serve to protect the American public's right to receive safe and high quality prescription drugs. They also serve to put on notice any would be violators that the fraudulent procurement of drugs and the adulteration and misbranding of drugs will not be tolerated and that such practices will be investigated and any prosecuted in a vigorous manner by Federal and State law enforcement officials and regulatory authorities.

The undercover operation we announce today is code named "pharmoney." It involved an FBI undercover agent who operated an enterprise by the name of Pharmacy Services Co. in Atlanta and which purported to be a hospital pharmacy management firm. The FBI agent dealt with physicians, pharmacists, drug wholesalers, and individuals throughout the United States who were involved in the drug diversionary process.

The investigation revealed and the criminal informations filed today allege basically two general types of illegal practices involving the distribution of otherwise legal prescription drugs.

First, many of the criminal informations allege schemes involving the fraudulent procurement of drugs. These informations allege that individuals would falsely represent to drug manufacturers that drugs were being purchased for use in such organizations as hospitals or international nonprofit organizations. Drugs are sold to such organizations by manufacturers at sometimes very low prices. The drugs so purchased would then be "diverted" from the represented uses to resale to consumers at substantial profit to the diverters.

As a result of such fraudulent procurement schemes, drugs are taken out of the legitimate distribution system. This jeopardizes the ability of manufacturers to trace drugs in the event of a product recall since the drugs are not used by the entity which ordered them. Regulatory authorities are also unable to monitor diverted drugs because the authorities have no way to check as to whether such drugs have been properly stored or handled in the distribution system so as to preserve potency.

The second broad category of illegal practices revealed by this operation concerns allegations in several of the criminal informations involving drug adulteration and misbranding.

Several defendants are alleged to have illegally removed drugs from their original packages and labeling; to have placed loose pills in plastic baggies or other unauthorized containers; and to have tampered with drug lot numbers, expiration dates and other required data such as removal of the word "sample" imprinted on individual capsules. Search warrants were executed in six States (Georgia, Tennessee, Mississippi, Alabama, Florida, and California). FBI agents and investigators with the Georgia Drugs and Narcotics Agency seized numerous quantities of adulterated and misbranded drugs (value equals \$620,000).

Seized by agents were hundreds of thousands of loose pills and liquids without lot numbers, expiration dates or other identifying data. These pills and liquids were seized in open boxes, used paper grocery sacks, cellophane bread wrappers, old soft drink plastic bottles, plastic baggies and other unauthorized containers. Many of these pills had been expired for 3 to 5 years. Electric erasers and silver paint used to conceal the sample notations on packs of birth control pills were also seized, along with razor blades, bottles of acetone, finger nail polish remover, and rubbing alcohol.

Mr. Bob Fay of the FBI will describe many of these items to you in more detail later on.

Named as defendants in the informations filed are physicians, manufacturers sales representatives, pharmacists and drug wholesalers.

The FBI and the Georgia Drug & Narcotics Agency are to be congratulated for undertaking this complex and important investigation. Significant quantities of adulterated and misbranded drugs have been prevented from reaching the consuming public. More importantly, however, I believe a clear message has been sent as to

the Federal and State commitment to investigate and prosecute these types of illegal, unsafe and dangerous drug distribution practices, as well as to make the drug distribution system safe for the consuming public.

Mr. Weldon Kennedy, Special Agent in Charge of the Atlanta FBI Office, will now explain to you in more detail how a typical drug diversion scheme works.

NINETEENTH CONGRESS

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U.S. House of Representatives  
 Subcommittee on Oversight and Investigations  
 of the  
 Committee on Energy and Commerce  
 Washington, DC 20515

August 5, 1985

The Honorable William von Raab  
 Commissioner of Customs  
 U. S. Customs Service  
 1301 Constitution Avenue, N. W.  
 Washington, D. C. 20229

Dear Commissioner von Raab:

I am transmitting a copy of a Subcommittee staff report entitled "Drug Diversion: Prescription Drug Diversion and the American Consumer: What You Think You See May Not Be What You Get". This report was prepared as part of the Subcommittee's ongoing investigation into the sources of, and dangers from, prescription drug diversion.

One obvious conclusion to be drawn from this report is that the most clear and present danger to the health and safety of Americans from the drug diversion market involves counterfeit or other pharmaceuticals reimported into the United States. I was shocked to discover that goods entered into this country as "American Goods returned" are routinely by-passed under Customs current procedures.

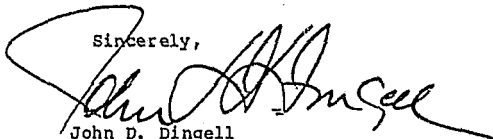
As you may be aware, the counterfeit Ovulen 21 birth control pills were entered in the ports of Miami and New York as "American goods returned". Neither Customs nor the Food and Drug Administration (FDA) thought to question why birth control pills allegedly made in the United States should be seeking reentry from Panama. These were, of course, foreign sourced counterfeits. However, even in the case of pharmaceutical products actually manufactured in this country, exported, and then reimported, there is no way that the laws of the United States can assure that these pharmaceutical drugs have been properly handled, stored and labelled. Accordingly, we believe that it is incumbent on the officials charged with assuring that unsafe or inefficacious drugs do not reach unsuspecting American consumers from abroad act to create conditions of import designed to minimize the risks from foreign supplies of pharmaceuticals.

The Honorable William von Raab  
August 5, 1985  
Page 2

The Subcommittee does not yet have evidence sufficient to justify a request that all imported pharmaceuticals be inspected and tested. However, we can see no reason why any pharmaceutical reimported into the United States should escape careful scrutiny. I am attaching a copy of a letter to Frank E. Young, Commissioner of the Food and Drug Administration asking that all pharmaceuticals entered as "American goods returned" be tested by FDA before they are released to the importer of record. I trust that you and Commissioner Young will act promptly to establish procedures to prevent the release of these potentially dangerous drugs until they have been thoroughly tested.

Under separate cover, the Subcommittee will also seek certain documents needed for our investigation. Your cooperation with this investigation to date has been very valuable. Should you have any questions regarding this request, please contact David Nelson or Stephen Sims of the Subcommittee staff at 225-5365.

Sincerely,



John D. Dingell  
Chairman  
Subcommittee on

Oversight and Investigations

cc: Members of the Subcommittee on  
Oversight and Investigations

The Honorable Frank E. Young  
Commissioner  
Food and Drug Administration

JDD:DNdb

*U.S. Customs**To: MHC  
OK  
LS*

**THE COMMISSIONER OF CUSTOMS**

WASHINGTON, D.C.

August 13, 1985

RECEIVED

INS-1-IC:C FP

AUG 13 1985

Subcommittee on Oversight  
and Investigations

Dear Mr. Dingell:

In your letter of August 5, 1985, you outlined concerns regarding the importation of pharmaceuticals, manufactured abroad or reentered into American commerce as American goods returned, citing a danger to the health and safety of American consumers. The Subcommittee's report, "Drug Diversion," has been reviewed; and we share your view that such merchandise should be carefully screened prior to release.

Regarding pharmaceuticals, the data base of our Automated Commercial System in fact flags all drugs by specific tariff reporting number. Merchandise entered as such is held pending Food and Drug Administration review and an FDA-form, FD-701, May Proceed Notice, is also required.

However, if this same merchandise is entered with a claim of American origin, classification for duty purposes changes to a "general" tariff reporting number (TSUS 800.00), and the alerts for FDA review are not activated.

The following actions are being taken immediately.

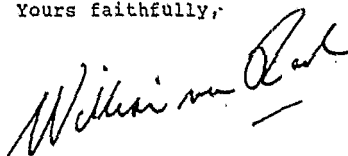
- o Criteria alerts have been added to the ACS data base to complement existing data; all pharmaceuticals entered with a claim of American origin will be denied release pending FDA action.
- o Import specialists have been directed to initiate a careful screening of entry summary packages involving pharmaceuticals, including all returned American goods claims.

- o FDA has been contacted and a meeting arranged so that a coordinated effort can be brought to bear on the problem. We will advise you of the outcome of this meeting.

In regard to the Subcommittee report, various firms involved in the documented diversion schemes were named. Risk alerts for these firms have been entered into our data base, and all future importations will be thoroughly screened. In addition, the Subcommittee report has been referred to our Office of Investigations for further action. We would appreciate having any additional information along these lines collected by the Subcommittee staff during their study. For your information, enclosed is an Import Alert disseminated in 1984 on the same subject.

Please be assured that we share your concern for the health and safety of the American consumer and appreciate your input in maintaining and improving the efficiency of our operations.

Yours faithfully,



The Honorable  
John D. Dingell  
Chairman, Subcommittee on  
Oversight and Investigations  
House of Representatives  
Washington, D.C. 20515

Enclosure

HAND DELIVER!





DEPARTMENT OF THE TREASURY  
U.S. CUSTOMS SERVICE  
CUSTOMS INFORMATION EXCHANGE



DEC 24 1984

CIE N-18/85  
January 14, 1985

RE: Telex No. 13193, dated December 3, 1984

Subject: Import Alert, Importations of Possible Counterfeit  
Drugs in Violation of Food and Drug Administration  
(FDA) Requirements

OTHER AGENCY COMPLIANCE CIRCULAR NO. 158

RES-2-08-CO:T:D:E: HF

BACKGROUND: This issuance contains confidential information which is deemed to be exempt from disclosure within the meaning of 5 U.S.C. and part 103, Customs Regulations. No part of the contents may be released without specific authorization from Headquarters.

Customs Headquarters has been advised by FDA Headquarters of possible counterfeit drugs being imported. Complaints by Searle Pharmaceuticals, Inc., concerning counterfeit ovulen-21 (oral contraceptive) tablets has prompted an FDA investigation.

It appears the subject drugs may be originating in Panama, Central and South America with importations through Miami and New York. However, other countries and other ports could be expected to be involved.

FDA is seeking the assistance of the Customs Service to withhold release of all suspect importations, pending their approval.

ACTION:

1. Noting the caveat concerning disclosure identified above under "Background", the substance of this issuance should be brought to the attention of all Customs officers.
2. Customs officers should be alert to importations of any drugs or pharmaceutical products from Panama and other Latin American Countries.

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PHONE (202) 225-4441

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CHIEF COUNSEL/STAFF DIRECTOR

U.S. House of Representatives  
Subcommittee on Oversight and Investigations  
of the  
Committee on Energy and Commerce  
Washington, DC 20515

August 5, 1985

The Honorable Frank E. Young, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Commissioner Young:

As you are aware, the Subcommittee on Oversight and Investigations has been conducting an investigation into the sources of, and the dangers from, prescription drug diversion. As is readily discernible from the recent Subcommittee staff report on the subject, previously furnished to you, the most clear and present danger to the health of American consumers appears to come from pharmaceuticals manufactured overseas or reimported from abroad.

As you can see from the attached copy of a letter to Commissioner William von Raab of the U.S. Customs Service, I have asked that all pharmaceuticals entered as "American goods returned" be denied entry into this country until your Agency has sampled and tested each entry to assure that the drugs are safe and efficacious.

Frankly, I see no reason why such entries would not automatically raise serious suspicions. Apparently, neither the FDA nor Customs felt that Ovulen 21 birth control pills reimported from Panama should be detained and tested. These entries through the ports of Miami and New York were foreign sourced counterfeits that entered the diversion market in the United States. Many of these counterfeit birth control pills reached unsuspecting consumers before either FDA or G.D. Searle, the legitimate patent and trademark holder, became aware of their existence and initiated recalls.

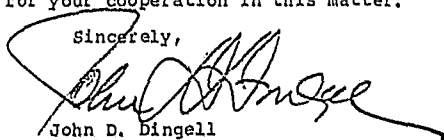
I trust that you and Commissioner von Raab will act quickly to implement the necessary procedures to assure that these potentially very dangerous pharmaceutical drug imports are inspected and tested automatically before they are released into the commerce of the United States.

The Honorable Frank E. Young, M.D.  
August 5, 1985  
Page 2

We would appreciate receiving copies of all memoranda of understanding agreed to and directives issued by your office or any other office within FDA implementing this request.

Should you have any questions regarding this request, please contact David Nelson or Stephen Sims of the Subcommittee staff at 225-5365. Thank you for your cooperation in this matter.

Sincerely,



John D. Dingell  
Chairman  
Subcommittee on  
Oversight and Investigations

cc: Members of the Subcommittee on  
Oversight and Investigations

The Honorable William von Raab  
Commissioner  
U.S. Customs Service

JDD:DNdb



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

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 Food and Drug Administration  
 Rockville MD 20857

August 21, 1985

The Honorable John D. Dingell  
 Chairman, Subcommittee on Oversight  
 and Investigations  
 Committee on Energy and Commerce  
 House of Representatives  
 Washington, D.C. 20515

Dear Mr. Dingell:

I write to respond to your August 5 letter requesting information about the Food and Drug Administration's (FDA) efforts to seek out drugs, entering this country as "American goods returned," that may actually be illegally diverted pharmaceuticals.

We share your concern about the potential dangers to public health posed by the drug diversion market and have been active in trying to identify and address both drug diversion and drug counterfeiting. Our import specialists are aware of the possibility that drugs entering this country, labeled as "American goods returned," may actually be illegally diverted drugs or otherwise in violation of the law. Further, FDA officials regularly hold national import conferences with the import program managers from each of our district offices, at which those import specialists are counselled to consider returned American goods as suspect. More recently, during our investigation of counterfeit Ovulen 21 birth control pills, our New York Import District, together with U.S. Customs officials, discovered potential problems associated with drugs entering the United States as "American goods returned." In response, that District began closer surveillance of such drugs as a means of assuring that potentially unsafe drugs not enter American markets.

Our recent experiences, and the findings of your investigation, have led us to conclude that closer surveillance of returned drugs is warranted. Therefore, we are preparing a special directive for all FDA offices that will further emphasize to our inspectors the need to examine closely all drugs identified as "American goods returned." Specifically, it will direct them to assure that the shipment's chain of custody can be documented back to the original manufacturer, that the drug's expiration date has not been passed, and that the reason for the goods' return is not indicative of adulteration or other violations of the Federal Food, Drug, and Cosmetic Act.

Page 2 - The Honorable John D. Dingell

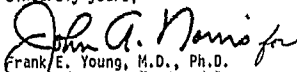
Under this new initiative, FDA will automatically detain all drugs that are American goods returned until adequate documentation is provided by the importer. Similarly, the Customs Service has revised its Automated Commercial System that tracks imports to ensure that all drugs entering the United States with a claim of American origin are held until FDA inspectors can examine them. In addition, although resource limitations prevent us from sampling every returned drug, we will continue our program of routinely sampling and analyzing certain drug imports, regardless of country of origin.

To insure that the Customs Service agreed with these procedures, FDA's top regulatory and field officials met with their counterpart officials at Customs on August 14 to discuss these actions, as well as other approaches for dealing with suspect drug imports. As you know, the Customs Service and FDA have a long-standing tradition of cooperation in the regulation of imported foods, drugs, and other products regulated by FDA. Furthermore, it is standard procedure for Customs officers to notify us of all products regulated by FDA that enter the United States from a foreign country, including those entering as returned American goods.

While I believe that this nation's drug supply remains safe, and that the vast majority of manufacturers and suppliers of our pharmaceuticals are honest and dedicated individuals, the aberrations we have seen recently are evidence that we must be ever vigilant against threats to the supply of safe and effective drugs.

If I can be of further assistance, please let us know.

Sincerely yours,

  
Frank E. Young, M.D., Ph.D.  
Commissioner of Food and Drugs

Mr. SIKORSKI. Mr. Allen, welcome. We thank you for coming here and assisting us and we commend you as well for your efforts over the last 2-plus years in this operation.

You have before you the Rules of the House of Representatives as well as the subcommittee. Do you have request for counsel?

Mr. ALLEN. No.

Mr. SIKORSKI. Do you have any objection to being sworn in, as is the custom of this subcommittee?

Mr. ALLEN. No, sir.

Mr. SIKORSKI. If not, will you stand and raise your right hand. [Witness sworn.]

Mr. SIKORSKI. Thank you.

Mr. Allen, do you want to make your statement.

**TESTIMONY OF RICHARD ALLEN, SENIOR AGENT, DRUGS AND NARCOTICS AGENCY, STATE OF GEORGIA**

Mr. ALLEN. Please, sir.

I am Richard Allen. I am a graduate of the University of Georgia. I am a registered pharmacist. I have some experience in hospital and retail pharmacy as well. I have been employed as a senior agent by the Georgia State Board of Pharmacy and the Georgia Drugs and Narcotics Agency since 1976. My duties have included the enforcement of both regulatory and criminal statutes regarding the distribution of controlled substances and prescription drugs, and as you have previously stated, the factual information which I will provide in my testimony is that which is alleged in search warrant affidavits and informations made public and disclosed at a press conference in Atlanta, GA yesterday, August 8, 1985.

I hope you will understand that my testimony cannot go outside the public record.

Yesterday the U.S. attorney for the Northern District of Georgia, the Atlanta office of the Federal Bureau of Investigation, and the Georgia Drugs and Narcotics Agency announced the initial results of a 2-year nationwide FBI undercover operation with the filing of criminal informations charging 43 individuals and 3 corporations with violating Federal wire fraud, mail fraud, conspiracy, interstate transportation of drugs obtained by fraud, and drug adulteration and misbranding statutes. The U.S. attorney said that there are at least are 40 other targets under active investigation.

The FBI was assisted in this Atlanta-based operation by the Georgia Drugs and Narcotics Agency and the Georgia Board of Pharmacy.

The undercover operation, code named "PHARMONEY", revealed, and many of the criminal informations allege, schemes of national and international scope, wherein false and fraudulent representations were made, directly and indirectly, to drug manufacturers that drugs were being purchased at preferential low prices for use of hospitals, nursing homes, clinics, foreign countries, and international nonprofit organizations. Instead, the drugs were resold at substantial profit for ultimate dispensing to consumers with prescriptions.

The FBI undercover agents, while operating Pharmacy Services Co. in Atlanta and purporting to be a hospital pharmacy manage-

ment firm, dealt with individuals in all parts of the United States who performed varied functions in this diversion process. The criminal informations charge both those who placed orders for drugs using false and fraudulent pretenses and representations to obtain the low purchase prices, and those who purchased such drugs diverted from hospital, clinic, nursing home, export, and charitable use, knowing such drugs to have been originally obtained from the manufacturer by fraud.

Persons charged include owners, corporate officers or employees of hospital pharmacy management firms, national and regional pharmaceutical wholesalers, retail drugstore chains, neighborhood pharmacies, physicians, clinics and drug manufacturers, in other words, sales representatives, as well as brokers and middlepersons.

Many of the criminal informations charge drug adulteration and misbranding, alleging some of the same defendants involved in fraudulent diversion to have also removed drugs from their original packaging and labeling, under less than good manufacturing practices, and placed loose pills in plastic baggies or other unauthorized containers without accurate and verifiable lot numbers, expiration dates, and other required data.

According to criminal informations, drugs were shucked or removed from their original packaging and labeling because: one, they were expired; two, the identifying stock number on their label, caused by the misrepresentation that they were for consumption by the nonpublic sector, had to be removed; three, they were manufactured under Spanish labels, without U.S. inspection and controls in Mexico; or four, they were marked "sample--not to be sold" and had been originally obtained from drug manufacturers under the false and fraudulent pretense that they would be dispensed for promotional purposes free of charge to patients of doctors and clinics.

Some defendants are charged with causing the removal of the word "sample" imprinted on individual capsules through scraping with razor blades or through application of the chemical acetone, fingernail polish remover, and rubbing alcohol. Other defendants are alleged to have purchased and resold such drugs across the United States for ultimate dispensing to consumers with prescriptions.

During this investigation the FBI, with the assistance of the Georgia Drugs and Narcotics Agency, conducted 13 searches in Georgia, Tennessee, Mississippi, Alabama, Florida, and California, wherein agents seized adulterated, misbranded and sample pharmaceuticals worth more than \$620,000. Included in those searches were the residence of P. Nelson Chambliss of Macon, GA on October 3, 1984; Hospital Discount Pharmacy of Tucker, GA on February 22 and February 26, 1985; Jim Wilson's Store-All Mini-Warehouse located in Marietta, GA on March 8, 1985; Don's Drugs in Tracy City, TN on April 11, 1985; Medical Plaza-Health Mart in Corinth, MS on April 23, 1985; the residence of Rick Quinn in Corinth, MS on April 23, 1985; the residence of Earl Steward in Linden, AL on April 25, 1985; Little Rexall Drug, Main Street, Linden, AL on April 25, 1985; River House of Earl Steward in Linden, AL on April 25, 1985; Rancho San Diego Pharmacy in La Mesa, CA on May 7, 1985; Valu-Med Pharmacy of Santee, CA on

May 8, 1985; and Hermax Drugs in Jacksonville, FL on June 5, 1985.

Named as defendants in the alleged national distribution of adulterated and misbranded baggie pharmaceuticals are physicians, manufacturers' sales reps., registered pharmacists, and drug wholesalers.

Drug thefts, charged as mail frauds, exceeding one-quarter of a million dollars were detected by the undercover operation, resulting in significant recoveries.

Arraignments on the criminal informations filed today and summarized in the attached chart will be scheduled to begin the week of August 12, 1985. Assistant U.S. attorney Gale McKenzie will be handling these cases.

Mr. SIKORSKI. Without objection, the lists attached to the press release will be inserted in the record.

[The lists follow:]



SUMMARY OF FEDERAL CRIMINAL CHARGES

<u>NAME</u>		<u>AGE</u>	<u>CITY/STATE</u>	<u>VIOLATION</u>	<u>MAX. SENTENCE</u>
ANDERSON, W. Richard	Physician (M.D.)	56	St. Petersburg, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulterated & Misbranded Drugs	1 yr/\$1,000
ASHER, Stephen Lee	VP Drug Wholesaler (Bindley-Western)	37	Indianapolis, INDIANA	18 USC 1341 Mail Fraud	5 yrs/\$1,000
ATKINSON, Tom B.	Pharmacist/Owner (Bolton Professional Pharmacy)	45	Atlanta, GEORGIA	18 USC 1341 mail fraud 21 USC 331(c) & 333(b) Adulterated & Misbranded Drugs,	5 yrs/\$1,000 3 yrs/\$10,000
BARNWELL, W. Edward, Jr.	VP Drug Wholesaler (Lawrence Pharmaceuticals)	55	Jacksonville, FLORIDA	18 USC 1343 Wire Fraud 21 USC 331(a) & 333(b) Adulterated & Misbranded Drugs	5 yrs/\$1,000 3 yrs/\$10,000
BIERMAN, Alan	Pharmacist/Owner (Valu-Med Pharmacy)	41	San Diego, CALIFORNIA	21 USC 331(a) & 333(b) Adulterated & Misbranded Drugs (2 cts)	6 yrs/\$20,000
BLECHMAN, Stephen	VP Drug Wholesaler (Cooperative Purchasing Consultants and others)	40	Hill Valley, CALIFORNIA	18 USC 1343 Wire Fraud	5 yrs/\$1,000
BURKLOW, Eddie R.	Drug Wholesaler (Benchmark Medical Services)	45	Marietta, GEORGIA	18 USC 1341 Mail Fraud 18 USC 1343 Wire Fraud	5 yrs/\$1,000 5 yrs/\$1,000

<u>NAME</u>		<u>AGE</u>	<u>CITY/STATE</u>	<u>VIOLATION</u>	<u>MAX. SENTENCE</u>
BURSTEN, Julian	Pharmacist/Employ- ee Generic Drug Wholesaler (Phar- meral, Inc.)	65	Pomona, NEW YORK	18 USC 1343 Wire Fraud	5 yrs/\$1,000
CASH, William E., Jr.	Pharmacist/Pres. Drug Wholesalers (Benchmark Medical Services & Pharm- acies Resources)	38	Roswell, GEORGIA	18 USC 1341 (2 cts) Mail Fraud	10 yrs/\$2,000
CHAMBLISS, P. Nelson	Drug Sales Rep (Armour Pharm.)	44	Macon, GEORGIA	18 USC 1341 (2 cts) Mail Fraud	10 yrs/\$2,000
CONTRERAS, Carlos S.	Physician (M.D.)	40	Dublin, GEORGIA	18 USC 1341 Mail Fraud	5 yrs/\$1,000
COOPERATIVE PURCHASING CONSULTANTS, INC.	Drug Wholesaler		Atlanta, GEORGIA Mill Valley, CALIFORNIA Greenwich, CONNECTICUT	18 USC 1343 Wire Fraud	\$500,000*
COOPER, James T.	Physician (M.D.)	50	Marietta, GEORGIA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulter- ated & Misbranded Drugs	1 yr/\$1,000
COOVERT, Earl J.	Pres/Gen Mgr Drug Wholesaler	40	Marietta, GEORGIA	18 USC 1341 (2 cts) Mail Fraud	10 yrs/\$20,000

\* The authorized fine for an offense committed after December 31, 1984, is the largest of--(a) the amount specified in law defining the offense; (b) double the gross pecuniary gain derived by the defendant from the offense; (c) double the gross pecuniary loss caused by the offense; or (d) the following: Any felony or a misdemeanor resulting in death--Individual defendant \$250,000--Other defendant \$500,000; Other misdemeanor punishable by more than 6 months--Individual defendant \$100,000--Other defendant \$100,000.

<u>NAME</u>		<u>AGE</u>	<u>CITY/STATE</u>	<u>VIOLATION</u>	<u>MAX. SENTENCE</u>
DRESDEN, GARY A.	Physician (M.D.)	44	St. Petersburg, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulterated & Misbranded Drugs	1 yr/\$1,000
EDWARDS, Donald S.	Drug Sales Rep (Ayerst Labs.)	32	Snellville, GEORGIA	21 USC 331(k) & 333(b) Adulterated & Misbranded Drugs	3 yrs/\$10,000
ESKENAZI, Samuel	Pharmacist/Owner (Cheshire Bridge Discount Drugs)	30	Atlanta, GEORGIA	18 USC 1343 Wire Fraud	5 yrs/\$1,000
GADDY, Dennis H.	Sales Mgr Generic Drug Wholesaler (General Generics)	30	Oxford, MISSISSIPPI	21 USC 331(a) & 333(b) Adulterate & Misbranded Drugs (2 cts)	6 yrs/\$20,000
GASSAWAY, Dennis L.	Drug Sales Rep (Roche Labs.)	35	Albuquerque, NEW MEXICO	18 USC 1341 Mail Fraud	5 yrs/\$1,000
GEMMILL, W. Michael	VP Gen Mgr Drug Wholesaler (Bindley-Western)	35	Atlanta, GEORGIA	18 USC 1341 Mail Fraud 21 USC 331(c) & 333(b) Adulterated & Misbranded Drugs	5 yrs/\$1,000 3 yrs/\$10,000
GENERAL GENERICS	Generic Drug Wholesaler		Oxford, MISSISSIPPI	21 USC 331(a) & 333(b)	3 yrs/\$10,000
GROSSMAN, Gerald	Physician/Pres Drug Wholesalers (Cooperative Purchasing Consultants and others)	47	Mill Valley CALIFORNIA	18 USC 1343 Wire Fraud	5 yrs/\$1,000
HALL, Thomas E.	Owner Drug Wholesaler (C & H Wholesale)	43	Atlanta, GEORGIA	18 USC 1343 (2 cts) Wire Fraud	10 yrs/\$2,000

<u>NAME</u>		<u>AGE</u>	<u>CITY/STATE</u>	<u>VIOLATION</u>	<u>MAX. SENTENCE</u>
HARWOOD, A. Clinton	Pharmacist (Hospital Discount Pharmacy)	25	Tucker, GEORGIA	21 USC 331(k) & 333(a) Adulterated & Mis- branded Drugs	1 yr/\$1,000
JOHNSON, Roger A.	Gen Mgr Drug Wholesaler (Calendar Corp.)	43	LaHabra Hgts, CALIFORNIA	18 USC 1343 Wire Fraud 21 USC 331(a) & 333(b) Adulterated & Mis- branded Drugs	5 yrs/\$1,000 3 yrs/\$10,000
KILMARK, Robert M.	Physician (M.D.)	45	St. Petersburg, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulter- ated & Misbranded Drugs	1 yr/\$1,000
KING, Kenneth	Sales Mgr Drug Wholesaler (Williams Generics)	25	Memphis, TENNESSEE	21 USC 331(a) & 333(b) Adulterated & Mis- branded Drugs (2 cts)	6 yrs/\$20,000
MACOSKY, Frank J.	Owner/Drug Wholesaler (Frank-N-Scents)	39	LaMesa, CALIFORNIA	18 USC 1341 Mail Fraud 18 USC 371 Conspiracy	5 yrs/\$1,000 5 yrs.\$10,000
MAPLES, Will	Pharmacist/Owner (Fairfax Drugs)	53	Fairfax, ALABAMA	18 USC 1343 Wire Fraud	5 yrs/\$1,000
McALISTER, Robert E.	Physician (M.D.)	36	Norcross, GEORGIA	18 USC 371 to violate 21 USC 332(b) & 333(a) Conspiracy re Adulter- ated & Misbranded Drugs	1 yr/\$1,000
MIDDLEBROOKS, Rollin P., III	Drug Sales Rep (Roche Labs.)	31	Albuquerque, NEW MEXICO	18 USC 1341 Mail Fraud	5 yrs/\$1,000
MLINAR, Robert	Pres/Gen Mgr Drug Wholesaler (TriState Pharma- cuticals)	45	Cincinnati, OHIO	21 USC 331(a) & 333(b) Adulterated & Mis- branded Drugs (2 cts)	6 yrs/\$20,000

<u>NAME</u>		<u>AGE</u>	<u>CITY/STATE</u>	<u>VIOLATION</u>	<u>MAX. SENTENCE</u>
MOORE, C. Donald	Pharmacist/Owner (Don's Drugs)	45	Tracy City, TENNESSEE	18 USC 371 Conspiracy 21 USC 331(c) & 333(b) Adulterated & Misbranded Drugs	5 yrs/\$10,000  3 yrs/\$10,000
NAIL, Harry M.	Sales Mgr Drug Wholesaler (Bindley-Western)	39	Atlanta, GEORGIA	21 USC 331(c) & 333(b) Adulterated & Misbranded Drugs (2 cts)	6 yrs/\$20,000
PHARMACY RESOURCES CORPORATION	Hospital Pharmacy Management Firm		Roswell, GEORGIA	18 USC 2314 (2 cts) Interstate Transporta- tion of Goods Obtained by Fraud	\$20,000
PIERCY, Bradley B.	Pharmacist/Owner (Hospital Discount Pharmacy)	50	Tucker, GEORGIA	18 USC 371 Conspiracy 21 USC 331(k) & 333(b) Adulterated & Misbranded Drugs	5 yrs/\$10,000  3 yrs/\$10,000
PLATZ, Charles A.	Pharmacist/Owner (Cheshire Bridge Discount Drugs)	30	Atlanta, GEORGIA	21 USC 331(c) & 333(a) Adulterated & Misbranded Drugs	1 yr/\$1,000
RAY, JOHN A.	Physician (M.D.)	62	St. Petersburg, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a). Conspiracy re Adulter- ated & Misbranded Drugs	1 yr/\$1,000
SCHLEIN, Leonard	Pharmacist/Owner (Rancho San Diego Pharmacy)	31	LaMesa, CALIFORNIA	18 USC 1341 Mail Fraud 21 USC 331(c) & 333(b) Adulterated & Mis- branded Drugs	5 yrs/\$1,000  3 yrs/\$10,000

<u>NAME</u>		<u>AGE</u>	<u>CITY/STATE</u>	<u>VIOLATION</u>	<u>MAX. SENTENCE</u>
STEWART, Earl, Jr.	Pharmacist/Owner (Little Rexal Drugs)	55	Linden, ALABAMA	18 USC 1343 Wire Fraud 21 USC 331(c) & 333(b) Adulterated & Mis- branded Drugs	5 yrs/\$1,000 3 yrs/\$10,000
TICKTIN, Harold J.	Physician (M.D.)	44	St. Petersburg, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulter- ated & Misbranded Drugs	1 yr/\$1,000
TURNER, David D.	Physician (M.D.)	59	Orange Park, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulter- ated & Misbranded Drugs	1 yrs/\$1,000
WALKER, Bruce E.	Physician (M.D.)	68	St. Petersburg, FLORIDA	18 USC 371 to violate 21 USC 331(b) & 333(a) Conspiracy re Adulter- ated & Misbranded Drugs	1 yr/\$1,000
WALLACE, Bill L.	Physician (M.D.)	45	Marietta, GEORGIA	18 USC 1341 (2 cts) Mail Fraud	10 yrs/\$2,000
WILEY, Kathy	Drug Sales Rep (W-S Enterprises)	28	Glasgow, KENTUCKY	21 USC 331(a) & 333(b) Adulterated & Mis- branded Drugs	3 yrs/\$10,000
WILSON, Jimmie L.	Pharmacist/Georgia Supervisor (Drug Emporium)	43	Atlanta, GEORGIA	18 USC 1341 Mail Fraud 21 USC 331(c) & 333(b) Adulterated & Mis- branded Drugs	5 yrs/\$1,000 3 yrs/\$10,000

Mr. SIKORSKI. Mr. Allen, how and when did the investigation start?

Mr. ALLEN. It started around 4 years ago, when my agency—Georgia Drugs and Narcotics Agency—was contacted by a hospital pharmacist. He told us he had been promised \$30,000 a month in profit.

Mr. SIKORSKI. \$30,000 a month?

Mr. ALLEN. \$30,000 a month. He had been promised \$30,000 a month in profits by a diverter who had approached him to reveal what they termed overstocking or oversurplusing the drugs carried in their hospital pharmacy. He approached us to see if there was anything wrong with this because it sounded too good to be true.

During this time we approached numerous State and Federal authorities determining what laws were being violated, because we, too, became interested in this case, and 2 years ago, the U.S. attorney's office in Atlanta agreed to open the case and the FBI assigned agents to the case at that point.

Mr. SIKORSKI. Yesterday criminal informations were charged against 43 individuals and 3 companies. Is it correct that these charges represent allegations?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. What happens when pharmaceuticals are sold after the expiration dates?

Mr. ALLEN. The product potency and effectiveness can no longer be assured.

Mr. SIKORSKI. Criminal informations that were made public yesterday alleged that expired pharmaceuticals were sold or offered for sale. Isn't that true?

Mr. ALLEN. Yes; the Bureau cited several examples at the press conference yesterday where ulcer medication was found with a May 1980 expiration date, which was recovered during one of the searches in 1985.

Mr. SIKORSKI. Five years later?

Mr. ALLEN. Yes, sir. There were birth control pills with expiration dates of September 1978 and January 1980.

Mr. SIKORSKI. So some of those were 7 years old?

Mr. ALLEN. Yes, sir; they were also seized.

Mr. SIKORSKI. Were any of these expired lots offered for sale to the consumers?

Mr. ALLEN. Yes, they were. A number of expired products were seized at retail pharmacies where they were being dispensed to consumers, and in some cases products such as this were sold to the FBI undercover agent.

Mr. SIKORSKI. So some of them were just seized right at your local corner drugstore?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. You said that more than \$620,000 worth of adulterated, misbranded, and sample pharmaceuticals were seized. What volume of pills and capsules is that?

Mr. ALLEN. Hundreds and hundreds of thousands.

Mr. SIKORSKI. You told me earlier that you could fill a room—my office, in fact.

Mr. ALLEN. Correct.

Mr. SIKORSKI. Twenty by twenty by twenty room?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. Easily with what you just recovered in your operation?

Mr. ALLEN. Well, really not even all of the 13 searches, just in some of them.

Mr. SIKORSKI. Just in some of the searches, in a few States in this country. And it is not unreasonable to assume, is it, that you just touched the tip of the iceberg, an iceberg that stretches across the country? Is that correct?

Mr. ALLEN. Yes.

Mr. SIKORSKI. So it is happening in Minnesota, or North Dakota, or Florida, or New York?

Mr. ALLEN. We have no reason to believe it is not, no sir.

Mr. SIKORSKI. Does the consumer benefit from the diversion? Do we get a cut rate if we are at the end of a chain that bought into this diversion?

Mr. ALLEN. No, sir; it was our experience that these drugs were generally sold at their normal retail price. At the most, you may get 25 cents off your prescription, and the diverters, everybody in the middle reaped the profits, and of course the quality and effectiveness of these drugs were questionable in many cases.

Mr. SIKORSKI. So we are talking about the consumer not only paying the same amount for these diverted products generally, or slightly less in maybe a few instances, but generally we don't get a break in terms of price, and we are also exposing ourselves to misdated, expired, misbranded, adulterated counterfeit drugs?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. Did the undercover operation intercept pharmaceuticals that would have likely caused adverse health effects if they were taken?

Mr. ALLEN. Yes; such items included heart medications, thyroid pills, birth control pills, vitamins, such as this.

Mr. SIKORSKI. And also if pharmaceuticals are not properly stored, or mishandled, they lose their potency. Isn't that correct?

Mr. ALLEN. Yes; several examples of this were found, such as pills that had been in an attic. They were already expired but they had been up there maybe 4 years later and had been exposed to heat of up to 105 degrees or higher.

Mr. SIKORSKI. Some of this is insulin that is supposed to be stored at 48 degrees?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. And it was up there for years in some parts of the summer, I would guess, at 100 degrees or higher?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. What methods were used to remove the markings on these samples? What do they say, sample only, not for resale, or what is the typical—

Mr. ALLEN. On the capsules and tablets some will have the word "sample" imprinted upon the surface. On some of your birth control pill packages there would be the words "sample, not to be sold" printed on the fringes of the cardboard. Some of these birth control packages, they would take electric erasers and erase these off, where you couldn't tell anything, that it has been used for anything other than a normal package.



Mr. SIKORSKI. So some of these are stamped right on the pills themselves, as well as on the package?

Mr. ALLEN. Correct. The pills themselves we found somewhere—we knew that razor blades had been used to scrape the word "sample" off; fingernail polish remover, acetone, had been used with a cotton swab to remove these words.

Mr. SIKORSKI. So you found instances where they used electric erasers, razor blades, rubbing alcohol, nail polish, and acetone?

Mr. ALLEN. Correct.

Mr. SIKORSKI. Go ahead.

Mr. ALLEN. Also, these birth control packages, each company has its own way of manufacturing their particular package, and in some instances silver airplane paint was used to paint over the words on the aluminum foil package, or they would cut out words on part of the insert, or they would either take a pencil or a pen and punch out the words "sample, not to be sold" within the package.

Mr. SIKORSKI. Some of these chemicals were used right on the pill itself?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. To erase the word "sample."

An affidavit was prepared on October 3, 1984, by the undercover FBI agent. Before doing that, you told me earlier and testified you are a pharmacist, is that correct?

Mr. ALLEN. Correct.

Mr. SIKORSKI. You graduated from what school?

Mr. ALLEN. University of Georgia College of Pharmacy.

Mr. SIKORSKI. How long ago?

Mr. ALLEN. 1974.

Mr. SIKORSKI. When you talk about adulteration and loss of potency because of improper handling, you know this as a professional, is that correct?

Mr. ALLEN. I feel that I do, yes sir.

Mr. SIKORSKI. On October 3, 1984, an affidavit was prepared by the FBI agent who was an undercover in support of the request for a warrant to search the carport attic of the residence of Peter Chambliss. What was Mr. Chambliss' job?

Mr. ALLEN. He was then a medical sales representative for Armour Pharmaceutical Co.

Mr. SIKORSKI. That is for Armour Pharmaceutical Co?

Mr. ALLEN. Correct.

Mr. SIKORSKI. And did the affidavit allege that Mr. Chambliss devised some schemes to defraud Armour of money and products?

Mr. ALLEN. Yes.

Mr. SIKORSKI. Does the affidavit allege that Chambliss filed false sales expense vouchers with Armour?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. Does it also allege that Chambliss resold expired Armour Pharmaceuticals after removing the labels rather than destroying them as he claimed to the company?

Mr. ALLEN. Yes.

Mr. SIKORSKI. I think it also alleges that Chambliss purchased drugs for the account of the Bleckley County Hospital at prices

well below Armour's average prices and then sold the drugs at substantial profits to buyers other than hospitals. Is that correct?

Mr. ALLEN. That is correct.

Mr. SIKORSKI. Does it also allege that Chambliss made numerous sales and diverted pharmaceuticals to Med Sales, a Hollywood, FL company, and others?

Mr. ALLEN. Yes. The affidavit alleges that there were seven hospital diversion sales to Med Sales between January and September 1984.

Mr. Chambliss also told the undercover agents that he sold diverted drugs with the labels removed to at least 12 different individuals or companies for at least the last 3 years.

Mr. SIKORSKI. This is one individual who told the agents that he had sold diverted drugs to at least 12 different individuals or companies in just 3 years. Did Mr. Chambliss take the undercover FBI agent to his home, and if so, what did the agent observe?

Mr. ALLEN. Yes, sir. On February 28, 1984, the agent posing as Billy Scott was shown the attic above the carport of the residence of Mr. Chambliss. The agent observed thousands of dollars worth of expired pharmaceuticals, some of which Chambliss said had been there for years.

Mr. SIKORSKI. Mr. Chambliss at this point didn't know that this agent was an FBI agent?

Mr. ALLEN. No, sir.

Mr. SIKORSKI. Does the agent's affidavit mention specific examples?

Mr. ALLEN. Yes, sir. In the presence of the agent, Mr. Chambliss put 44,000 thyroid tablets, 90 percent of which were expired, into a brown paper grocery bag. Moreover, when Chambliss dropped some of these tablets into the fiber glass attic insulation, he retrieved the pills and put them into the bag, and according to the affidavit, Mr. Chambliss allegedly laughed, wondering what was going to happen when someone who was allergic to the fiberglass took the pills.

Mr. SIKORSKI. Did Chambliss and the agent put this bag in the agent's van, and if so, what happened to the pills?

Mr. ALLEN. This was on another occasion, where he put—

Mr. SIKORSKI. This is the oil?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. Go ahead.

Mr. ALLEN. He had put 8,500 capsules which had been expired for 3 years or 2 years—excuse me—into another brown paper bag, and he put them in a van, and while in the van, the van accidentally stopped, the pills accidentally fell out of the sack onto the floor of the van, and when the van pulled into a filling station to retrieve the capsules, and the door opened, they fell out into oil slicks on the pavement, and Mr. Chambliss insisted on picking up these capsules, commenting that the oil coating would just make them easier to slide down the old folks' throat.

Mr. SIKORSKI. So we have got expired pills taken from an overheated attic, put into brown paper bags, dropped in some instances in fiberglass insulation, in another instance dropped in an oil slick at a gas station and still returned to the bag presumably from the diverter's perspective to continue into the chain, as he said, easier to slide down the old folks' throats.

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. What was the temperature in the attic when the drugs were observed by the agent?

Mr. ALLEN. August 15, 1984, around 11:15 in the morning, the temperature was found to be 103 degrees Fahrenheit.

Mr. SIKORSKI. And this, as you testified earlier, would seriously degrade the drugs, even assuming they have any potency left after their expiration date?

Mr. ALLEN. Yes, sir; the manufacturer advised the agent that in order to avoid decomposition, the drugs specified in the attic shouldn't be exposed to temperatures in excess of 86 to 90 degrees Fahrenheit, and some of the drugs found, as you earlier mentioned, had to be refrigerated.

Mr. SIKORSKI. Let me just finish with one question. Did Chambless offer to sell illegal weapons, such as automatic machineguns and switch-blade knives, to undercover agents?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. The people we talk about in the allegations—we are talking about 14 pharmacists, 12 doctors, and 20 businessmen, sales representatives, and corporate executives. Are these the kinds of people that you have seen in this drug diversion scheme?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. Typically white-collar professionals, skilled?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. They are not people who injure or kill people with knives and guns, is that the case?

Mr. ALLEN. Not that we are aware of, no, sir.

Mr. SIKORSKI. They injure and kill people with bad drugs, expired drugs and counterfeit drugs?

Mr. ALLEN. We can only—I can't really comment on that.

Mr. SIKORSKI. We can only assume that if these drugs, as described from your observations and work in this area, get into the chain, they have the potential to harm people, not with knives and guns, but with bad drugs.

Mr. ALLEN. These type drugs could get into the chain and were dispensed to the consumers, they do have the potential, yes, sir.

Mr. SIKORSKI. Thank you, Mr. Allen.

The gentleman from New York.

Mr. ECKERT. I would like to ask about misbranding and adulteration. In cases of expired lots and samples, were the drugs removed from their original containers?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. Wouldn't that make it very difficult, it not impossible, for the lot number in case of recall?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. How were the drugs packaged or stored?

Mr. ALLEN. Any number of ways, as explained by the U.S. attorney yesterday. Hundreds of thousands of loose pills were seized without labels or expiration dates. They were stored in either open boxes, cellophane bread wrappers, shopping bags, plastic soft drink bottles and glass jars. These baggies were among the most popular of containers for storage and transportation.

Mr. ECKERT. That type of handling, does it cause the drugs to become adulterated?

Mr. ALLEN. Yes, sir. The treating of the samples tended to cause this, as well as the storage methods in containers, an FBI spokesman yesterday described one instance where vitamins were placed into a medicine bottle containing residue from an insomnia medication. He also showed unsanitary containers, such as soft drink bottles, where pills were stored in bulk or liquids were stored in bulk.

When sold to the customers, the pharmacist would put these in a regular prescription bottle.

Mr. ECKERT. Among these products that had become adulterated, were there any items that tend to be prescribed for children or for elderly people?

Mr. ALLEN. Yes, sir; there are antibiotics, the type that you reconstitute with water, that are often prescribed for children, and there was heart medication frequently used by elderly persons, which were identified yesterday by the FBI spokesman, and these were among the drugs removed from the original packaging and improperly stored.

Mr. ECKERT. So senior citizens with heart trouble might have gotten bad drugs?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. What were some of the drugs? Do you recall off-hand?

Mr. ALLEN. Nitroglycerin, used for angina, the long-term heart medications that you must take as maintenance medication. There were a number of drugs which are supposedly the top prescribed drugs in the country for ulcer medication, potassium supplement tablets, which are used by any number, any aged person, for heart ailments and other ailments, and really from one end of the spectrum to the other, we pretty much had examples of everything.

Mr. ECKERT. So because of this a senior citizen with heart trouble might well have his life threatened?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. This is clearly a nationwide problem. You indicated in your opening remarks the investigation continues, and that there are about 40 targets. I know you can't provide names, but is your investigation limited to one State, one geographical area, or is it far broader?

Mr. ALLEN. No, sir; it includes individuals and companies throughout the United States and even activities in other countries.

Mr. ECKERT. Could you describe for us how these drugs went from salesmen to retail drug outlets?

Mr. ALLEN. I am sorry, could you repeat the question?

Mr. ECKERT. Can you describe how these drugs went from salesmen, or wherever, to the retail drug outlets? How were they diverted? What is the process? How did it occur?

Mr. ALLEN. There are any number of ways. Can I have just 1 minute?

Mr. ECKERT. Sure.

Mr. ALLEN. These tablets or pills, or what have you, they went from—are you speaking like of the sample medication?

Mr. ECKERT. Or any kind, just a general feel for how this occurs.

Mr. ALLEN. They could go in any number of ways, from drug sales representatives possibly selling their samples to physicians

giving their samples away to individuals who—any number of ways your imagination can come up with.

Mr. ECKERT. What about not-for-profit hospitals?

Mr. ALLEN. OK. We looked at those in two different ways. The not-for-profit hospitals, these hospitals order the drugs. The hospital would then sell them for substantial profits to diverters. Diverters would then put them into a distribution chain wherein eventually it wound up on the shelves of major wholesalers and then it would be sold to your retail drug stores.

Mr. ECKERT. So not-for-profit hospitals buy substantially below even discount price?

Mr. ALLEN. Yes.

Mr. ECKERT. And sell an oversupply to diverters at a markup, make a profit for the not-for-profit hospital, and the diverter makes a substantial profit as well selling.

Mr. ALLEN. Correct.

Mr. ECKERT. Are the target investigations the same type of the future, as already charged?

Mr. SIKORSKI. Will the gentleman yield?

Mr. ECKERT. Yes.

Mr. SIKORSKI. He hit some. You have pharmacies, you have doctors, clinics, hospitals. There are also the charitable organizations as well.

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. And then there are those foreign, at least using foreign names and companies, whether they are legitimate or not, to order out and then divert back and they come in as American goods returned.

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. Does that kind of cover the range of scheme?

Mr. ALLEN. That pretty much covers it.

Mr. SIKORSKI. And yet the samples can be involved in any of those professional clinics or agencies; is that correct?

Mr. ALLEN. Yes. You will have to bear with me. I was seeing so much of it it all sort of runs together.

Mr. SIKORSKI. But you have come across bogus, fraudulent charities too that buy and then sell to diverters?

Mr. ALLEN. Well, at this point I really can't comment on that.

Mr. ECKERT. Are the targets of your investigation, your ongoing investigation the same type as already charged? They are very similar things, just more of them?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. Thank you.

Mr. SIKORSKI. Thank you.

The schemes touch all regions of the country, which you have already testified to, and they also affect all age groups, especially the vulnerable, as the gentleman from New York pointed out. You have got antibiotics that are especially important to kids that are out of date or in some case just counterfeit, worthless flour, sugar, or some other substance; and while that kid is going through the fever, going through the reaction, that antibiotic that everyone thinks he or she is being administered is not an antibiotic at all, and you have got old people who depend upon these drugs for their medical problems who are given fake or expired or adulterated

drugs as well, so it affects all age groups, affects all regions, and involves a host of companies.

We have got one in the Wall Street Journal article this morning which talks about your searches in Georgia and Tennessee and Mississippi, Alabama, Florida, and California. Mr. Thompson said yesterday—"indicates drug diversion practices are quite widespread." Those are his words.

Three of the defendants are from Bindley-Western Industries, Inc., an Indianapolis-based drug wholesaler. One of the representatives, as I understand it, was from Ayerst Laboratories, a unit of New York-based American Home Products Corp. Another of the defendants was from Drug Emporium, Inc., an Ohio-based drugstore chain with 48 stores. We talked about the Armour Pharmaceutical Co., which is owned by Revlon, Inc., and that is just some of the people involved. I do not want to get into things that you are constrained not to talk about, but is that a pretty good indication of the fact that this problem stretches across all regions and isn't just a problem down in Atlanta?

Mr. ALLEN. No, sir. It definitely is not just a problem in Atlanta.

Mr. SIKORSKI. It just happens through your efforts and some very dedicated people you went and spent some time and resources and got a hold of the tail of this problem in your area.

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. A search warrant was obtained on May 7, 1985, for the Rancho San Diego Pharmacy in La Mesa, CA; is that correct?

Mr. ALLEN. Yes, that is correct.

Mr. SIKORSKI. An affidavit was filed in support of that search warrant by FBI Agent Carl F. Christiansen; is that correct?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. The pharmacist that owned the business was Leonard Schlein; is that correct?

Mr. ALLEN. According to documents we have seen, yes, sir.

Mr. SIKORSKI. And according to the affidavit Schlein engaged in a variety of activities. He told the undercover FBI agent that he purchased Mexican drugs, hired Mexican children to put the drugs in baggies, and brought the drugs through Customs to his pharmacy; is that correct?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. What did he do with these drugs then?

Mr. ALLEN. He sold them to the undercover agent, and the undercover company in Atlanta, and he also stated that he sold the goods through his friends and family in New York.

Mr. SIKORSKI. Did Schlein tell the FBI agent that he dealt in drug samples?

Mr. ALLEN. Yes, sir. Schlein stated that he did a lot of sample business using them mostly in third-party billing instances with Medicare, worker's compensation, and a private third-party company named PCS.

Mr. SIKORSKI. So he got these Mexican drugs, had these kids shuck them and put them into baggies, and then they carried them or he brought them across the border?

Mr. ALLEN. He did.

Mr. SIKORSKI. And then he sold them in many instances to third-party purchasers: the Medicare Program, worker's compensation programs, and a private company?

Mr. ALLEN. This is what is alleged in the affidavit, yes, sir.

Mr. SIKORSKI. Did he show the FBI agent plastic bottles containing samples which had been removed from their original packages and labeling?

Mr. ALLEN. Yes, sir. He also told his customers these particular capsules had the words samples left on them. He told his customers this word was pronounced "sample" and was the name of a French manufacturer.

Mr. SIKORSKI. It works with J.C. Penney. He had paid people to punch the pills out of these bubble packs; is that right?

Mr. ALLEN. Yes, sir. The affidavit alleged that he said he paid 1 penny per pill.

Mr. SIKORSKI. To the kids?

Mr. ALLEN. Yes, sir, and he told the agent that he had a friend who had young girls who worked at his store punching out these pills.

Mr. SIKORSKI. Did he ship various lots of Mexican drugs to the Atlanta undercover operation?

Mr. ALLEN. Yes, sir. They were very often in large baggies. Of course, they had no lot numbers, no drug names, no manufacturers' names, no warnings, directions whatsoever, and recall would be practically, if not totally, impossible, and moreover the Mexican pharmaceuticals are not approved for distribution in the United States in any case.

Mr. SIKORSKI. So in this instance, as the gentleman from New York pointed out, it is impossible to do any recall should a problem occur with these drugs, in terms of adulterated or impotent, and they show up—say someone was lucky enough, a doctor prescribed an antibiotic to a kid. The antibiotic did not work. In the rare instance that some analysis was done of that antibiotic, instead of just going to a different antibiotic, and that antibiotic turned out to be a fake or even harmful, there would be no way to trace that back, because lot numbers, account numbers, all the traditional, and even those are not very specific mechanisms for recall, means are eliminated because of the scheme. That is one problem.

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. The second problem is these drugs have never been FDA approved. If they had come through the border in a regular shipment, they never would have been—if they had been stopped, in the rare instance they had been stopped and held, they never would have been approved by the FDA for distribution in the country; is that correct?

Mr. ALLEN. That is correct.

Mr. SIKORSKI. Counsel has a question.

Mr. SIMS. Thank you, Mr. Chairman.

Mr. Allen, does the affidavit indicate whether or not the accused person had an easy time or a difficult time bringing these Mexican drugs through U.S. Customs and into the United States?

Mr. ALLEN. The affidavit alleged that he was no longer worried about coming through the border with these capsules. He had an easy time getting through.

Mr. SIMS. Thank you, Mr. Chairman.

Mr. SIKORSKI. And he did this over a period of some years; is that correct:

Mr. ALLEN. We are not exactly sure how long he had been doing it. At least for a—

Mr. SIKORSKI. Significant amount of time?

Mr. ALLEN. Yes, sir.

Mr. SIKORSKI. This is one of the schemes. Did he not also tell the FBI that he had accounts with U.S. drug manufacturers to also obtain products at low prices?

Mr. ALLEN. Yes, sir. He had stated he purchased drugs from Lederle Laboratories at a low clinic price in his pharmacy.

Mr. SIKORSKI. The gentleman from New York.

Mr. ECKERT. Was an affidavit filed by FBI Agent Christiansen in conjunction with the search warrant obtained on April 23, 1985, for the Medical Plaza Health Pharmacy in Corinth, MS?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. Who is the owner?

Mr. ALLEN. Rick Quinn.

Mr. ECKERT. Did he deal in samples of diverted medicines?

Mr. ALLEN. Yes, sir. According to the affidavit, Mr. Quinn asked the undercover FBI agent, upon their first meeting, "Are you legal?" When the agent replied, "Yes, kind of," Quinn replied, "Well, there is very little that I do that is legal."

Quinn displayed to the agent hundreds of baggies which were stored in drawers built under the counter in his pharmacy.

Mr. ECKERT. Did Quinn indicate how he removed the words indicating that the drugs were samples?

Mr. ALLEN. Yes, sir. He told the agent that, according to affidavit, that he had used high school students for several years to do this. The students worked in the backroom of his pharmacy, and moreover, he stated that he even used his children aged 6 and 3 to perform this task.

Mr. ECKERT. Were you able to find out from Mr. Quinn just how profitable trading in samples of diverted medicines was for him?

Mr. ALLEN. Yes, sir. According to affidavit, he told the undercover agent he dealt only in cash, and that he had made more than \$75,000 per year, which was more than he cleared on his pharmacy.

Mr. ECKERT. He picked up an extra \$75,000 a year in cash?

Mr. ALLEN. Yes.

Mr. ECKERT. In diverted drugs?

Mr. ALLEN. According to the affidavit, that is what Mr. Quinn stated to the agent.

Mr. ECKERT. Thank you.

An affidavit for a search warrant for the hospital discount pharmacy of Tucker, GA, contained information provided by a pharmacy employee named Vicky Shorb, is that correct?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. What did Ms. Shorb say?

Mr. ALLEN. Yes, I can summarize it. She said that the owner and pharmacist at this hospital discount, Mr. Bradley Piercy, had asked her to remove the pharmaceutical tablets and capsules from their



original packaging, and to remove the sample designations where these capsules had such markings.

Ms. Shorb said that other pharmacy employees were told to do the same things when they were not performing their regular duties such as being a clerk within the pharmacy.

Ms. Shorb stated that she handled many expired drugs, and that the cleaning process resulted in the mixing of tablets and capsules of different lots and expiration dates in the same bottles.

The work took place in the basement of the pharmacy, where it was not uncommon for employees to drop the goods on the floor and then pick them up and continue cleaning them. According to Ms. Shorb, dropped medicine was placed into the same boxes as the rest of the other pharmaceuticals.

Mr. ECKERT. Just drop it on the floor, pick it up, mix it in a bottle of drugs. You might have some that are good, some that are long expired, and some that are picked up off the floor with the dirt?

Mr. ALLEN. This is what she alleges, yes, sir.

Mr. ECKERT. Did the Georgia Drugs and Narcotic Agency agent make statements in that same affidavit?

Mr. ALLEN. Yes, sir. An agent stated that during a visit to the pharmacy, she had discovered adulterated, an adulterated drug by the name of Feldene during a January 1985 inspection of the pharmacy.

She stated that during a subsequent visit on February 22, she found capsules with the word "sample" printed on them in a bottle on the pharmacy shelf.

The agent also noticed numerous drugs in baggies on the premises, some contained slips of paper with the drug name on it, others had paper slips with the quantities, some contained a package insert which comes along with the packages, others contained only a torn-off portion of a piece of packaging showing a drug name, and various other adulterated packages or tablets were found.

Mr. ECKERT. I yield back my time.

Mr. SIKORSKI. I thank the gentleman.

Mr. Allen, we have completed in less than an hour a record of amazing statements that point out a very serious threat, a danger to the American consumers. It is helpful sometimes when you are talking about these issues, and since we are close to the health profession, to use the old—it hurts when I laugh.

I know you showed me earlier a little cartoon that had been titled "Pharmoney," which is the code name for the sting operation that you are involved in. It is a United Press Syndicate cartoon showing an elderly women talking to what appears to be a doctor, perhaps a pharmacist, someone in the medical profession. She says, "I feel a lot better since I ran out of those pills you gave me." That helps to point out some of the problems that we have.

My constituents, Mr. Eckert's constituents, just can't go into a drugstore and be confident that what they think they are purchasing is exactly what they are purchasing, that it is potent, that it is safe and effective, that it was not interrupted somewhere in the distribution chain, and something that they don't want has replaced it. It is a serious threat.

All indications are it is over a billion-dollar-a-year business in this country, thousands of sources, including some of the most respected members of local communities. Yet, it is a serious problem, and it has the kind of infinite potential for dangerous mislabeled and counterfeit drugs getting into the system.

The problem, as I understand it, is that we have got a lot of money, big dollars that are very attractive to a lot of people. At the same time, we have Government regulations that are less than strict, and finally we have too many people in the industries affected who are turning their backs on the problem, participating in this hear-no-evil, see-no-evil, speak-no-evil kind of situation.

Is that a fair analysis?

Mr. ALLEN. Yes, sir.

If I may add a point: The public is not aware of what they are getting. We have also run into the fact that your pharmacists, in many of these drugstores, in good faith bought what they felt were legitimate products, and they were being defrauded also. So, stepping out of my role I have been in for 2 years, as a pharmacist and for the health profession, there are still a lot of honest, good people out there, and they are being taken advantage of by this system.

Mr. SIKORSKI. Absolutely. You know I have had discussions with you. I have talked to many of these people as well, raised the issue, and in fact have been instrumental in the investigation undertaken by the subcommittee as well as your investigation.

Mr. ALLEN. Correct.

In particular, my employers at the board stressed to me—they say that if there is anyway, to let these people know not every pharmacist in the country is involved in this and is not guilty of this.

Mr. SIKORSKI. Your board announced yesterday, and I quote,

As a result of this investigation, the finding regarding the methods by which drug samples are being misused is obvious that it is impossible to ensure the integrity of drug samples have been maintained and have not become adulterated. The Georgia Board of Pharmacy plans to introduce legislation in the 1986 session of the general assembly banning sampling of all prescription drugs in the State of Georgia.

There is a press release from the National Association of Boards of Pharmacy, the national group, similar to the Georgia group, which raises the same kinds of concerns about for sample pharmaceuticals being misused in this way, and it is one thing the subcommittee will be looking at, as well as the things that the chairman has already undertaken with regards to American goods returned.

Do you have anything else?

Mr. ECKERT. Samples are only a portion of it, are they not?

Mr. ALLEN. Yes, sir. The adulteration and misbranding problem seems to be primarily with samples, not ruling out other problems, and we had it broken into two phases. We felt the adulteration problems and the pricing problems were another phase.

Mr. ECKERT. We have the samples whether they come from the salesman, the doctor; but we also have a problem with hospitals that sell what is an oversupply for profit, and the charities, genuine or not genuine. So, there is just a wide area for a diverter to draw from, is there not?

Mr. ALLEN. Yes, sir.

Mr. ECKERT. The gentleman from Minnesota indicated earlier we are really dealing here in your investigation with just the tip of the iceberg. It is a pervasive national problem.

Mr. ALLEN. That seems to be, yes, sir.

Mr. ECKERT. We have no estimates of what deaths—we have no way of calculating how many people, elderly people, children might have lost their lives because of this.

We have no idea yet, do we?

Mr. ALLEN. There is no way to tell—

Mr. ECKERT. But we know it is happening?

Mr. ALLEN. We can only assume those things.

Mr. ECKERT. State licensing and that sort of thing isn't sufficient because the counterfeit birth control pills of last fall all went—all had State license dealings with them.

Mr. ALLEN. Yes, sir.

Mr. ECKERT. Mr. Chairman, I think this is a very important national health issue, and I am pleased that you and Chairman Dingell are working on this. I think it is very important for American consumers to know that when they purchase a drug, a prescription drug, that what they have bought is what they get, because otherwise it can be life-threatening.

Thank you.

Mr. SIKORSKI. Thank you for your diligence in pursuing this, as well.

Mr. Allen, anything?

Mr. ALLEN. No, sir.

Mr. SIKORSKI. Thank you.

I want to make the record clear we have finished within an hour.

Thank you.

[Whereupon, at 11:10 a.m., the subcommittee adjourned, to reconvene at the call of the Chair.]

## PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING

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THURSDAY, SEPTEMBER 19, 1985

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. John D. Dingell (chairman) presiding.

Mr. DINGELL. The subcommittee will come to order.

This morning the subcommittee continues a series of hearings on prescription drug diversions and counterfeiting. This the subcommittee views as a matter of considerable importance. We have voluminous and distressing evidence from previous hearings that American consumers cannot be certain that the prescription drugs that they purchase are safe and effective.

Our hearing witnesses today are all from the private sector. They bring unique personal knowledge of the day-to-day operations of the pharmaceutical market. Each witness has volunteered considerable knowledge and expertise to assist the subcommittee in its inquiry, and each has important information to add to the record. I know that I speak for all of my colleagues on the subcommittee in expressing my genuine appreciation to these persons for their cooperation and assistance to the subcommittee.

The witnesses today will be Mr. Stanley Kowitt, Mr. Eddie Burklow, and Mr. Stephen Eckstein. Mr. Kowitt operated a pharmaceutical wholesale company for many years that specialized in diverted merchandise. He was convicted of criminal violations in 1983 as part of an extensive case in south Florida involving an estimated \$10 million worth of pharmaceuticals. They were obtained from U.S. manufacturers through real and bogus charities, and through hospital diversion schemes.

Mr. Kowitt made available to the committee staff all of the information regarding this matter and will testify regarding a number of internal documents obtained from drug manufacturers in the course of his legal defense. These documents will indicate that a number of manufacturers were well aware, or should have been well aware, that their products were being diverted, yet they continued to sell to these accounts.

The committee wants to observe that Mr. Kowitt is to be particularly commended for his assistance to the committee in view of the difficult circumstances in which he finds himself.

Mr. Burklow was a salesman and most recently an executive of several pharmaceutical companies. He pleaded guilty to criminal violations in a recent case in Atlanta. Mr. Burklow's cooperation over a period of several months materially assisted the development of the Government's case and the execution and completion of the investigation. He is well familiar with the practices of sales representatives especially as these practices relate to the use and abuse of drug samples.

Again, the committee has reason to be particularly appreciative to Mr. Burklow and to express our appreciation and commendations to him for his assistance in these difficult matters.

Mr. Eckstein is a private investigator who has been employed by several pharmaceutical companies. He is an expert in overseas pharmaceutical diversion schemes and practices. And again, his assistance is extremely valuable to the committee. And the Chair wishes to commend and to thank each of our witnesses today for the assistance which they give us, particularly Mr. Burklow and Mr. Kowitt because the Chair is appreciative of the unfortunate situations in which they find themselves.

The Chair wants to make just a couple of additional comments. This subcommittee, its members on both sides of the aisle, have been extremely active in trying to see to it that not only our laws are appropriately enforced on diversion, but to see to it that the mechanisms, staff, personnel, and administrative machinery were sufficient to the task which is imposed upon it.

The committee has at all times found great weaknesses in the administrative structures, not by reason of the lack of will or the skills of the customs inspectors, but rather because the Office of Management and Budget has demonstrated a remarkable determination to reduce the number and the competence of the inspectors of the Customs Service at the ports and elsewhere.

This, we believe, has been extremely hurtful, and I am particularly pleased that the committee and others concerned with these matters have undertaken efforts which, at this point, have raised the budget to provide for not cuts in the Customs Service, but rather an additional 800 new customs agents at the ports, who will provide enormous increases in our capability of dealing with the problem of entrance of illegal commodities into the United States.

An example of the reason that this committee has been concerned was recently the question of illegal and counterfeit entries into the United States. We observed that birth control pills, counterfeit in character, were coming in which were very difficult for the administrative machinery to detect, in good part, because of the lack of adequate numbers of personnel available so to do.

Late yesterday evening the Commissioner of the Food and Drug Administration called the subcommittee. He advised us of an open criminal investigation now going on involving reimportation from Hong Kong of an American-produced antibiotic. The medication was tested and found to be potent. So there appears in this instance to be no health threat.

Clearly, the travails and the travels of this antibiotic, having moved from here to Hong Kong and back, raise real questions as to whether or not in the process that antibiotic could have been exposed to conditions which would have either resulted in contamina-

tion or in loss of effectiveness. Happily, it appears that, at least on the basis of testing, it retains its potency.

The antibiotic in question was repackaged and relabeled, an apparent FDA violation, and entered duty free, an apparent customs violation. And I would point out that, given the distance that it has moved and given the lack of evidence of adequate protection of that particular commodity in its travels, one can observe that other commodities moving from here to Hong Kong and back could, not inconceivably, have arrived at a situation where they would have either been unsafe or would have been lacking in efficacy.

The committee wants to applaud the vigilance of FDA in this case. We believe that this is what the agency is supposed to do, and we believe that it underscores in a significant way the problem with pharmaceutical imports, as pointed out by the subcommittee in a June 1985 staff report and in a series of letters between the subcommittee and FDA and Customs in August.

I am pleased to announce that, as a result of those earlier hearings of the subcommittee, that FDA and Customs have both greatly increased their surveillance of pharmaceutical imports. One must observe, because of the lack of increase in personnel and budget, that probably those efforts are being done at the expense of other responsibilities of those two agencies. But nonetheless, an important concern of the committee is at least being considered rather more carefully by the agencies.

I am releasing further correspondence between the subcommittee and these agencies which will be available tomorrow morning in the offices of the subcommittee. Because of the open criminal investigation, the Chair can make no further comments and provide no further details on this matter at this time.

The Chair wants my colleagues on the subcommittee to understand that their participation in these hearings and their efforts have resulted in a significant benefit to the public, and the Chair wants to commend the members of the subcommittee.

The Chair at this time has to go elsewhere to attend another committee meeting. The Chair is going to ask the distinguished member of the subcommittee, Mr. Ron Wyden, to preside in my absence. I am sure he will do a good job.

Mr. WYDEN [presiding]. Does the gentleman from Virginia wish to make an opening statement?

Mr. BLILEY. Not at this time.

Mr. WYDEN. The gentleman from Florida.

Mr. BILIRAKIS. Thank you, Mr. Chairman, I want to thank Chairman Dingell for his interest in this subject and for his willingness to continue this investigation in this very significant area.

I feel very strongly that consumers need faith in the drugs that they purchase, and that's without any question. I represent a district of many elderly. Close to 50 percent of my district fall into that category. And of course, they take more drugs, in general, and consequently are much more susceptible. So I have a great interest in this subject.

Mr. WYDEN. I thank the gentleman from Florida.

On my own behalf, by way of an opening statement, I want first of all to commend the gentleman from Michigan, Mr. Dingell, for

his tremendous leadership which has been made clear previously, and has already begun to produce some results.

Today we are going to get a glimpse into an ominous and chilling underworld of rampant criminality involving the illegal purchase and resale of pharmaceutical drugs in this country, a network that has been aided and abetted by a rogues gallery that literally seems to have a Ph.D. in lawbreaking. The intricate and unquestionably illegal drug diversion conspiracies that we're going to see this morning can only work if the small percentage of hospitals, health care providers, and pharmacies either covertly or overtly go along with the various schemes that have developed to divert pharmaceutical drugs out of the traditional marketing pipeline.

What we are going to see today is that this game can only work if all three players—the hospital, the pharmaceutical drug manufacturer, and the diverter—work together. And it seems clear to me that while the vast majority of health care providers and health care manufacturers are honest and reputable, there are a goodly number in this country that simply have been blinded by the lure of easy money. They've been blinded by the lure of easy money and the opportunity for huge profits that these illegal conspiracies afford.

Again, I want to commend the gentleman from Michigan for his fine work.

Also, the gentleman from Minnesota has had a long-standing interest in this and has contributed greatly, and I want to recognize him for any opening statement he would like to make.

Mr. SIKORSKI. I thank the chairman.

As the subcommittee begins its third hearing dealing with the sources and dangers of prescription drug diversion, I would like to commend the chairman for pursuing this menacing problem so thoroughly and vigorously.

In our last two hearings we have learned that although drug diversion isn't new, it has become alarmingly widespread. Every hour of every day there are more and more drugs being counterfeited, improperly disposed of, mishandled, mislabeled.

Every day more and more sales representatives, hospitals, businessmen and women, nonprofits, doctors, and pharmacists—and now, even some manufacturers—have jumped into the drug diversion game. They are seduced by the lure of enormous profits, scant Government regulation, and by fierce competition in the drug industry itself.

Yet, the shocking truth remains that many whom we have entrusted with our fundamental health needs are more interested in making a quick buck than in curing our ills. Consequently, American consumers jeopardize their health every time they get a prescription filled at their local drugstore.

We began looking into the problem of drug diversion as a result of last year's nationwide distribution of nearly 2 million counterfeit Ovulen-21 birth control pills that somehow made their way into the country from Panama. One thing is certain: The pills didn't sprout legs, walk across the border, and hop onto the shelves of our Nation's drugstores.

In truth, we know from our previous hearing that the bogus pills were funneled with great speed and ease through our traditional

distribution system, slipped from wholesaler to distributor to retailer through complex and elusive diversion schemes.

At our last hearing we were told that many of the pills similar to the Ovulen-21 pills and other diverted drugs such as insulin and thyroid medicine were stored in an attic where the temperature exceeded 100 degrees. That's almost 50 degrees above the storage temperature required to preserve the drugs' efficacy.

Today we will learn that an importer, a retailer, and several wholesalers and distributors were repeatedly warned or had some reason to be cautioned that the Ovulen-21 pills were fake, and yet they still sold or passed on the phony pills without ever notifying the Food and Drug Administration.

We will also see proof that some major drug manufacturers knew that hospitals and other organizations they supply are illegally selling drugs to diverters, that they play deaf, dumb, and blind and do little to stop this dangerous practice.

I want to thank the witnesses today for appearing before us because their testimony will shed more light on this important issue. We need to end this problem so that American consumers can be certain that the drugs they are buying are not dangerous but truly safe and effective.

Mr. WYDEN. I thank the gentleman from Minnesota.

Our first witness is Mr. Stanley Kowitt.

If you will come forward, Mr. Kowitt?

Let the record show that he is accompanied by counsel today.

Mr. Kowitt, it is the practice of this subcommittee to swear all witnesses. Do you have any objection to being sworn?

Mr. KOWITT. No, sir, I don't.

Mr. WYDEN. Please rise and raise your right hand.

[Witness sworn.]

Mr. WYDEN. Let me advise you as well, Mr. Kowitt, there is a copy of the committee's rules available for you as well throughout your appearance today. We will make a copy of your prepared remarks, any prepared remarks that you have, a part of our hearing record. And if you would like to just summarize your principal concerns this morning, that will afford plenty of time for questions.

#### TESTIMONY OF STANLEY KOWITT, PHARMACIST, NEW YORK CITY

Mr. KOWITT. Thank you, Mr. Chairman.

Mr. Chairman, I am a 47-year-old pharmacist who grew up working in my father's drugstore and who later worked for numerous independent pharmacies and chain drugstores in New York and Florida. In 1972 I went to work for a small wholesaler of diverted pharmaceuticals, where I learned the wholesale business, and 1 year later formed my own company, where I worked full-time until I sold my interest to my partners in June 1984.

During the 12 years that I was actively involved in buying and selling diverted pharmaceuticals, I personally had direct contact with and bought product from more than 50 other wholesalers specializing in diverted pharmaceuticals. I had frequent contact with the principles and managers of these companies, I sold merchandise to more than 15 of the largest drugstore chains in the country,



many listed on the New York Stock Exchange, and either I or my partners talked to the buyers of these chains on a weekly basis.

My customers also included more than 25 of the largest full-service wholesalers in the country with whom I enjoyed an excellent business relationship.

In April 1982, I was indicted and subsequently convicted of conspiring with others to defraud 27 major pharmaceutical companies through a scheme which your staff report deals with in great detail. Motions in that case are still pending.

During the Government's investigation of this case, they subpoenaed the books and records of numerous drug manufacturers that sold product to three Miami hospitals. Although the Government decided not to include these purchases in their subsequent indictment, the material was provided to me as part of the pretrial discovery process, and I, in turn, made them available to this committee.

Those documents showed what I and others in the industry believed for years; namely, that many drug companies either actively or passively assist in the diversion of their product. I found conclusive evidence that some companies continued to sell their product even after they learned that the hospital was diverting their products and even after they received letters from the salesmen warning that these hospitals were diverting.

It showed clearly that at least 20 major pharmaceutical companies sold quantities of products to these hospitals that was conservatively 100 times larger than they could have possibly have consumed themselves, notwithstanding the fact that many of these companies had warnings on their invoices indicating that merchandise they sold was for the in-house use of the ordering institution only.

I discussed many of these purchases in detail in my written statement, and to save time, will just touch on a few examples of what I mean.

Ayerst Laboratories sold a 12-bed not-for-profit hospital over 12,000 bottles of a prescription eardrop in a 2-month period, as well as a 48-year supply of their antiepilepsy drug, or 844,000 tablets, in a 6-month period. Abbott Laboratories sold the same hospital a 38-year supply of their tranquilizer drug, or 667,500 tablets, in an 8-month period. Meade Johnson sold a 260-bed for-profit hospital 2,216,000 tablets and 622,800 doses of a liquid vitamin with fluoride preparation, or what amounted to a 30-year supply in a 3-month period, even though this product is usually contraindicated in areas of fluoridated water like Miami.

The owner of these three hospital pharmacies confirmed to me years later that virtually all of the salesmen from these companies were aware that he was diverting. After a while it becomes quite evident that although some manufacturers are clearly unhappy with the diversion of their products, many others use the diversion industry as a means of selling tremendous quantities of competitive products and realizing stupendous profits.

Yet, when confronted with diversion, they quickly point their finger at others and deny involvement. To my knowledge, not a single civil lawsuit resulted from the diversion through these hospi-

tals or as a result of the diversion through the bogus charities, which was part of my trial.

Perhaps the reason that lawsuits are not initiated by manufacturers who claim to be victimized by diversion is fear of what embarrassing and potentially damaging information will emerge. For example, my trial uncovered the following: Whitehall Laboratories sold to a customer that claimed to be a charity at their lowest export prices, and yet earned a gross profit of \$85,742 on a sale of \$109,058. Internal memos disclosed that the company was aware of the possibility the order would be diverted, but decided to sell anyway because of the attractive profit of 79 percent.

Products ordered or quoted on included: heat liniment for sore and aching muscles, Neet dipilatory for removal of hair from ladies' legs, Freezone corn remover, and Outgrow for ingrown toenails, all for needy people in Third World countries who probably wore no shoes;

That Ciba-Geigy Pharmaceutical Co. donated outdated merchandise to charity and in one instance took a tax write-off of \$154,754 for products that were unsaleable because they lacked childproof caps and had a cost of goods of only \$6,555;

That Becton Dickinson sold the largest order in the history of their company to a broker for transshipment to Zaire, formerly the Belgian Congo. This order was for 13.5 million U-100 disposal insulin syringes worth \$1 million, and sold to a bankrupt country of 16,585,000 people, with a 35 percent illiteracy rate and little refrigeration facilities for insulin.

In my 12 years of buying and selling diverted merchandise, I found that certain companies' products always seemed to be available in large quantities from many different sources and other companies' products seemed hardly ever to be available. Abbott, Allergan, Bristol, Cooper, Lederle, Meade Johnson, Merrell-Dow, Syntex, Wallace and Warren Teed—now Adria—goods were plentiful, while Lilly, Burroughs-Wellcome, Merck Sharp & Dohme, Smith Kline Beckman and Upjohn goods were very scarce. All other companies' products fell somewhere in between with merchandise available intermittently.

There are two primary factors that are responsible for the diversion industry, and both are totally under the control of the manufacturer. The first is the tremendous price differential between ordering entities, up to 80 percent in some cases. The second is the internal structure of the drug companies that places great emphasis on the sales of competitive items, which are the ones involved in diversion.

Sales quotas must be met or sales people may be fired. Bonuses, commissions, and promotions are based on sales in excess of quotas. Helping diverters was the only way that a salesman or his manager could retaliate against a salesman that was dumping merchandise into his territory and hurting his sales.

Your recent staff report defines diverted merchandise as "any brand-name product that is not obtained directly from the manufacturer or an authorized distributor." To this I would add that true diverted products are made in the United States, sold by licensed wholesalers in original sealed packages that meet all the requirements of the FDA for sale in the United States. This is the

only kind of merchandise that I sold, and it posed no health hazard to the American consumer.

This kind of product must be distinguished from the sale of physician samples which have been repackaged, misbranded, adulterated, and outdated and which are clearly and undeniably illegal under existing law and are a definite potential danger to consumers.

Unfortunately, your staff report does not go far enough to distinguish between these very different types of products. Although I and most other pharmacists are aware of the existence of individuals who are usually not licensed and who purchase physician's samples from doctors and salesmen, usually for cash, and then adulterate and repackage these items for sale to retail stores, again usually for cash, this is nothing that I or most other diverter wholesalers are involved in.

Throughout the years, all of my customers insisted on merchandise whose packaging was identical in every way to the packaging they received when buying the identical item directly from the manufacturer.

Because it may be impossible to distinguish stolen or well-made counterfeits from bona fide goods, they pose a special problem. To my knowledge, the only time a counterfeit found its way into the national distribution system was the Ovulen that you are investigating. The packaging of this product, although good enough to fool some people, was not good enough to fool many others who, like myself, refused to buy this product. This unique experience proved that the existing system works, and the product was quickly identified, recalled and traced back to the original importer.

If those people responsible for making the pills and those who distributed it knowing it was fake are dealt with harshly, then that along with the tremendous exposure this committee has given to the problem should go a long way to ensuring that this type of thing never happens again.

In my remaining minutes I would like to very briefly touch on two of the concerns expressed by the committee in their staff report.

The first is recalls. Let me assure you that products sold through the diversion market in original sealed packages are recalled when necessary just as quickly and efficiently as products bought directly from the manufacturer. Every customer I sold to bought the identical product from both me and the manufacturer. Therefore, in the event of a recall, he would be notified by the manufacturer, check his inventory, and remove all recalled items regardless where originally purchased.

The second concern dealt with the handling and storage of diverted merchandise. The realities of the marketplace pretty well ensure that diverted merchandise is sold quickly and shipped and stored properly. The owner of the merchandise knows that if he does not handle, store, and ship his goods properly, they may explode from the cold, melt or discolor from the heat, or get broken or crushed. The result is that he would lose a considerable amount of money since his merchandise would become unsaleable.

In addition, all licensed wholesalers are inspected on a spot basis periodically by the Food and Drug Administration and often by

local authorities as well to ensure that storage facilities are clean, air-conditioned, heated, and that all products are stored properly.

In conclusion, your staff report states that, "If foreign counterfeits can be kept out of the domestic market, if expired products were not relabeled, and if all pharmaceuticals were properly shipped and stored, the diversion market would be the consumer's friend."

I am here to tell you that in my experience, that is exactly the case with all diverted pharmaceuticals sold in original sealed containers and bought by the large drugstore chains and wholesalers of this Nation.

That concludes my prepared statement. I would be glad to take any questions.

[The prepared statement of Mr. Kowitt follows:]

P R E P A R E D            S T A T E M E N T  
O F  
S T A N L E Y        K O W I T T

I am a 47 year old pharmacist who grew up working in my father's drug store and who later worked for numerous independent pharmacies and chain drugstores in New York and Florida. In 1972, I went to work for a small wholesaler of diverted pharmaceuticals where I learned the wholesale business and one year later formed my own company where I worked full time until I sold my interest to my partners in June 1984.

During the 12 years that I was actively involved in buying and selling diverted pharmaceuticals, I personally had direct contact with and bought product from more than 50 other wholesalers specializing in diverted pharmaceuticals and had frequent contact with the principals and managers of these companies. I sold merchandise to more than 15 of the largest drugstore chains in the country (many listed on the New York Stock Exchange ) and either I or my partners talked to the buyers of these chains on a weekly basis. My customers also included more than 25 of the largest full service wholesalers in the country with whom I enjoyed an excellent business relationship.

In April 1982, I was indicted and subsequently convicted of conspiring with others to defraud 27 major pharmaceutical companies through a scheme which your Staff Report deals with in great detail. Motions in that case are still pending. During the government's investigation of this case, they subpoenaed the books and records of numerous drug manufacturers that sold product to three Miami hospitals. Although the government decided not to include these purchases in their subsequent indictment, the material was provided to me as part of the pretrial discovery process and I in turn, made them available to this committee. Those documents showed what I and others in the industry believed for years. Namely, that many drug companies either actively or passively assist in the diversion of their product. I found conclusive evidence that some companies continued to sell their product even after they learned that the hospital was diverting their product and even after they received letters from their salesman warning that these hospitals were diverting. It showed clearly that at least 20 major pharmaceutical companies sold quantities of products to these hospitals that was conservatively 100 times larger than they could possibly have consumed themselves.... notwithstanding the fact that many of these companies had warnings on their invoices indicating that merchandise they sold was for the in house use of the ordering institution only.

For the purposes of illustration, I assumed that the ordering hospital was full to capacity at all times and each patient received the manufacturers suggested dosage of medication every day. I found that Abbey Hospital, a 12 bed not for profit hospital, ordered and was shipped by Ayerst Labs. a 42 year supply or 844,000 tablets of their anti-epilepsy drug, Mysolene 250 mg, in a 6 month period and over 12,000 of their prescription ear drops, Auralgan, in a 2 month period. At the same hospital, Abbott Lab. sold a 38 year supply of their tranquilizer, Tranxene, or 667,500 tablets in an 8 month period; a 14 year supply of their antibiotic, Erythrocin 250 mg, or 250,000 tablets in 7 months; and a 7 year supply of their potassium supplement, K-Lor Packets, or 123,840 doses in 8 months.

To Coral Gables Hospital, a 77 bed for profit hospital, Merrell National Drug Co. sold 8,250 packages of A.V.C. Vaginal Cream and Suppositories in 2 months. Bristol Labs. sold over 100,000 capsules of their antibiotic, Polycillin 250mg, and another 2100 bottles of Polycillin Liquid all within a 3 month period.

To Miami Dade Hospital, a 260 bed for profit hospital, Meade Johnson sold a 30 year supply of their vitamin with fluoride preparation, Poly-vi-flor tablets and liquid within a 3 month period. This was 2,216,000 tablets and 622,800 doses of liquid of which 850,000 tablets and 202,000 doses of liquid were shipped within a single 10 day period. All of this even though vitamins with fluorids preparations are usually contraindicated in areas of fluoridated water such as Miami. Meade Johnson also sold 1,800,000 capsules of their stool softener and laxitive preparations, Cloace 100 mg and Peri-Colace, or a 12½ year supply of product in only 5 months. Syntex Lab. sold 29,000 tubes of their steroid preparation Synalar Cream, in one years time and 360,000 capsules of their asthma preparation, Aarane, (but only 504 Aarane Inhalers which are devices necessary in order to be able to use the capsules) all within a 5 month period. Marion Lab. sold 4.7 years worth of their capsules for blood circulation, Favabid, or 897,000 capsules in a single month. Cooper Labs. sold 540,000 Oz of their bronchial dilator, Elixophyllin, and 367,840 oz of their potassium supplement, Kayciel, within 6 months. Boehringer Ingelheim sold 850,000 tablets and 131,000 suppositories of their laxitive preparation, Dulcolax, in a 3 month period. Smith Miller Patch sold 40,476 bottles of their decongestant eye drops, Vasocon and Vasocon A, within 10 months. Johnson and Johnson sold 35,880 cycles of their birth control pills, Ortho Novum, in 6 months even though this hospital had no family planning center or outpatient department. Breon Labs thought nothing of this hospitals sales going from \$328.30 in 1973 to \$81,266.82 in 1974 and agreed to sell to them 48,000 assorted packages of their asthma preparation, Bronkometer-2, within a 1 year period. Wallace Lab., Allergan Pharmaceuticals, Lederle Lab., Knoll Pharm.,

Pfizer Lab., Winthrop Lab., and others all showed similar inclination towards closing their eyes to an obvious pattern of over ordering on the part of the hospital. The owner of these 3 hospital pharmacies confirmed to me years later that virtually all of the salesmen from these companies were aware that he was diverting. After awhile it becomes quite evident that although some manufacturers are clearly unhappy with the diversion of their product, many others use the diversion industry as a means of selling tremendous quantities of competitive products and realizing stupendous profits. Yet, when confronted with diversion, they quickly point their finger at others and deny involvement.

To my knowledge, not a single civil lawsuit resulted from the diversion through these hospitals or as a result of the diversion through the bogus charities which was part of my trial. Perhaps the reason that lawsuits are not initiated by the manufacturers who claim to be victimized by diversion is fear of what embarrassing and potentially damaging information will emerge. For example, my trial uncovered the following:

That Whitehall Laboratory sold to a customer that claimed to be a charity at their lowest export prices and yet earned a gross profit of \$85,742 on a sale of \$109,058. Internal memos disclosed that the company was aware of the possibility the order would be diverted but decided to sell anyway because of the "very attractive profit of 79%". Products ordered or quoted on included Heet Linament for sore and aching muscles, Neet depilatory for removal of hair from ladies legs, and Freezezone corn remover and Outgrow for ingrown toenails for needy people in Third World Countries who probably wore no shoes....

That Ciba-Geigy Pharmaceutical Company donated outdated merchandise to charities and in one instance, took a tax write off of \$ 154,754 for products that were unsaleable because they lacked child proof caps and had a cost of goods of only \$6555.

That Becton Dickinson sold the largest order in the history of their company to a broker for trans-shipment to Zaire, formerly the Belgum Congo. This order was for 13½ million U-100 disposable insulin syringes worth \$1,000,000 and sold to a bankrupt country of 16,585,000 people with a 35% illiteracy rate and little refrigeration facilities for insulin.

In my 12 years of buying and selling diverted merchandise, I found that certain companies products seemed always to be available in large quantities from many different sources and other companies products seemed hardly ever to be available. Abbott, Allergan, Bristol, Cooper, Lederle, Meade Johnson, Merrell-Dow, Syntex, Wallace and Warren Teed (Adria) goods were plentiful while Lilly, Burrough-

Welcome, Merck Sharpe & Doms, Smith Kline Beckman and Upjohn goods were very scarce. All other companies products fell somewhere in between with merchandise available intermittantly.

There are two primary factors that are responsible for the diversion industry and both are totally under the control of the manufacturer. The first is the tremendous price differential between ordering entities... up to 80 % in some cases. The second is the internal structure of the drug companies that places great emphasis on the sales of competitive items which are the ones involved in diversion. Sales quotas must be met or salespeople may be fired. Bonusses, commissions and promotions are based on sales in excess of quotas. Helping diverters was the only way that a salesman or his manager could retaliate against a salesman that was dumping merchandise into his territory and hurting his sales.

Your recent Staff Report defines diverted merchandise as any brand name product that is not obtained directly from the manufacturer or an authorized distributor. To this I would add that true diverted products are made in the U.S.A., sold by licensed wholesalers in original sealed packages that meet all the requirements of the FDA for sale in the United States. This is the only kind of merchandise that I sold and it posed no health hazard to the American consumer. This kind of product must be distinguished from the sale of physician samples which have been repackaged, misbranded, adulterated and outdated and which are clearly and undeniably illegal under existing law and are a definite potential danger to consumers. Unfortunately your Staff Report does not go far enough to distinguish between these very different types of product. Although I, and most other pharmacists are aware of the existance of individuals who are usually not licensed and who purchase physician samples from doctors and salesmen (usually for cash) and then adulterate and repackage these items for sales to retail stores (again usually for cash), this is nothing that I or most other diverter-wholesalers are involved in. Throughout the years, all of my customers insisted on merchandise whose packaging was identical in every way to the packaging they received when buying the identical item directly from the manufacturer.

Because it may be impossible to distinguish stolen or well made counterfeits from bonafide goods, they pose a special problem. To my knowledge, the only time a counterfeit found its way into the national distribution system was the Ovulen that you are investigating. The packaging of this product, although good enough to fool some people, was not good enough to fool many others who, like myself, refused to buy the product. This unique experiance proved that the existing system works and the product was quickly identified, recalled and traced back



to the original importer. If those people responsible for making the pills, and those who distributed it knowing it was fake are dealt with harshly, <sup>e</sup>than that along with the tremendous exposure this committee has given to the problem should go a long way to insuring that this type of thing never happens again.

In my remaining minute, I would like to very briefly touch on two of the concerns expressed by the Committee in their Staff Report. The first is recalls. Let me assure you that products sold through the diversion market in original sealed packages are recalled when necessary just as quickly and efficiently as products bought directly from the manufacturer. Every customer I sold to bought the identical product from both me and the manufacturer. Therefore, in the event of a recall, he would be notified by the manufacturer, check his inventory and remove all recalled items regardless where originally purchased.

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In conclusion, your Staff Report states that "if counterfeits can be kept out of the domestic market, if expired products were not relabeled, and if all pharmaceuticals were properly shipped and stored, the diversion market would be the consumer's friend." I am here to tell you that in my experience that is exactly the case with all diverted pharmaceuticals sold in original sealed containers and bought by the large drugstore chains and wholesalers of this nation.

Mr. WYDEN. Mr. Kowitt, thank you for that statement.

We will begin the questioning with the gentleman from Minnesota.

Mr. SIKORSKI. I thank the chairman.

Mr. Kowitt, what precautions did you take to make sure that the drugs you sold were safe?

Mr. KOWITT. I took the same precautions with those drugs as I did with any other pharmaceuticals that I purchased throughout my career. That is, I naturally bought from licensed wholesalers whom I knew to be in the business of selling pharmaceuticals. I paid by check naturally, and received an invoice from these companies.

Most importantly, probably, is that I inspected the merchandise myself to make sure that these products met all the requirements that I know that they have to meet, the labeling, et cetera, that it wasn't subjected to heat and that gelatin capsules weren't congealed, et cetera.

Mr. SIKORSKI. So when we are talking about this diversion system, we are not talking about people standing on a street corner late at night buying illegal drugs?

Mr. KOWITT. Definitely not.

Mr. SIKORSKI. We're talking about something that you maintain the regular business relationship with the people you bought from?

Mr. KOWITT. Yes. I called these people, ordered the same merchandise from these people sometimes for years. These people carried many different lines of product, and I would reorder the same items month after month.

Mr. SIKORSKI. You were in business in the fall of 1983, is that correct?

Mr. KOWITT. Yes, that's correct.

Mr. SIKORSKI. Did you have reason to inspect some Ovulen 21—I think there is a box there in front of your counsel—birth control pills being offered for sale in the diversion market?

Mr. KOWITT. Yes, I did. These are not the ones that I happened to take a look at.

Mr. SIKORSKI. No. Those we know are counterfeit Ovulen-21 that made it to market. These are the authentic ones. The differences are hard, I guess, from a regular person's perspective, to tell.

You got a load on a pallet, is that what happened?

Mr. KOWITT. Yes. As a favor to another wholesaler, a Northeast wholesaler, I agreed to accept delivery of 10,000 to 15,000 cycles—a cycle being a month's supply.

Mr. SIKORSKI. So these would be 300,000 to 450,000?

Mr. KOWITT. Actual tablets, you mean?

Mr. SIKORSKI. Yes.

Mr. KOWITT. Yes. But it's generally referred to in terms of cycles.

Mr. SIKORSKI. Cycles.

Mr. KOWITT. A month's supply.

Mr. SIKORSKI. OK.

Mr. KOWITT. Because as you can see, they're sealed hermetically.

Mr. SIKORSKI. Right.

Mr. KOWITT. And they're not sold separately. This is one selling unit. And there must have been 10,000 to 15,000, maybe as many

as 20,000 thousand of them that I accepted on behalf of another wholesaler into my warehouse.

He had sold the merchandise to somebody in Florida and was trying to save the freight of having the merchandise shipped from his supplier in Miami up to the Northeast and back to the person he had sold it to. I had no ownership interest in this.

Mr. SIKORSKI. OK. Just so I understand, they came from a supplier in Miami.

Mr. KOWITT. Uh-huh.

Mr. SIKORSKI. And this distributor—or wholesaler?

Mr. KOWITT. It's a wholesaler.

Mr. SIKORSKI. Wholesaler in New York?

Mr. KOWITT. It was in New Britain, CT. His name was H.L. Moore Drug Exchange.

Mr. SIKORSKI. H.L. Moore.

Mr. KOWITT. Right.

Mr. SIKORSKI. Up there. And he bought from a firm in Florida?

Mr. KOWITT. He had purchased merchandise from the Lantor Corp., which is a company owned or operated by a Fermin Alfonso.

Mr. SIKORSKI. In Miami. So instead of shipping them up and then back, he asked you as a favor that you take custody or possession of these pills?

Mr. KOWITT. That's correct.

Mr. SIKORSKI. And they came in a delivery of 10,000 to 15,000 maybe 20,000?

Mr. KOWITT. That's correct.

Mr. SIKORSKI. Cycles, which would be anywhere from 300,000 to 500,000 actual tablets.

Who was the ultimate purchaser?

Mr. KOWITT. The ultimate purchaser was Eckerd Drugs. It was going to their warehouse in Clearwater.

Mr. SIKORSKI. They had arranged to purchase the entire shipment?

Mr. KOWITT. Yes. From H.L. Moore.

Mr. SIKORSKI. And who brought the Ovulen-21 to you?

Mr. KOWITT. Mr. Alfonso himself delivered them to my warehouse late one afternoon.

Mr. SIKORSKI. In shipping crates?

Mr. KOWITT. In cardboard boxes.

Mr. SIKORSKI. In cardboard boxes. Did he offer to sell you any of the Ovulen-21?

Mr. KOWITT. Yes. When he got through unloading, he told me that the had more product available and if I could sell it, he would be interested in selling it to me.

Mr. SIKORSKI. What was your reaction?

Mr. KOWITT. Well, this was late in the day when he told me this, so I didn't do anything until the next morning. But when I came into the office the next morning, I called three other local wholesalers, pharmacists, people that I thought might be able to give me some input as to whether this product could be sold. And I learned that this product had been offered to all three of these people, and they all had rejected it.

Mr. SIKORSKI. Did they tell you why?

Mr. KOWITT. Well, they said the packaging—they suspected the packaging might not be what it should be.

Mr. SIKORSKI. And who were these people that you had talked to?

Mr. KOWITT. Yes, one was a wholesaler by the name of Med Sales, and I spoke to Mr. Ed Picard. Another was a wholesaler by the name of S&A Drug, and I either spoke to Howie or Stan Ackerman.

Mr. SIKORSKI. They're brothers?

Mr. KOWITT. They're brothers, yes. They own and operate the business.

The third person I spoke to was a pharmacist friend of mine by the name of Allen Pelar, who operates a company called Prescription Specialists.

Mr. SIKORSKI. And they all told you that they rejected purchasing these from Mr. Alfonso based on the packaging?

Mr. KOWITT. That's correct.

Mr. SIKORSKI. And you then inspected the packaging?

Mr. KOWITT. Yes, I did. Then I went and opened the packaging. I wanted to find out what they were talking about.

Mr. SIKORSKI. In fact, they were talking about the things didn't look like the real thing?

Mr. KOWITT. Well, upon careful examination of the product, I noticed that the product had the number 401 stamped on both sides of the tablet. The name Searle, which should appear on one side of these tablets, was missing. And that was the problem with it.

Mr. SIKORSKI. Which raises the question, has to raise, the question in your mind that these are the authentic, the real genuine things, is that correct?

Mr. KOWITT. No. I don't see the word "Searle" on these, unless my eyes are playing tricks with me.

Mr. SIKORSKI. Those have 401 stamped on one side?

Mr. KOWITT. Yes. I don't see "Searle," and I don't think it's—

Mr. SIKORSKI. Those are counterfeit.

Mr. KOWITT. OK. It was a different lot number. The lot number that I had brought to me was, I believe, a lot number 441, and it wasn't boxed, and it was in a blue envelope, it was not in a white envelope.

Mr. SIKORSKI. So the counterfeit ones you had weren't like these counterfeits.

Mr. KOWITT. It did not look like these.

Mr. SIKORSKI. They were in a different labeling?

Mr. KOWITT. Yes. They were not boxed as you see this boxed. They were loose envelopes in large cartons, and they were blue.

Mr. SIKORSKI. I see. Maybe we shouldn't—here are the ones that look like yours, the light-blue envelopes.

Mr. KOWITT. They look much more familiar. Yes, these look exactly like the ones that I have seen.

Mr. SIKORSKI. And that's a tipoff that they are not the authentic thing, is that right?

Mr. KOWITT. Well, it's a tipoff that something is unusual about it, so much so that I took the time to call the G.B. Searle Co. and asked for the customer service department to find out if they, in fact, distribute a product in the United States without their name on it. This Ovulen product without their name on it. And the

young lady kept me on hold for a while and then came back to me and said that as far as she knew, they did not.

Mr. SIKORSKI. You didn't call and say, "This is Mr. Kowitt"—

Mr. KOWITT. No, sir, I didn't. At this point I was just trying to find out what was happening.

Mr. SIKORSKI. You called anonymously and got your information and then hung up?

Mr. KOWITT. Correct.

Mr. SIKORSKI. You then contacted H.L. Moore?

Mr. KOWITT. Correct. I called a Norman Miller, who works for H.L. Moore Drug, and told him what I had learned from these other people, including the G.B. Searle Co.

Mr. SIKORSKI. You didn't call Rome up at H.L. Moore Co.?

Mr. KOWITT. Mr. Rome was the president of the company, who was not in the office at that particular moment, although I have dealt with him over the years. But he has an associate by the name of Norman Miller, who handled this particular transaction.

But Mr. Miller told me that he would have to call Mr. Rome on the telephone and discuss it with him and get back to me. And about an hour after I made my phone call, he called me back and said that he had discussed it with Mr. Rome and they had decided under no circumstances do they want to sell this product if it wasn't exactly like the merchandise that—

Mr. SIKORSKI. You shared with them the information that you received from Searle?

Mr. KOWITT. Yes, I did. And they then told me that they had contacted their bank and they had started the process of stopping payments for this merchandise.

Mr. SIKORSKI. The payment on the check from H.L. Moore to Mr. Alfonso doing business as Lantor?

Mr. KOWITT. Lantor Corp. Correct.

Mr. SIKORSKI. And they asked you to pick the check up?

Mr. KOWITT. Well, somehow the check was wired or transferred to a bank down in Miami, and they asked me if I wouldn't go down to Miami immediately and pick up that check for them.

Mr. SIKORSKI. Did you do that?

Mr. KOWITT. I did that, yes. I spent quite a few hours doing it.

Mr. SIKORSKI. And what was the reaction of Mr. Alfonso?

Mr. KOWITT. Well, apparently, H.L. Moore called Mr. Alfonso to cancel the order and tell them to come and pick the merchandise up, which he did. And he was quite upset with me. When he came in to pick up the merchandise, he tried to assure me that this merchandise was an older batch of Ovulen, a batch that they made before they started stamping their names on the pills.

Now, I informed him that I had been selling this product, frankly, for 10 years.

Mr. SIKORSKI. From the beginning?

Mr. KOWITT. From the beginning. And I had sold their—several of their packages, their what you call "clinic package" and their regular stock package. And at no time did I ever see a product without their name on.

Mr. SIKORSKI. And did you also tell them that you had talked to Searle's customer service?

Mr. KOWITT. Yes, I absolutely did.

Mr. SIKORSKI. But he still was adamant that the——

Mr. KOWITT. Yes, he was.

Mr. SIKORSKI. Was Eckerd told that the pills were likely to be counterfeit?

Mr. KOWITT. I have no idea. I know that H.L. Moore canceled his order with Eckerd, but what reason he gave, I don't know.

Mr. SIKORSKI. Did you discuss the matter with other people in the diversion market?

Mr. KOWITT. The only other person I discussed it with at a later date was Mr. Marvin Sandler of Interstate Drug. I had occasion to talk to him on the telephone, and I told him what had transpired. And he informed me that he had purchased some of this merchandise from Lantor Corp. a while ago, and he seemed surprised at what I had told him. He put me on hold. He wanted to check his inventory to see what I was talking about. And when he came back to the telephone, he told me had sold through on the product.

Mr. SIKORSKI. Did he say how many?

Mr. KOWITT. No, he did not.

Mr. SIKORSKI. So this is Interstate Drug Exchange that had bought some and——

Mr. KOWITT. Correct.

Mr. SIKORSKI [continuing]. Sold through. Had he notified the FDA, do you know, after you talked to him?

Mr. KOWITT. I don't know whether he did or he didn't. I doubt seriously if he did. He had told me he had bought a lot of products from Lantor and he's never had any problem with them. And we discussed the possibility of the product being perhaps made by Searle for a family planning center or for some special purpose.

I know I certainly did not feel that this product posed any health threat to the American public, or I would certainly have called the FDA. And I really believe that he felt the same way.

Mr. SIKORSKI. Well, it seems that there was one standard employed for business and another standard employed for protecting the health of the people involved. You weren't going to buy any, and you talked to your friend who asked you to do a favor for him and alerted him, and he canceled. Your other friend, other business associates informed you of their concern about this. They were so concerned that they wouldn't buy into it, but not concerned enough about it to notify the Food and Drug Administration that's responsible for safe and effective drugs.

Mr. KOWITT. My concern was of a very technical nature. I wasn't sure myself whether the packaging met all of the requirements of the Food and Drug Administration.

Mr. SIKORSKI. Well, let me just say that I think that you were sufficiently concerned to call anonymously. If it were just a technical problem, then there was no reason to be concerned and to ask Searle directly, with your name and the rest of it, saying, "I've got these 300,000 to 500,000 pills sitting here, and they're going to Eckerd Drug system. Rome asked me to take them. I called these other three, and they say"—and let them fully deal with the issue.

Do you know if anyone called the FDA?

Mr. KOWITT. Amongst the people that I spoke to?

Mr. SIKORSKI. Yes. Moore or——

Mr. KOWITT. I have no knowledge about that at all.

Mr. SIKORSKI. You don't know if H.L. Moore called the FDA?

Mr. KOWITT. I have no way of knowing, sir.

Mr. SIKORSKI. Did Med Sales?

Mr. KOWITT. Again, I have no way of knowing. I really didn't discuss it with them.

Mr. SIKORSKI. S&A?

Mr. KOWITT. No way of knowing.

Mr. SIKORSKI. Prescription Specialists, you have no—

Mr. KOWITT. No way of knowing.

Mr. SIKORSKI. This occurred in late fall or early winter of 1983?

Mr. KOWITT. Correct. And it turned out to be the very first time a counterfeit product had been introduced into the distribution system, to my knowledge. It wasn't something that we routinely looked out for. But I could assure you that anybody in the business today is certainly aware of that possibility.

Mr. SIKORSKI. Well, we do know that Interstate Drug Exchange and some other experienced wholesalers and self-acknowledged diverters knew that some questionable pills were being offered for sale, and nobody notified the public health authorities.

Mr. KOWITT. That's true. But again, the questionable part dealt basically with what I thought was a legal technicality on the packaging of the product.

Sir, can I just add something?

Mr. SIKORSKI. Yes, I understand, and I understand your position here, and I thank you for coming today and helping us out, and your concern. But when something smells fishy, it's time to bring the anglers in to deal with the problem.

Mr. KOWITT. Well, perhaps it will help if I explain the thought process of what was going through my mind when I looked at this. Perhaps that will help you to understand why I didn't call.

The thought of it being counterfeit crossed my mind for an instant. But upon thinking about it, it just didn't make sense, because if somebody was going to go to the time and trouble and effort and expense to counterfeit a product, I don't think they would counterfeit a product with such intricate packaging that sold for \$2.50 or \$3 a package and leave the name of the manufacturer off it. That just didn't make any sense to me.

I know there are so many other products available that cost a dollar and more a tablet, why would anybody go to this bother and then leave the name of the manufacturer off? I equated it to somebody counterfeiting a \$1 bill and putting Abraham Lincoln's picture on it. It just made no sense.

Mr. SIKORSKI. Well, then why didn't you tell Searle about it?

Mr. KOWITT. Well, frankly, at that point I forgotten about it.

Mr. SIKORSKI. Why didn't you tell FDA about it, be a good guy?

Mr. KOWITT. I am sorry I didn't.

Mr. SIKORSKI. Yes. And so is everyone else, and the women that had children because they got pregnant because of it, and unknown problems.

I thank you.

Mr. WYDEN. I thank the gentleman from Minnesota.

The gentleman from Virginia.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. Kowitt, could you further distinguish between good diversion and bad diversion? Do you think, for example, we should outlaw all diversion, or should we seek to stop only that which is carried out by unethical diverters who repackaging and adulterate, et cetera? Is it possible? And do you have any suggestions?

Mr. Kowitt. Well, I think a lot of the problem with what you call unethical or obviously illegal repackaging and distribution deals with samples. And I have always wondered why it was necessary for a manufacturer to sample a product that's been on the market for 10 or 20 or 30 years. This made no sense to me.

I would think that if the manufacturers, instead of giving samples of products—which by the way are probably stored in the trunks of salesman's cars or, if they happen to live in Florida, they'll store it in an attic, as you know, or in a garage that's not air-conditioned—if instead of sampling, if they simply made cards available to patients to take to a drugstore and let the drugstores fill the initial prescription for 3 or 5 or 10 capsules, that would make more sense.

Mr. BLILEY. But the second part of my thing is that if you distinguish between good diversion and bad diversion, as you attempted to do, how do we as a legislative body deal with that? Do we simply outlaw all diversion or do we set up laws to deal strictly with unethical diversion, and illegal packaging?

Mr. Kowitt. What I was trying to say basically was that merchandise that's diverted but sold in original sealed packages, merchandise that's made in the United States and meets all the labeling requirements of the Food and Drug Administration for distribution in the United States, is fine.

It's the other kind which emanates from samples, mostly samples that are taken out of the original packaging so that you don't know the lot number and you don't know the expiration date and are not sold by bona fide wholesalers, it's out and out illegal for any wholesaler to sell a repackaged product, period. And anybody that does it knows they're violating the law.

Mr. BLILEY. Well, I realize that, but following up on what my colleague from Minnesota said, if ethical diverters don't inform the FDA of the possibility that a particular lot is an illegal repackaging for diversion, how are we likely to come across it?

I mean, we obviously do not have the resources or the ability to have a Federal inspector full time at every diverter's warehouse in the country. I mean, if you folks don't inform the FDA and 90 percent plus of this is going to go through, I mean, how can we, without the cooperation of you guys—

Mr. Kowitt. Congressman, perhaps I can answer it this way. In all of the years that I was in business, I did not get offered, nor did I purchase, merchandise that was repackaged or not in the original containers. That's the point. I was never brought in bags of pills that were dumped from other bottles and things. I just wasn't. I didn't buy and sell that product, and so I had no reason to come across it and no reason to notify anybody.

I am sure there are people that deal in that kind of product, but I wasn't one of them.

Mr. BLILEY. Had you heard of Mr. Alfonso and were you familiar with his company before you acted as—



Mr. KOWITT. No, I had never heard of him. Even though he was in Miami, I had never heard of him nor had I ever had any contact with him before.

Mr. BLILEY. I see. Thank you.

Thank you, Mr. Chairman.

Mr. WYDEN. I thank the gentleman from Virginia.

Mr. Kowitt, some questions for you, and the subcommittee has prepared a chart so we can get into this area in greater detail. The staff will put that chart up at this point.

But let me ask you a couple of preliminary questions before we go to the chart, Mr. Kowitt.

Mr. Kowitt, in preparing for your defense, your defense in the criminal case, you got access to a large number of documents subpoenaed by the Government from the pharmaceutical companies, didn't you?

Mr. KOWITT. Yes, that's correct.

Mr. WYDEN. Now, you voluntarily provided the subcommittee with a number of these documents which illustrate that pharmaceutical manufacturers knew, or should have known, that their products were being diverted, is that correct?

Mr. KOWITT. Yes, that's correct.

Mr. WYDEN. Now, we have prepared a chart that shows the basic diversion process, and I want to go through this with you, because, as I said, it seems to me that there are people who are blinded by the lure of easy profits, and you have to have three parties to really make the basic diversion process work.

Now, in the case that we're talking about, the goods were sold to three hospital pharmacies which are operated by the same company and then diverted to Southern Trading & Export Co. Southern resold to various companies, including yours. Is that correct?

Mr. KOWITT. That is correct.

Mr. WYDEN. All right. Now we would like to review some documents with respect to how this diversionary scheme worked. The first couple of exhibits relate to sales by Ayerst Laboratories to Abbey Hospital. Ayerst is owned by American Home Products, which also owns Wyeth, Ives, and other pharmaceutical companies, is that correct?

Mr. KOWITT. Yes. They also own Whitehall Laboratories.

Mr. WYDEN. The first invoice was dated November 1, 1974, and it indicates that Ayerst sold Abbey Hospital 2,752 units of Auralgan, which is an eardrop medication. Is that correct?

Mr. KOWITT. Yes, that's correct.

Mr. WYDEN. I would ask that that document be put into the record as Exhibit 1. [Exhibits referred to begin on p. 97.]

The second invoice that I think you have shows that Ayerst sold Abbey 6,036 units of Auralgan on April 30, 1975; is that correct?

Mr. KOWITT. Yes, that's correct.

Mr. WYDEN. The third invoice shows that on May 22, less than a month later, Abbey bought another 6,000 units of Auralgan. Now, my question to you is, isn't this volume of sales to a 12-bed hospital way, way, way beyond what could possibly be used?

Mr. KOWITT. Yes, sir, it certainly is. I estimate that a 12-bed hospital might use 100 to 200 bottles of these eardrops per year. So the

12,000 bottles sold to Abbey Hospital within a 30-day period would last that hospital over 50 years.

Mr. WYDEN. Now, we see from these and other invoices that Abbey Hospital ordered 844 bottles, each containing 1,000 tablets of Mysolene. What is Mysolene? And again, why in the world would a 12-bed hospital order well over three-quarters of a million tablets of this over a 7-month period?

Mr. KOWITT. Mysolene is used to treat epilepsy, and certainly the hospital could not possibly use this volume of merchandise. If the hospital were always filled to capacity and every patient took the suggested dosage of four tablets per day, the quantity that Abbey ordered in a 7-month period would have lasted that hospital 48 years. It had to indicate diversion.

Mr. WYDEN. I mean, any reasonable person right at that point would have said that a diversionary scheme was in process.

Mr. KOWITT. I certainly would think so.

Mr. WYDEN. Exhibit 2, which you have, is an interoffice memo from Ayerst, indicating that the company had checked out Abbey and knew of the relationship between Abbey Hospital and Lionel Harris of Southern before they decided to sell.

Now, the second paragraph of the memo states, "You may remember back in 1973 I wrote you with all the information we had on L. Harris and Abbey Hospital and requested what to do, sell them or not sell them. I was told to sell."

Now, that's exhibit 2, and I would ask that that be put into the record.

Exhibit 3 is an interoffice memo from Boehringer Ingelheim, Ltd., dated October 31, 1974, that summarizes the information they got on Abbey from Ayerst. The memo, or the pertinent part, reads,

In discussing their record with Ayerst Laboratories of New York, I discovered that they purchased large quantities beyond what their usage could possibly be in such a small hospital, and that they have an unusual credit arrangement with Ayerst. They pay cash in advance.

I would ask that that exhibit, exhibit 3, be put into the record.

Now, the memo concludes that Boehringer should also use the cash-in-advance method when dealing with Abbey.

Now, my question to you, Mr. Kowitt, is, do these internal company memos suggest to you that Ayerst was well aware, was fully cognizant that their sales to Abbey Hospital were, in fact, being diverted?

Mr. KOWITT. Yes, sir, they do.

Mr. WYDEN. OK. Do most hospitals or wholesalers pay cash in advance?

Mr. KOWITT. No, not usually. They might for their initial order, until credit is established, but it is most unusual to be asked to pay cash in advance on a continuing basis.

Mr. WYDEN. Despite the information from Ayerst, did Boehringer Ingelheim sell pharmaceuticals to Abbey?

Mr. KOWITT. Yes, they did.

Mr. WYDEN. The fourth exhibit I want to go through with you, exhibit 4, a purchase agreement between Abbey Hospital and/or Miami-Dade and Boehringer Ingelheim, dated December 12, 1984, that document had specific language against resale in it, is that correct?

Mr. KOWITT. Yes, that's correct. But that's not unusual, and it apparently didn't mean very much. For example, Marion Laboratories had similar restrictions on their invoice against resale, and yet they sold Miami-Dade Hospital, a 260-bed hospital, 897,000 capsules of an item called Pavabid, which is used for blood circulation, within a single 30-day period. And this quantity amounted to a 4.7-year supply if every patient took the manufacturer's suggested dosage every day.

And also, Syntax had similar restrictions, and yet sold Miami-Dade 29,000 tubes of a topical cream called Synalar in a single year.

Mr. WYDEN. Well, why do the manufacturers put these restrictions in their invoice, given your last response?

Mr. KOWITT. I think it has something to do with a possible attempt on their part to protect themselves against possible Robinson-Patman liability.

Mr. WYDEN. Did Abbey make unusually large purchases of drugs from Boehringer?

Mr. KOWITT. Yes, they did. I found that Abbey Hospital and Miami-Dade purchased 8,500 bottles of 100 tablets each of a laxative tablet called Dulcolax within a 3-month period of time. And also during this same period they purchased 2,636 boxes of 50 Dulcolax suppositories.

Mr. WYDEN. Assuming that all beds in all three of the hospitals were full all the time and each patient took the recommended dosage of Dulcolax each day, how long would 8,500 bottles of 100 tablets and 2,636 boxes of 50 suppositories last?

Mr. KOWITT. Well, based on the manufacturer's suggested dosage of one to three tablets per day or one suppository per day, I calculate that it would take all three hospitals, full to capacity at all times, 4½ years to use what they purchased in 3 months.

Mr. WYDEN. Did Boehringer require cash in advance for these sales?

Mr. KOWITT. Yes, they did.

Mr. WYDEN. Did you find evidence that Allergan Pharmaceuticals, which is out of Irvine, made sales of unusually large quantities of pharmaceuticals to Miami-Dade?

Mr. KOWITT. Yes, they did. In one 3-month period they sold to Miami-Dade, again a 260-bed hospital without an outpatient department, 5,568 bottles of 5 cubic centimeters and 5,132 bottles of 15 cubic centimeters of an antibacterial eyedrop called Blephamide.

In addition, during that same period of time, they sold them over 5,000 bottles of another eyedrop called Epifrin.

Mr. WYDEN. Exhibit 5 which you have is a December 1974 exchange of correspondence between Allergan and Miami-Dade which discusses the prices Allergan would charge for certain volumes of purchase by the hospital.

What is your opinion of the estimated usage listed in the December 4 letter from the hospital?

Mr. KOWITT. Well, the bid calls for over 35,000 bottles of five different eyedrops to be purchased within a 1-year period of time. This volume is well beyond what a 260-bed hospital without a special clinic or outpatient department could possibly use themselves. And the fact that Allergan did not question them and actually

shipped huge quantities of the drugs I mentioned in my last response, the 10,000 Blephamide and the 5,000 Epifrin. That makes me conclude that they were a willing party to diversion.

Mr. WYDEN. Exhibit 6 shows the yearly sales of primary asthma medication by Breon Laboratories to Miami-Dade General Hospital. Is there anything unusual about these figures?

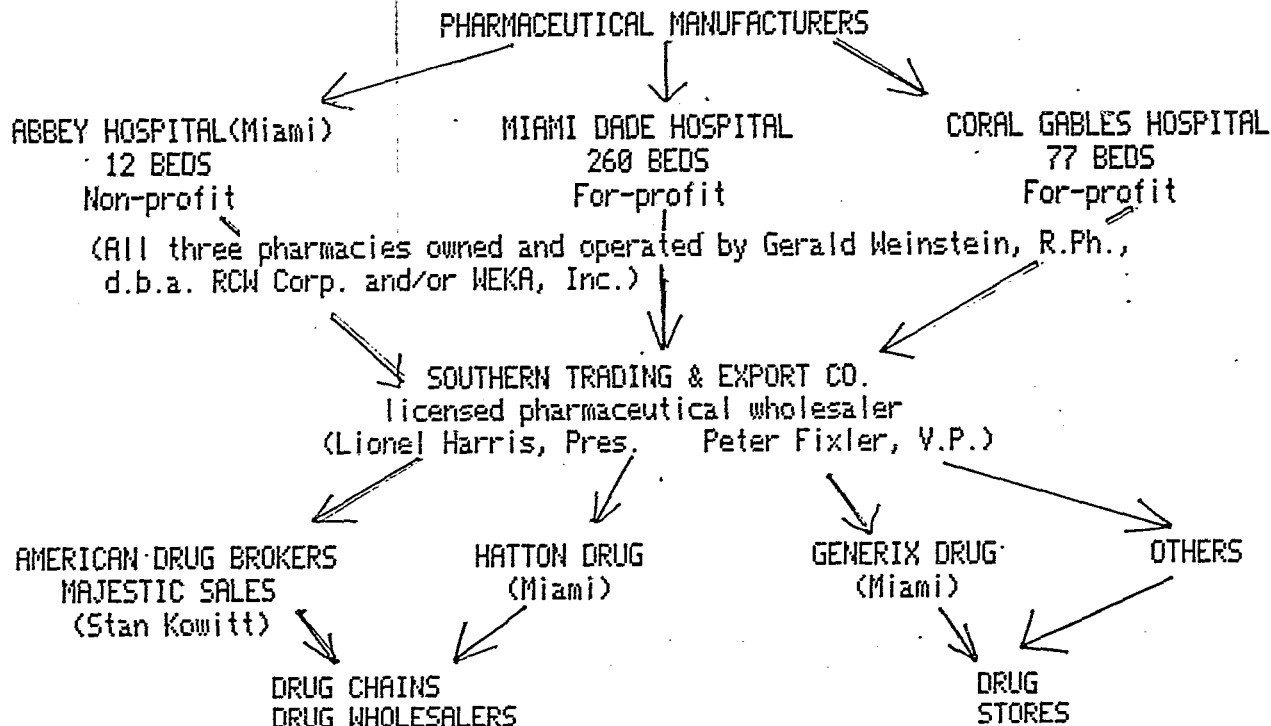
Mr. KOWITT. Yes. In 1973 the total sales to the hospital were only \$328.30. In 1974, when they started to divert products, that amount had skyrocketed to \$81,266.82, an amount that is well beyond the ability of the hospital to use. And by 1976 their sales had returned back to normal levels of \$342.89.

Now, in addition, according to a contract which they had with Breon, Breon agreed to sell to Miami-Dade 48,000 packages of a bronchial dilator inhaler, 6,000 pints of the same item in liquid form, and 3 million tablets of the same drug in tablet form. And they, too, have to be considered a willing partner to diversion.

[Testimony resumes on p. 111.]

[The exhibits referred to follow:]

# HOSPITAL DRUG DIVERSION



# Ayerst AYERST LABORATORIES

Exhibit 1  
CUSTOMER RECORD

PAGE 1 PAGE 1 (34)

SOLD TO:  
ABBEY-FOUNDATH INC.  
5190 S W 8TH ST  
CORAL GABLES FL  
33134

06308

SHIP TO:

SOLD TO:  
ABBEY FOUNDATH INC  
5190 S W 8TH ST  
CORAL GABLES FL  
33134

NO STATEMENT WILL BE SENT  
To insure proper credit return  
remittance stub with payment

REMITTANCE STUB  
# 1505 12 740511 11

TERMS: 25 30 DAYS FROM INV DATE/NET 31

TEL CLASS	SHIP FROM (SEE REVERSE SIDE FOR ADDRESS)	TERRITORY	ACCOUNT NO.	SUB. NO.	MO	DAY	YR.	INVOICE NO.	ACCOUNT NO.	MO	DAY	YR.	INVOICE NO.
12	CHAMBLEE	1505	23-99211	31	11	01	74	203982	2399211	11	01	74	203982
PRODUCT DESCRIPTION		SIZE	QUANTITY (UNITS)	NDC NO.	NET UNIT PRICE	NET AMOUNT							
AURALGAN		15 CC	2752	1000-15	1.02	2,807.04		D E T A C H H E R E  RETURN THIS PART FOR PROPER CREDIT. DETACH AND MAIL WITH YOUR CHECK.  TO: AYERST LABORATORIES P. O. BOX 101205 ATLANTA, GEORGIA 30348  0289 48 014 184 54					
GRISACTIN 250MG		100 CP	2000	0443-21	8.52	1,704.00							
MYSOLINE 250MG		1000 TB	3000	0430-91	33.21	9,963.00							

DISCOUNT ALLOWED IF PAID BY

12/01/74

INVOICE TOTAL 14,474.04

12/01/74 14,474.04



**AYERST LABORATORIES**

CUSTOMER RECORD

PAGE 1 (39)

SOLD TO:  
 ABBEY FOUNDATH INC  
 5190 S W 8TH ST  
 CORAL GABLES FL  
 33134

SHIP TO:

SOLD TO:  
 ABBEY FOUNDATH INC  
 5190 S W 8TH ST  
 CORAL GABLES FL  
 33134

00360

TERMS 25 30 DAYS FROM INV DATE/NET 31

NO SHIPMENT WILL BE MADE  
 To insure proper credit return  
 requires (1)g. with original.

REMITTANCE STUD

23-99211	31	05/30/75	249230	2399211	043075	249230
----------	----	----------	--------	---------	--------	--------

PRODUCT	SIZE	QUANTITY (UNITS)	NDC NO. OR	NET UNITPRICE	NET AMOUNT	
AURALGAN	15 CC	6036	1000-13	1.02	6156.72	D E T A C H H E R E TO: AYERST LABORATORIES P. O. BOX 101205 ATLANTA, GEORGIA 30348
MYSOLENE 250MG	1000 TB	112	0430-91	33.21	3719.52	
THIODSULFIL FORTE	100 TB	212	0786-81	3.75	795.00	
PURCHASE ORDER NUMBER						
5131						

DISCOUNT ALLOWED IF PAID BY 05/30/75 INVOICE TOTAL 10671.24 05/30/75 10671.24

SUBJECT TO TERMS AND CONDITIONS ON REVERSE SIDE. ANY PROVISIONS BY PURCHASER NOTWITHSTANDING.

AYERST LABORATORIES  
 DIV. OF AMERICAN HOME PRODUCTS CORP.



**Ayerst** AYERST LABORATORIES

CUSTOMER RECORD  
PAGE 1 (19)

SOLD TO:  
ABBEY FOUNDATION, INC  
5100 S W 8TH ST  
CORAL GABLES FL  
33134

*OK*

SHIP TO:

SOLD TO:  
ABBEY FOUNDATION, INC  
5100 S W 8TH ST  
CORAL GABLES FL  
33134

TERMS 2% 30 DAYS FROM INV DATE/NET 31

NO PAYMENT WILL BE MADE  
TO ORDER WITHOUT THIS CHECK  
ENDORSED AND WITH SIGNATURE

REMITTANCE SLIP  
1975 12 25 75

LINE	QUANTITY	UNIT	PRICE	AMOUNT	DISC	NET	DATE	AMOUNT		
12	CHAMBLEE	1905	23-99211	31	05/27/75	255012	2399211	05/27/75	255012	
PRODUCT	QUANTITY	UNIT	NDC NO.	NET UNIT PRICE	NET AMOUNT					
AURALGAN	13	CC	60001	1000-19	1.02	6,120.00	RETURN THIS PART FOR PROPER CREDIT. DETACH AND MAIL WITH YOUR CHECK TO: AYERST LABORATORIES P. O. BOX 101205 ATLANTA, GEORGIA 30348  0709-13, 010-247-54			
AYSOLINE 250MG	1000	TB	108C	0430-91	33.21	3,586.68				
THIOSULFIL FORTE	100	TB	200C	0786-81	3.75	750.00				
PURCHASE ORDER NUMBER 8135										

00376

DISCOUNT ALLOWED IF PAID BY

06/21/75

INVOICE TOTAL

10,456.68

06/21/75

10,456.68

SUBJECT TO TERMS AND CONDITIONS ON REVERSE SIDE.  
ANY PROVISIONS BY PURCHASER NOTWITHSTANDING.

F.F.D. NO. 11-2174(7)

AYERST LABORATORIES  
DIV. OF AMERICAN HOME PRODUCTS CORP.

AYERST LABORATORIES



# AYERST LABORATORIES Exhibit 2

I N T E R N A L   C O R R E S P O N D E N C E

TO : Mr. W.L. Sharp	LOCATION	New York
FROM: L.R. Martin	LOCATION	Chamblee, Ga.
SUBJECT: Custodian of Records Request	DATE	August 8, 1978

01460

Dear Bill:

Attached is the piece of correspondence in our files. Per Sales Department instructions, all 1974 and back correspondence has been destroyed.

~~You may remember back in 1975 that you were in the office in connection with Dr. Harris's case. He had requested that we provide him with some information on the file. I was told that you may have had access to the file.~~

I also wrote Fred Dreyssing a letter explaining their request to buy a huge amount of PENBRITIN that never did materialize. Fred may have this letter.

Sorry I can't be of more help.

Sincerely,

*RLM*

LRM/bk

attachment

Mr. W.L. Sharp  
 L.R. Martin  
 Abbey Hospital, etc.

New York  
 Chamblee, Ga.  
 May 12, 1975

Dear Bill:

~~This is the account that has been buying Ayerst products and shipping  
 the overseas. I thought we had this as a pool account. However, recent  
 research indicated territory 1505-1 is still getting credit for this business.~~

Please pool the following hospital under chain-wholesaler:

Abbey Foundation, Inc.  
 5190 S.W. 8th St.  
 Coral Gables, Fla. 33134  
 Account No. 23-912AA

Abbey Foundation, Inc., 5190 S.W. 8th St., Coral Gables, Fla., Account  
 No. 09-00065 should be left to 1505 since this is the regular business or  
 products sold for hospital use.

Thanks for your help.

Sincerely,

LRM/bk

Attachment/Invoice



BOEHRINGER INGELHEIM LTD.  
INTER-OFFICE MEMORANDUM

Exhibit 3

In Reply, Refer to:  
JTM-10-29

TO: Mr. Joseph Ashey DATE: October 31, 1974  
FROM: Mr. James T. McFarland  
SUBJECT: Abbey Foundation Incorporated

A preliminary investigation of the Abbey Foundation Incorporated reveals that they are a rather small hospital with a good credit rating and a prompt payment record.

In discussing their record with Ayerst Laboratories, New York, NY, it was discovered that they purchase large quantities beyond what their usage could possibly be in such a small hospital and that they have an unusual credit arrangement with Ayerst; they pay cash in advance. A representative of Ayerst indicated that they are unaccount to be careful with and one which a formal cash in advance relationship would be recommended.

I suggest that a cash in advance basis should be the method in which we do business with this company. I have requested additional reports which should shed further light on their credibility, and I will pass them along to you as soon as they are received.

*James T. McFarland*  
James T. McFarland

JTM/cb

Exhibit 4

Boehringer Ingelheim



Hospital Purchase Agreement

BETWEEN Boehringer Ingelheim Ltd. 33 W. Tarrytown Road Elmsford, New York 10523 (914) 592-4311	AND NAME AND ADDRESS OF HOSPITAL, INSTITUTION, GOVERNMENT AGENCY NAME Abbey Hospital, Coral Gables, Florida STREET ADDRESS and/or Miami Dade General Hospital CITY Miami, Florida STATE ZIP CODE TELEPHONE NO.
--	--

WHO AGREES TO PURCHASE FROM BOEHRINGER INGELHEIM LTD. THE FOLLOWING ITEM(S):				
QUANTITY	PRODUCT CODE	DESCRIPTION	PACKAGE SIZE	BID PRICE EACH
1008	7086	Alupent complete units	15cc	2.52/ea
1008	7085	Alupent complete refill units	15cc	2.15/ea
360	7201	Alupent tablets	100	4.83/c

~~The drugs, supplies, etc. under this agreement are sold by Boehringer Ingelheim Ltd. with the express understanding that they will be sold or dispensed only to patients in the contract hospital or institution.~~

Orders may be placed for shipment to more than one destination. Boehringer Ingelheim Ltd. assumes transportation and delivery charges, f.o.b. destination. Terms are 2% 30 days, net 45 days from date of invoice.

Minimum order size is \$50.00.

If any general reduction in prices on the above items becomes effective during the terms of this agreement that results in prices lower than the bid price on this agreement, the above hospital or institution will receive the benefit of such reduction on the unshipped portion of the agreement.

The customary return goods policy of Boehringer Ingelheim Ltd., as set forth in their published schedule of prices, shall apply.

This agreement is subject to acceptance by Boehringer Ingelheim Ltd. and commences on 11/28/74 and terminates 11/27/75

BOEHRINGER INGELHEIM LTD. SALES REPRESENTATIVE	SIGNATURE <i>Allen Green</i>	DATE <i>12/12/74</i>	TERRITORY NO. <i>7108</i>
AUTHORIZED APPROVAL BY BOEHRINGER INGELHEIM LTD.	SIGNATURE <i>Edward K. McIntyre</i>	DATE <i>12/12/74</i>	TITLE
AUTHORIZED APPROVAL BY INSTITUTION (CUSTOMER)	SIGNATURE <i>[Signature]</i>	DATE <i>12/12/74</i>	CONTRACT NO. <i>10206</i>



BOEHRINGER INGELHEIM LTD.

INTER-OFFICE MEMORANDUM

TO: C. Martin

DATE: [REDACTED]

FROM: S. Minitier

cc: J. Brennan  
W. McCarthy  
G. Yocum

SUBJECT: Bid Prices for Abbey Hospital

Today I received an oral bid request for the following quantities and products for Abbey Hospital from Juan Arias.

[REDACTED]

Torecan tabs	600 bottles a month
Torecan supps	720 pkgs a month
Serentil tabs	1152 btls a month
Persantine tabs 100's	720 btls a month
Persantine 1000's	5000 btls a month
Catapres tabs	300 btls a month

Thanks, I shall await your reply.

*Sh...*

MIAMI-DADE GENERAL HOSPITAL  
9333 S.W. 152ND STREET  
MIAMI, FLORIDA 33157

Exhibit 5

TELEPHONE: (305) 251-2500

December 4, 1974

Allergan  
2525 Dupont Drive  
Irvine, California 92664

Attn: Judy Williams

Dear Sirs:

Hospital reinvitation to bid  
We are asking for your final bid on the following items as per our conversation.

Item	Size	Est. Usage
Blephamide	5cc	10,000
"	10cc	7,500
" Opth. Oint.	3.5 gm.	1,200
Bleph 10	5cc	3,000
"	10cc	2,200
Bleph 30	1-cc	1,500
Albalon	15cc	1,000
Epifrin 1/2%	15cc	1,000
" 1/2%	15cc	1,000
" 1%	15cc	1,000
" 2%	15cc	500
" 1/2%	5cc	500
" 1%	"	750
" 2%	"	500
Liquifilm	2/3 Oz.	1,000
"	2 oz.	5,200
P.V. Carpine	all strengths	3,500
Eclipse Sunscreen Lotion	4 oz.	1,500
" Suntan Lotion	5 1/2 oz.	2,500
Vanseb	3 oz.	500
Vanseb T	3 oz.	200

Please address your reply to the attention of the pharmacy director.

Sincerely yours,

Miami-Dade General Hospital  
*Gerald M. Weinstein*

Gerald M. Weinstein  
Director of Pharmaceutical Services

December 19, 1974

Gerald M. Weinstein  
 Director of Pharmaceutical Services  
 Miami-Dade General Hospital  
 135 S. W. 152nd Street  
 Miami, Florida 33157

Dear Mr. Weinstein:

The bid prices shown below are net prices to Miami-Dade General Hospital for the period January 1, 1975 to December 31, 1975.

		<u>NET PRICE</u>		
Amide	5cc	#022	1.48	2.12
Amide	10cc	#023	2.74	2.96
Amide Ointment		#313	1.26	1.40
n-10	5cc	#018	1.15	1.24
n-10	10cc	#020	1.44	1.52
n-10	2.5cc	#011	.52	
lon	15cc	#154	1.62	
lin 1/4%	15cc	#221	2.02	2.24
lin 1/2%	15cc	#119	2.23	2.43
lin 1%	15cc	#122	2.45	2.72
lin 2%	15cc	#058	2.66	2.76
lin 1/2%	5cc	#118	1.30	1.44
lin 1%	5cc	#121	1.37	1.52
lin 2%	5cc	#059	1.44	1.60
lin Wetting Sol.		#082	.58	
lin Wetting Sol		#015	1.12	1.20
Aspirine	#094, 096	#090,091,092,093,	1.26	1.60
Sunscreen Lotion		#820	1.51	1.75
		#806	1.12	1.36
-T		#822	1.26	

*quoting price  
11/16/75*

In the event of any further service, please do not hesitate to contact me.

Sincerely,  
  
 Gerald M. Weinstein  
 Director of Sales Services

Gerald M. Weinstein  
 Director of Sales Services

BREON LABORATORIES INC.  
CUSTOMER SALES

Exhibit 6

MIAMI DADE GENERAL HOSP  
9333 S W 152ND ST  
MIAMI FLA

06 170 510400 5 DECEMBER 1973  
DEPT TERR ACCOUNT CLASS PAGE 1.

DESCRIPTION	AMOUNT		COMPARISON WITH PREVIOUS DATE
	CURRENT MONTH	YEAR TO DATE	
1197 BRONKOTABS 1CC S		10.86	10.86
1189 BRONKEPHRINE 1ML 25		16.00	16.00
1200 BRONKOLIXIR 16 OZ		6.24	6.24
1339 BRONKOSOL 2-1C HL		273.60	273.60
1041 ALEVATRE SOL 6OZL		21.60	21.60
BREON RX TOTAL		328.30	328.30
ACCOUNT TOTAL		328.30	328.30



BREON LABORATORIES INC.  
CUSTOMER SALES

WEMA INC  
DEA MIAMI-DACE GEN  
R-ESP PHCY  
9333 SK 152NC ST

C6 17C 81270C 5 DEC. 1974  
DEPOT TERR ACCOUNT CLASS PAGE 1

DESCRIPTION	AMOUNT		COMPARISON WITH PREVIOUS DATE
	CURRENT MONTH	YEAR TO DATE	
1185 BRCANCTASS 1CCCS		11,833.04	11,833.04
1197 BRCANCTASS 100 S		16,619.10	16,668.24
PRGD GR TOTAL		28,452.14	28,441.28
1189 BROKAFPHRINE 1ML 25			.16.00-
1200 BRCANCLIXIR 16 OZ			6.24-
1335 BRCANCMETER-2 10 PL		13,999.20	13,999.20
1336 BRCANCMETER-2 20 PL		25,212.60	25,212.60
1337 BRCAN-2 1CML REFILL		3,198.40	3,198.40
PRGD GR TOTAL		42,410.20	42,410.20
1359 BRCANCCCL 2-10 PL		6,058.80	5,785.20
1711 BRCANCSOL 10 PL	2,397.60	2,397.60	2,397.60
PRGD GR TOTAL	2,397.60	8,456.40	8,182.80
1041 ALEVATRE SCL 60ML		136.80	115.20
1620 FERGLM TABS 100		116.64	116.64
1632 FERGLM TABS 1000		1,542.60	1,542.60
PRGD GR TOTAL		1,658.64	1,658.64
FRNCA RX TOTAL	2,397.60	81,114.18	80,785.88
0032 CAP&FILE SALT 1CCS		152.64	152.64
AMERICAN FERMENT TOTAL		152.64	152.64
ACCOUNT TOTAL	2,397.60	81,266.82	80,938.52

*in real*

BREON LABORATORIES INC.  
CUSTOMER SALES

MIAMI CLICE GENERAL HOSP  
9333 SW 152ND ST  
MIAMI FL 33157

06 170 510400 5 DECEMBER 1976  
DEPT YEAR ACCOUNT CLASS PAGE 1

DESCRIPTION	AMOUNT		COMPARISON WITH PREVIOUS DATE
	CURRENT MONTH	YEAR TO DATE	
1155 EPONKOTABS 1000S			674.24
1197 EPONKOTABS 100 S			2,280.32
PROD GR TOTAL			2,954.56
1335 EPONKOMETER-2 10 ML			1,768.40
1334 EPONKOMETER-2 20 ML			2,069.80
1337 EPONK-2 10ML REFILL			79.20
PROD GR TOTAL			3,917.40
1336 EPONKOSOL 2-10 ML			907.20
1430 FERSON TABS 100			27.36
1432 FERSON TABS 1000			56.00
PROD GR TOTAL			111.36
BREON RX TOTAL			7,884.52
ACCOUNT TOTAL			7,684.52

BREON LABORATORIES INC.  
CUSTOMER SALES

MIAMI DADE GENERAL HOSP  
9333 SW 152ND ST  
MIAMI FL 33157

D6 170 510400 5 MARCH 1978  
DEPOI TERM ACCOUNT CLASS PAGE 1

DESCRIPTION	AMOUNT		COMPARISON WITH PREVIOUS DATE
	CURRENT MONTH	YEAR TO DATE	
1711 BRCARUSCL 1C PL		24.31-	24.31-
1771 BRCARUSCL 1C PL	367.20	367.20	367.20
PRED GR TOTAL	367.20	342.89	342.89
BRECA RX TOTAL	367.20	342.89	342.89
ACCLAT TOTAL	367.20	342.89	342.89

Mr. WYDEN. Did Abbott make unusually large sales to one or more of the Miami area hospitals, Abbott Labs?

Mr. KOWITT. Abbott Labs, yes. In one 8-month period Abbott sold 405,500 tablets of a drug called Tranxene, 7.5 milligram, and 262,000 tablets of the same drug Tranxene, 3.75 milligram.

Now, this is a tranquilizer that shortly thereafter became a controlled substance, and I think probably still is controlled today. Assuming again that every patient took the suggested manufacturer's dosage every day and that the hospital were always filled to capacity, this represents a 38-year supply of medication for the hospital.

And again, using the same assumptions, Abbott also sold Abbey a 14-year supply of an antibiotic called Erythrocin in 7 months and a 7-year supply of a potassium supplement called K-lor in just 4 months.

Mr. WYDEN. Did Bristol Laboratories—that is a division of Bristol-Myers—ship unusually large volumes of Polycillin, an antibiotic, to Miami-Dade in 1976 and Coral Gables in 1977?

Mr. KOWITT. Yes. In 1976, Miami-Dade Hospital received 4,116 bottles of their antibiotic liquid called Polycillin in 100-cubic centimeter size, and 1,440 bottles of 100 capsules of Polycillin.

Now, Coral Gables, which is one-third the size of Miami-Dade, in just a 3-month period in 1977 bought 2,136 bottles of Polycillin liquid and 1,008 bottles of Polycillin capsules. That's a lot.

Mr. WYDEN. I have some additional questions. But I think it's pretty clear that Miami is just awash in medicine, according to your appraisal. Is that correct?

Mr. KOWITT. It was at that time.

Mr. WYDEN. Does Bristol-Myers have any other subsidiaries that sold to Miami-Dade?

Mr. KOWITT. Yes. Bristol-Myers also owns Mead Johnson Laboratories. Now, they sold Miami-Dade 2,216,000 tablets and 622,000 doses of a liquid vitamin with fluoride combination called Poly-vi-fluor, and this within a 3-month period. Now, within a single 10-day period of time, they sold them 850,000 tablets and 202,000 doses of the liquid, all within 10 days.

Now, what makes this a particularly flagrant example of a manufacturer aiding in the diversion of their product is the fact that this vitamin contains fluoride, which is a cumulative poison and is contraindicated in areas where the water already has fluorine in it, like Miami.

Mr. WYDEN. I have some additional questions along these lines, Mr. Kowitt. I particularly appreciate that last point you made about the ramifications of fluoride in Dade County. It proves beyond a doubt that we aren't just talking about some harmless kind of arrangement where you can make easy money and nobody gets hurt. And the fact is that people in this country are getting hurt. You have already brought us some clear evidence, most recently that example in Florida, of where the consequences are very clearly harmful.

I will have some additional questions, but I want to yield to my colleague, whom I know has got a great interest in this because he comes from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. Kowitt, you haven't served any time in prison as a result of your convictions yet, have you?

Mr. KOWITT. No, I have not. My case is still pending.

Mr. BILIRAKIS. Your case is still pending. Have you been made any promises by any of the authorities if you would be willing to testify here today?

Mr. KOWITT. No, sir, I have not.

Mr. BILIRAKIS. And you are testifying for what reason?

Mr. KOWITT. Well, I had accumulated all of this information in preparation for my trial, and I was never able to introduce this in my trial. The judge precluded me from bringing this up, and here it was sitting. And I read the staff report, and I thought that it would be very timely.

Mr. BILIRAKIS. So at this point you care—is that what you're saying?

Mr. KOWITT. Oh, I certainly do.

Mr. BILIRAKIS. Mr. Kowitt, following up with some of the questioning by the chairman, Mr. Wyden, these drugs that were sold to Miami-Dade Hospital, might some of them have been counterfeit? Were they all diversions?

Mr. KOWITT. Well, I would strongly doubt it because, as I indicated in my opening statement, the owner of those hospital pharmacies indicated to me years later that the salesmen for the drug companies were aware of what was happening, and in each case he was ordering the merchandise directly from the manufacturer. In other words, as you can see, it went from the manufacturer to his hospital to Southern Trading to me and some others.

So I think there is no chance that there could have been counterfeits in that.

Mr. BILIRAKIS. Might they be buying some counterfeit drugs that we don't know about, or at least that's not contained in any of these exhibits?

Mr. KOWITT. I strongly doubt it, sir.

Mr. BILIRAKIS. You strongly doubt it. Why would you strongly doubt it?

Mr. KOWITT. Because they had direct accounts with every major pharmaceutical company, this hospital did, and that's where, as far as I know, they bought all of their merchandise. I don't know of them buying it anywhere else.

Mr. BILIRAKIS. All right. You don't know of any, but they obviously purchased all of this merchandise in order to make money, to make some quick money, isn't that correct, through the diversion process?

Mr. KOWITT. Well, I think they did it for two reasons: to make a profit, and also to lower their unit acquisition costs, because they did use some of this merchandise themselves.

Mr. BILIRAKIS. Yes. But not very much——

Mr. KOWITT. Well, percentagewise.

Mr. BILIRAKIS [continuing]. As has been established.

Mr. Weinstein, was he the owner of the pharmacies in question in the three hospitals?

Mr. KOWITT. This was Gerald Weinstein.

Mr. BILIRAKIS. Yes, Gerald Weinstein.

Mr. KOWITT. He was not involved in my trial.

Mr. BILIRAKIS. Yes.

Mr. KOWITT. He owned all three companies, that's correct.

Mr. BILIRAKIS. He owned them?

Mr. KOWITT. Correct. They were leased departments within these hospitals.

Mr. BILIRAKIS. OK. So he leased departments within the hospitals, so the hospitals did not stand to make any profit or any money at all as a result of all of this?

Mr. KOWITT. I don't know what his arrangement was with the hospital. I have no idea. I don't know whether he just simply paid a monthly rent or whether it was a percentage of his sales or—I have no idea.

Mr. BILIRAKIS. Have you worked for Eckerd Drugs?

Mr. KOWITT. No, I worked for Superex and Waylon's and several others, but—

Mr. BILIRAKIS. The competition.

Do you know if Eckerd's had any other involvement in purchasing substantial quantities of diverted or counterfeit drugs, other than Ovulen?

Mr. KOWITT. Well, as I said before, I had never run into a counterfeit product in the 12 years that I was in the business, so I can't comment any further about that. Eckerd was a major buyer, along with most other chains, of diverted pharmaceuticals from me and from other wholesalers.

Mr. BILIRAKIS. Should Eckerd have known, or did they know, in your opinion, that they were purchasing diverted drugs? Or purchasing counterfeit drugs?

Mr. KOWITT. Well, certainly they didn't know they were purchasing counterfeit drugs, and I don't know that they did, other than that I read they were involved in this Ovulen thing. But as far as diverted pharmaceuticals go—

Mr. BILIRAKIS. Excuse me, sir. In other words, you read that they were involved in that, and that is your only knowledge, as far as Eckerd is concerned?

Mr. KOWITT. I only know what I read in that paper, that some was found in their warehouse, and that's all I know about.

Mr. BILIRAKIS. Do you know whether any of it was found on their shelves, on the drugstore shelves?

Mr. KOWITT. I have no idea. I don't know.

Mr. SIKORSKI. Would the gentleman yield?

Mr. BILIRAKIS. Yes.

Mr. SIKORSKI. I thank the gentleman for yielding.

You said that you know—you certainly know that they didn't know that these were counterfeit drugs?

Mr. KOWITT. Oh, no. As far as the regular diverted merchandise goes, only because there has never been another example of it is what I was trying to say. You're implying that the diverted drugs they had been buying for years might also include counterfeit drugs, and I am saying that I doubt it, because nobody has ever heard of a counterfeit drug before this Ovulen episode.

Mr. SIKORSKI. You are aware that the Ovulen-21 instance only came through by happenstance, by accident? I mean we only know about it by accident.

Mr. KOWITT. Yes.

Mr. SIKORSKI. Even though other people had inklings of it, that never came to the proper authorities, so it is not beyond the realm of comprehension that the same thing is occurring elsewhere, and there is some very good indications that it did.

Mr. KOWITT. I can't rule out the possibility, that's true.

Mr. SIKORSKI. I thank you, and I thank the gentleman.

Mr. BILIRAKIS. Yes. I suppose it is probably a good idea to inquire of Eckerd's in that regard, but I would ask you, sir, as a pharmacist, apparently you were in it for an awfully long time, do you know whether Eckerd's maintains controls which assure that expired, adulterated, or otherwise impure drugs are returned to the manufacturers?

Mr. KOWITT. I would almost guarantee it, because in the State of Florida, where they operate most of their stores, they are regulated not only by the Food and Drug Administration that inspects their facilities, but also by the Department of Health and Rehabilitative Services, and I think even the Board of Pharmacy comes in and inspects their shelves on a very regular basis.

Mr. BILIRAKIS. Which shelves? The wholesale shelves or the warehouse shelves?

Mr. KOWITT. As a matter of fact, I believe Eckerd was one of the companies that would refuse a product from me, if I offered it to them with less than 1 year's dating. I mean they were very conscious of dating, and in the past, for example, I had offered them product that had the word "clinic package" on it. Perfectly legal to sell, but they refused, because they wanted product that was identical in every way to what the manufacturer was shipping to them directly.

Mr. BILIRAKIS. How serious is having an expired, clearly expired drug on the pharmacy shelf?

Mr. KOWITT. Well, if you find one bottle here or there, it is certainly possible, because virtually every drug today has an expiration date, and it is possible to overlook one. They have several thousand drugstores. Well, that's all I know.

Mr. BILIRAKIS. Mr. Kowitt, in the latter part of your testimony, you inferred that the owner of the merchandise knows that if he does not handle, store, and ship his goods properly, they may explode from the cold or discolor from the heat or get broken or crushed. The result is that he would lose a considerable amount of money since his merchandise would become unsalable.

So basically they have got to push this merchandise if they know that it is diverted and/or counterfeit.

Mr. KOWITT. Well, what I was trying to say, is that the realities of the marketplace are such that when you have a salable product at a good price, it doesn't sit on your shelves very long. Their inventories turn very frequently, and I don't think an outdated product was really a problem.

If anyone had shipped an outdated product to me, for example, they would have gotten it right back. I don't recall the last time I have received an outdated product, and I did personally check my merchandise.

Mr. BILIRAKIS. OK. Perhaps a lack of knowledge on my part is hampering me in formulating the questions quite as well as I would like.

If the corner drugstore, an independent drugstore that is owned and operated, you know, by the same person, is able to get bad drugs, knowingly bad drugs, counterfeit or otherwise, expired, et cetera, that person would clearly push those drugs first; right?

Well, first of all, to get it off his shelves, because it's—

Mr. KOWITT. Well, if it's original merchandise that he bought from the manufacturer, I don't know what each manufacturer's policies are. But when I was practicing pharmacy, I just used to return it or give it back to the salesman.

Mr. BILIRAKIS. Well, how about if the corner drugstore bought drugs from a hospital knowing darned well—I mean common sense dictates it's diverted.

Mr. KOWITT. As long as it's in the original package and it's not sitting in a bag or a Coca Cola bottle or something like that, you should be able to get credit from the local company salesman.

Now each company may vary as to the policy.

Mr. BILIRAKIS. OK. I will yield to the chairman.

Mr. WYDEN. I appreciate the gentleman yielding. I think he asked an important question. Along the same lines, I would be interested in knowing which companies were least likely to have their merchandise diverted and which companies were most likely to have these products available, and based on your experience down there, I gather you can give us a thoughtful list.

Mr. KOWITT. Yes. The companies that I found least likely to be available, and the ones that I had the hardest time getting, if ever, were Burroughs-Wellcome, Ely-Lilly, Smithkline-Beckman, Upjohn, Merck, Sharp & Dome. Those companies stand out in my mind as being virtually nonexistent, to me, at least, in the diversion market.

Mr. WYDEN. And those that were most often available?

Mr. KOWITT. The ones that were most often available over the longest period of time, from the most number of sources, included Allergan, Abbott, Bristol Labs, Cooper, Lederle, Squibb, Smith Miller Patch, which is now CooperVision, I believe, Syntex, Wallace, and Warren-Teed, now called Adria.

Mr. WYDEN. If the gentleman will just let me ask one other, why do some companies have little or no diversion problem, and others have a substantial one, in your view?

Mr. KOWITT. My own theory on that is it's the philosophy of the company. Some companies really don't want their products diverted and therefore keep very tight controls on their sales personnel and on the ordering entities. While others apparently find it convenient to use diverters as a means of selling large quantities of very competitive products, and leveling out their inventory and making very large profits.

Mr. WYDEN. I appreciate the gentleman from Florida yielding. I am going to ask that the record be left open at this point so that we can ask additional questions in writing, Mr. Kowitt, with respect to some of these other exhibits that are critical to our understanding of this particular situation. And I thank the gentleman from Florida for allowing me to ask those questions on his time.

[Testimony resumes on p. 214.]

[Response to questions referred to, exhibits, and related documents follow:]



## SUBCOMMITTEE QUESTIONS AND RESPONSES BY STANLEY KOWITT

*Question.* Are you familiar with Knoll Pharmaceutical Company and did they make unusually large sales of a product to any of these three hospitals?

*Answer.* Yes. Between October 1975 and November 1976, Knoll sold large quantities of many products including almost 2 million tablets of their asthma medication called Quadrinal to Miami Dade Hospital.

*Question.* Why would the company countenance such sales?

*Answer.* One reason was because they were making a nice profit. According to internal company memos, it cost Knoll \$1.00 to manufacture a bottle of 100, which was sold to the hospital for \$3.50. Likewise, a bottle of 1000 cost only \$7.51 but was sold for nearly \$30.00.

*Question.* Exhibit 7 is a May 1977 internal memorandum on the Quadrinal matter. According to the memo, the sales of Quadrinal were handled through a special account established by two of Knoll's salespersons. The memo estimates that as much as \$200,000 in Quadrinal business passed through the account in only two years. The memo concludes that:

"For the past 2 years we have all heard over and over again about the great sales accomplishments of Miss Rome and the Southeast division while all the time these accomplishments were at the expense of the KPC sales force. Rather than being angry I am depressed that KPC has let these people get away with this for so long."

This memo suggests that the management of Knoll didn't know or didn't care what their sales representatives were doing, would you agree?

*Answer.* Yes—probably didn't care because the incredibly large purchases of these and other products should have altered them to the fact that their products were being diverted.

*Question.* Wouldn't a high volume of diversion of a product by a salesman tend to destroy the purchases for that product in the area by local accounts?

*Answer.* Yes, but my experience is that the salesman made sure that the diverter sold the product outside the salesman's area. He stopped cooperating if his merchandise was resold in his territory.

*Question.* Cooper Laboratories had several divisions selling to Miami Dade. Did either of them make large sales during this time period?

*Answer.* Yes—for example, over 40,000 units of Vasocon and Vasocon-A were sold to this hospital in 10 months by Smith Miller Patch Division. Also Cooper Lab division sold 540,000 oz. of their bronchial dilator, Elixophyllin, and 367,840 oz. of their potassium supplement Kavciel in 6 months. These are truly staggering quantities.

*Question.* Did a Smith, Miller and Patch salesman raise questions about sales to Miami Dade Hospital with his superiors?

*Answer.* Yes. Mr. Fred Ellis, who was a sales rep for the company in the Miami area, sent letters to his district manager and others raising questions about the prices and volumes sold to Miami Dade Hospital and told them that it was probable that Miami Dade was diverting. However, the company ignored his letters and kept on selling.

*Question.* Exhibit 8 is a computer run of sales to Miami Dade Hospital by Smith Miller Patch. What were sales in dollars and units in 1974 and 1975?

*Answer.* In 1974, Miami Dade bought 12 units of eye drops for a total worth of \$59.00. In 1975 when they started diverting, the figures shot up to 45,457 units with a total value of \$41,011.

*Question.* Exhibit 9, a May 30, 1975 internal Cooper memo, states that:

"As a result of finding marked bottles of Vasocon Regular and Vasocon A, originally shipped to Miami Dade General Hospital, in drugstores in New York (Manhattan) and Connecticut (Hartford), I notified Mr. Harris of Miami Dade that we would ship no more merchandise for SMP, CLD, or ORAL-B to him."

Did Cooper in fact cut Miami Dade off?

*Answer.* No. I found invoices that indicated that they continued to sell extremely large quantities of merchandise for another 6 months.

*Question.* So, despite a huge increase in sales, a warning from their own salesmen and the fact that the products they sold to Miami Dade were turning up in drugstores, the company continued to sell to the hospital?

*Answer.* Yes.

*Question.* Carter Wallace's sales agreement states that purchases are for "inpatient use only and that no merchandise so purchased will be resold to retail stores, chain stores, wholesalers or other hospitals. How much product did they sell to this 77 bed hospital for their own use?

*Answer.* Far more than they could possibly have used. For example, 3000 bottles of their ear drops Vosol/Vosol H.C. with 2 months; 96,000 tablets of their tranquiliz-

er Miltown in 2 months or 5 times as much as every patient taking the manufacturer's suggested dosage could consume in that time period; and finally, 539,200 tablets of their muscle relaxant Soma/Soma Compound in 8 months, or 7 times what every patient taking the suggested dosage every day could consume.

*Question.* Mr. Kowitt, I take it that many other pharmaceutical manufacturers made highly questionable sales to one or more of the three hospitals?

*Answer.* Yes.

*Question.* I ask unanimous consent that these examples appear in the record. Could you simply state the names of the companies?

*Answer.* Yes. Lederle Laboratories, a division of American Cyanamid; Merrill-National, a division of Merrill-Dow; Ortho Pharmaceutical, a division of Johnson and Johnson; Marion Laboratories; Pfizer Laboratories; Syntex Labs; Warren Teed Pharmaceuticals, now called Adria Laboratories; Whitehall and Winthrop Laboratories, a division of Sterling Drug.

## REPLY MESSAGE

Exhibit 7

TO G. Bendele

F  
R  
O  
M

KNOLL PHARMACEUTICAL COMPANY

30 NORTH JEFFERSON ROAD  
MAY 1 - 1977

WHIPPANY, NEW JERSEY 07981

SUBJECT: Loss of Chain and Wholesale business to SH Division

DATE:

FOLD-

It has become obvious that several chain and wholesale accts.

have been buying Quadrinal at a discount price from a special  
account set up for the benefit of ALENE ROWE and BILL ARONSTEIN

in Miami. In my division alone Rite-aid, Revco, District Wholesale  
and who knows how many others have been buying bulk quantities of

Quadrinal 100's from this account for the past two years. The amount  
and indications are staggering. Using the sales figures provided to

PLEASE REPLY TO SIGNED

us on Miss Rowe's progress as much as 200,000 dollars in Quadrinal  
business has passed through this account during the past two years.

Figuring the 25% discount involved it has cost Knoll Pharmaceutical  
\$50,000 in Quadrinal sales this past two years. Knoll has not been

OLD-

the only one hurt, \$15,000 in ethical gain bonus money has not been  
properly distributed to deserving division bonus pool sales


standings have been altered, and at review time the sales figures

DATE

SIGNED

SEND WHITE AND PINK COPIES WITH CARBONS INTACT. PINK COPY IS RETURNED WITH REPLY.

## REPLY MESSAGE

G. Bendale	F	<b>KNOLL PHARMACEUTICAL COMPANY</b> 30 NORTH JEFFERSON ROAD  WHIPPANY, NEW JERSEY 07981
	R	
	O	
	M	

RE: Loss of sales to SE division cont'd DATE: \_\_\_\_\_

used often did not accurately reflect the hard work of our sales reps.

For the past two years we have all heard over and over again about

the great sales accomplishments of Miss Rowe and the SE division

while all the time these accomplishments were at the expense of the

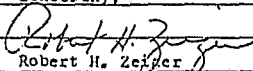
KPC sales force. Rather than being angry and I am depressed that KPC

has let these people get away with this for so long. The damage is

done, what does KPC intend to do about this.

SE REPLY TO \_\_\_\_\_ SIGNED \_\_\_\_\_

Sincerely,

  
Robert H. Zeiger

P.S. Feel free to circulate this letter as I would like my position

on this matter known.

SIGNED \_\_\_\_\_

SEND WHITE AND PINK COPIES WITH CARBONS INTACT. PINK COPY IS RETURNED WITH REPLY.



7% - APRIL 1975		TOTAL DOLLARS		8.500%	APRIL - JUNE 1975	
100000000000		1352	185			
100000000000	62	124	12			
100000000000	1%	216	12			
100000000000	3%	462	12			
100000000000	4%	457	12			
EXPENSE		1776	12			
MORTGAGE POMIC		320	12			
MORTGAGE TP	1%	304	12			
	2%	480	12			
	3%	768	12			
	4%	2972	12			
TRANSFER		2316	12			
WASCOON - 5ml		3970	12			
	15ml	5180	12			
WASCOON A		23104	12			
WASCOON		17572	12			
		205	12			
DENTAL BILLS	5005	21	12			
MERCH. TRNS	505	12	12			
LIQ F	1005	24	12			
LIQ T	1005	24	12			
STANDARDOL		3	12			
ATTORNEY CHG		223	12			
PROCURER CHG		258	12			
PROCURER HC CHG		432	12			
PROCURER 1/2 5ml		144	12			
	2% 5ml	288	12			
		35012	12			

NOTE: - over 49,000 units of WASCOON - T. Use 100000000000 - A. Sold to Miami Paper in 10 Mo

Memorandum

Exhibit 9

Cooper

Parsippany, New Jersey

To : A. A. Lcwenthal, R. J. ~~Lewis~~ Lewis, J. Dealy

From : E. J. Browning

Date : May 30, 1975

Subject: MIAMI-DADE GENERAL HOSPITAL

As a result of finding marked bottles of Vasocon Regular and Vasocon A, originally shipped to Miami-Dade General Hospital, in drug stores in New York (Manhattan) and Connecticut (Hartford), I notified Mr. Harris of Miami-Dade that we had shipped the merchandise from SMP, CLD, and ORAL-B to him.

The telephone conversation was long - Mr. Harris maintained his innocence time after time. He "blamed" his customers (mostly overseas); asked for our proof, stating that we could see his records of invoices, etc. My position was - "we have positive proof that merchandise we sold to you, initially, turned up in the retail trade in the U.S., and we are shutting off this source of illicit supply". I did not divulge "our proof" beyond the fact that we had "found irrefutable evidence that merchandise we had sold to him had appeared in the retail trade in various parts of the U.S." I stated that this was not just my decision, but a fully discussed, general decision by the heads of SMP, CLD and ORAL-B together with the advice of legal counsel, that this was our position.

I hope this is the end of this.

EJB:ac

*E. J. Browning*  
E. J. Browning

*Cooper continues to seek for 6 months*

NOTE: They continue to seek as usual long after this

MIAMI DADE PURCHASES

1975

ORAL-B

	<u>20s</u> <u>5.04 dz</u>	<u>30s</u> <u>1.95 dz</u>	<u>40s</u> <u>2.60 dz</u>	<u>60s</u> <u>2.60 dz</u>	<u>Amosan</u> <u>20s</u> <u>5.04 dz</u>	<u>Amosan</u> <u>40s</u> <u>8.68 dz</u>	<u>TOTAL</u>
JAN	--	--	288 dz	432 dz	200 dz	100 dz	\$ 3,748.00
FEB	--	432 dz	576 dz	288 dz	200 dz *	100 dz *	\$ 4,651.80
MAY	--	--	--	--	300 dz	100 dz	\$ 2,380.00
					* @ 4.20 dz	@ 7.23 dz	
TOTAL	--	\$ 842.40	\$2,246.40	\$1,872.00	\$3,360.00	\$2,459.00	\$10,779.80

Customer also purchased in 1975: 10 Quinaglute 250's @ \$40.76 - \$407.60  
 12 SusPhrine 12's @ \$7.65 - \$91.80

\$11,279.20

SKIPPED 27,792 TOOTH BRUSHES IN 3 MONTHS  
 320,400 DOSES OF AMOSAN IN 5 MONTHS

128



MIAMI BEBE PURCHASES

1975

	<u>ELIX PT.</u> 80	<u>ELIX QT</u> 2.00	<u>ELIX GAL</u> 4.90	<u>ELIX KI 80Z</u> 1.20	<u>KAY CIEL PT</u> 74	<u>KAY CIEL GAL</u> 4.90	<u>TOTAL</u>
JAN	--	828	--	--	--	--	\$ 1,656.00
FEB	2,448	834	325	288	3,000	150	\$ 8,519.50
MAR	2,508	750	350	360	3,072	144	\$ 8,632.28
APR	2,448	864	360	372	3,336	130	\$ 9,002.44
	<u>7404 pt</u>	<u>3276 qt</u>	<u>1035 gal</u>		<u>9402 pt</u>	<u>427 gal</u>	
TOTAL	\$ 5,923.20	\$ 6,552.00	\$ 5,071.50	\$ 1,224.00	\$ 6,961.92	\$ 2,077.60	\$22,810.22

355,776 oz of BUYNOR IN 4 MONTHS  
204,260 oz of KAYCIEL IN 4 MONTHS



**SOUTHEAST WHOLESALE DRUG CO.**

3080 S.W. 38TH COURT  
MIAMI, FLORIDA 33146  
305-445-0531

22785

INVOICE NO: 22785

SHIPPED TO:

SOLD TO:

INVOICE DATE: 11-03-75

MAJESTIC SALES  
2501 S.W. 56 AVE.  
W. HOLLYWOOD, FLA.  
ZIP # 33023

NAME

CONTENTS: MERCHANDISE

DEA #FS. 0087090

CUSTOMER ORDER NO. OR DATE				SHIPPED		SALESMAN NO:		
DISC.	%	QTY.	SIZE	DESCRIPTION		LEGEND	W/L	AMOUNT
		228	100	9-ACHROMYCIN V CAPS 500MG				1137.60
THIS IS A NET INVOICE. NO FURTHER DISCOUNT ALLOWED								
LEGEND				WARNING				TOTAL
1. DEA	2. Price Change	ANY PRODUCTS NAMED IN THIS INVOICE & LABELED "CAUTION FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION" IS SOLD FOR SUCH USE ONLY.				TOTAL		1,137.60
3. Nonstate	4. Exempt Nonstate					POSTAGE		
5. Refrigerals					INSURANCE			
6. Out of Stock - Please Reorder					TOTAL			
7. Partial Order Filled - Please Reorder Balance								
WE DO NOT STOCK ITEMS ORDERED BUT NOT SHOWN								
CUSTOMER CODE				0000001++ADD++				

*PAIN*  
11/3/75

ORIGINAL INVOICE



LEDERLE LABORATORIES DIVISION

AMERICAN CYANAMID COMPANY  
P O BOX 4272  
ATLANTA GA 30302  
(90224)

PLEASE RETURN TO  
P O BOX 100414  
ATLANTA GA 30344

INVOICE

Depressant and Stimulant Drug  
Federal Registration No. PL 0342994

ORDER NO. 3914  
ABREY HOSPITAL  
5190 S W 8TH ST  
CORAL GABLES FLA  
33134

INVOICE NO. 8972  
ABREY HOSPITAL  
5190 S W 8TH ST  
CORAL GABLES FLA  
33134

PAGE 1

ORDER NUMBER		DATE		TERMS		INVOICE NO.			
3914		6/27/74		2Y 15TH PROX.		8972			
DEPT.	SK	PT	DEPT.	SIS NO.	TC	RD	TEAR.		
800	222	200		11825	08	0	14144		
							A/R NO.		
							40531		
CODE NO.	LOC.	QTY.	UN.	PRICE	BYH.	DESCRIPTION	STYLE PKG.	P/C	AMOUNT
488034		36	1038	0		ACHRO V CAPS 250MG	1000		37368
						SPECIAL PRICE			
									37368**

NA 8413 REV. 2-71 2-71 C-STIMULANT OR DEPRESSANT DRUG  
The description is subject to LEADER'S standard terms and conditions of sale, as set forth on back hereof, notwithstanding any previous agreement to the contrary. CUSTOMER FILE



LEDERLE LABORATORIES DIVISION  
 AMERICAN CYANAMID COMPANY  
 P O BOX 4272  
 ATLANTA GA 30302  
 (304)551-1111

PLEASE  
 REFER TO  
 P O BOX 100864  
 ATLANTA GA 30334

INVOICE

PLEASE REFER ALL INQUIRIES TO THE CUSTOMER SERVICE REPRESENTATIVE AT THE ABOVE ADDRESS.

BNDD Registration No. PL 004299

TO (BUYER)  
 ARBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA  
 33134

SHIP TO  
 ARBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA  
 33134

PAGE 1

ORDER NUMBER		DATE		TERMS			INVOICE NO.	
2213		4/02/74		2T 15TH PROJ			751	
DEPT.	BH PT.	DEST	SIB NO	TC	XD	TEAR	A/R NO	
R00	222	200	11825	08	0	14144	40633	
CODE NO	LOC	QTY	UNIT PRICE	SYM	DESCRIPTION	STYLE PKG	P/C	AMOUNT
488034	1	36	1038	0	ACHRD V CAPS 250MG	1000		37368
					SPECIAL PRICE			
								37368*

MA 5413 REV. 9-72 3-73

C - STIMULANT OR DEPRESSANT DRUG

CUSTOMER FILE

The amount is subject to ALLEYS STAMPS TERMS AND CONDITIONS OF SALE. No net here or best brand. Manufactured by the product indicated in PETER



LEDERLE LABORATORIES DIVISION  
 AMERICAN CYANAMID COMPANY  
 P O BOX 4772  
 ATLANTA GA 30302

PLEASE  
 RETURN TO  
 P O BOX 100564  
 ATLANTA GA 30347

INVOICE

PLEASE REFER ALL INQUIRIES TO THE CUSTOMER  
 SERVICE REPRESENTATIVE AT THE ABOVE ADDRESS.

BNDD Registration No.

PL 0042994

BUYER  
 ABBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA  
 33134

SELLER  
 ABBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA  
 33134

PAGE 1

ORDER NUMBER		DATE		TERMS		INVOICE NO.		
3599		5/29/74		2 1/2 15TH PROX		11367		
DEPT.	SH. RT.	DEST	BIG NO	IC	RD	TERR	A/R NO.	
800	222	200	11825	08	0	14144	40633	
CODE NO.	LOC	QTY.	UNIT PRICE	SYM	DESCRIPTION	STYLE PKG	P/C	AMOUNT
488034	1	48	1038	0	ACHRO V CAPS 250MG	1000		49824
					BALANCE OF ORDER			49824**

NA 5413 REV. 8-73

C — STIMULANT OR DEPRESSANT DRUG

CUSTOMER FILE

The information is subject to LEDERLE'S STANDARD TERMS AND CONDITIONS OF SALE, or the form on file, based upon the company's most current information in effect.

LEDERLE LABORATORIES DIVISION  
 AMERICAN CYANAMID COMPANY  
 P O BOX 4272  
 ATLANTA GA 30302  
 (EXCELLEN)

PLEASE  
 MAIL TO  
 P O BOX 100444  
 ATLANTA GA 30334

INVOICE

PLEASE REFER ALL INQUIRIES TO THE CUSTOMER SERVICE REPRESENTATIVE AT THE ABOVE ADDRESS.

BNDD Registration No.

PL 004299

5-1386

ORDER 22

(BUYER)  
 ABBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA  
 33134

ABBEEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA  
 33134

LES TO  
 WITH  
 TITED

PAGE 1

ORDER NUMBER		DATE		TERMS		INVOICE NO.			
4122		8/16/74		2% 15TH PROX		5117			
DEPT.	SH. PT.	DEST	SIS NO	TC	XD	TERR.	A/R NO.		
800	222	200	11825	08	0	14144	40633		
CODE NO	LOC	QTY	NET UNIT PRICE	SYM	DESCRIPTION		STYLE PKG	P/C	AMOUNT
488034	I	48	1038	0	ACHRO V CAPS 250MG		1000		49824
					SPECIAL PRICE				49824*

NA 5413 REV 8-73 8-73

C—STIMULANT OR DEPRESSANT DRUG

CUSTOMER FILE

The information is subject to 21 CFR 312.63 (b) (2) AND CONDITIONS OF SALE, as set forth on each label. Specifications are preliminary unless noted by 89118



LEDERLE LABORATORIES DIVISION  
 AMERICAN CYANAMID COMPANY  
 P O BOX 4272  
 ATLANTA GA 30302  
 (SELLER)

BUYER  
 ORDER NO.  
 P O BOX 100864  
 ATLANTA GA 30334

INVOICE

PLEASE REFER ALL INQUIRIES TO THE CUSTOMER SERVICE REPRESENTATIVE AT THE ABOVE ADDRESS.

BNDD Registration No. PL 00429

(BUYER)  
 ABBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA.  
 33134

(BUYER)  
 ABBEY HOSPITAL  
 5190 S W 8TH ST  
 CORAL GABLES FLA.  
 33134

PAGE 1

ORDER NUMBER		DATE				TERMS			INVOICE NO.	
4235		9/06/74				25 15TH PROX			1734	
DEPT.	SH. PT.	DEST.	BIS NO	TC	XD	TERR	A/R NO.			
800	222	200	11825	08	0	14144	40833			
CODE NO	LOC.	QTY.	NET UNIT PRICE	SYM	DESCRIPTION		STYLE PKG	P/C	AMOUNT	
488034	1	48	1038	0	ACHRO V CAPS 250MG		1000		47824	
					BALANCE OF ORDER				49824*	

NA 5413 REV. 8-73 B-73

C - STIMULANT OR DEPRESSANT DRUG

CUSTOMER FILE

This document is subject to SELLER'S STANDARD TERMS AND CONDITIONS OF SALE, as set forth on back hereof. Authorization for purchase is subject to SELLER'S



2 Copies FS  
for E. J. ...

**CYANAMID**  
AMERICAN CYANAMID COMPANY

4235

ORDER TYPE:  TRANSCRIPT OF ORDER  AUTHORIZATION TO RETURN MERCHANDISE FOR CREDIT  TURNOVER ORDER

SHIP TO: Whitney Hospital

Carol Galloway

ART. ACCOUNT TC FERR. RD TERMS  \$100 ORDER  \$50 ORDER  DO NOT INCREASE

DATE: 9-3 NOW SHIPPED TAKEN BY TIME 10:00 NOW ORDERED R/M NUMBER CP

CODE NO.	NO. PKGS.	UNIT PRICE	CYANAMID PRODUCTS	STYLE PKG.	P/C	TOTAL
	48	\$1.38	Archival 250	1000		
			*Special Price			
			4880-34			
			36			

SALES

ALL TRANSACTIONS ARE SUBJECT TO APPROVAL BY CYANAMID

H. ICR DEPARTMENT MEMO

MerrellMERRILL-NATIONAL LABORATORIES  
Division of Richardson-Merrell Inc  
Cincinnati, Ohio 45215

DRL AUG 30 1974

Date August 28, 1974

To Mr. D. R. Lee

From H. L. Thomas

Subject INTERNATIONAL CHRISTIAN RELIEF  
Collingswood, N.J.

Copies to

HOCampbell  
CWCill  
WMMutchinson  
APSchellinger

Don, as we discussed on the telephone before you left on vacation, an unusual situation has developed involving the subject account. International Christian Relief is presumably a nonprofit, charitable organization whose expressed purpose is to provide relief services to needy Christians in foreign lands. Funding is obtained from the parent organization, The International Council of Christian Churches, Inc., which is supported by participating churches nationally.

Following is the brief, but involved, history of our dealings with this organization:

- Our first contact was in the form of two letters dated March 29, 1974 from ICR requesting bids on Bendectin and Hiprex. Also mentioned in these letters were the following non-Merrell products: Atarax Tabs, Vistaril Caps, NegGram Caps, Pyridium and Macrodantin.

Darius Associates Inc., Washington, D.C. was designated as ICR's purchasing consultant and all bid responses were to be addressed to Darius.

- APSchellinger handled these letters and responded with a quotation dated April 19 for 3,000/100's of Bendectin at \$8.03 per bottle. At this time, the account was not opened on our books.
- In a telephone conversation on May 7, Mr. William Blank (Darius Associates) and APSchellinger discussed additional bid prices for AVC and Hiprex.
- Subsequently, a note was sent to Patricia Pompo (#26171) by APSchellinger requesting her to follow-up with the account and process a new account application.
- The new account application was prepared by PPompo on May 17 and was received in Cincinnati on May 21 along with the opening order from the account (\$15,672 of AVC and Hiprex). A check was received with the order.

## INTERDEPARTMENT MEMO

**Merrell**

MERRELL-NATIONAL LABORATORIES  
 Division of Richardson-Merrell Inc.  
 Cincinnati, Ohio 45215

Date August 28, 1974  
 To Mr. D. R. Lee  
 From H. L. Thomas  
 Subject INTERNATIONAL CHRISTIAN RELIEF  
 Collingswood, N.J.

Pg. 2

Copies to

APSchellinger approved the application and forwarded to Customer Service. WMHutchinson called ICR's bank and the bank stated that ICR maintained an account in "low five figures and had no loans outstanding". Account was opened on this basis.

- . Also on May 21, APSchellinger sent a letter to Mr. William Blank (Darius) confirming their May 7 telephone conversation and quoting bid prices on AVC, Bendectin and Hiprex. A duplicate copy was sent for Mr. Blank to sign and return confirming acceptance of the bid prices.
- . The opening order (\$15,672) was picked up at our Philadelphia depot on May 23.
- . On June 28, a second order was picked up at our Philadelphia depot. The order was for \$16,362 of AVC and Hiprex (payment not in advance, but was received before the due date).
- . Also on June 28 a quotation for an unspecified number of Tenuate 250's at \$21.17 per bottle was sent to ICR by APSchellinger; apparently in response to a request from Pat Pompo. No shipments of this product have been made because ICR does not have a DEA registration number.
- . About July 23, ICR was contacted by WMHutchinson regarding a donation of DTP products which were nearing the outdate.
- . ICR stated they could use the DTP and on July 29 a sizeable shipment of these products was made from Cincinnati to a warehouse located in Kenilworth, Maryland (near Washington, D.C.).
- . On July 31, a third order was picked up at our Philadelphia depot. The order was for \$23,387.40 of AVC and Hiprex. Payment has not been received as yet, but is not payable until September 10.
- . In early August, JMAnderson (#24000), whose division coincidentally uses the Kenilworth, Maryland warehouse for storage of samples, happened to see the shipment of DTP. Noticing it was a Merrell product, he asked the warehouse manager who it belonged to and received an answer of Mr. A. Perlman. Perhaps also coincidentally,

*check  
 calls* →

## INTERDEPARTMENT MEMO

**Merrell**

AMERRELL-NATIONAL LABORATORIES  
 Division of Richardson-Merrell Inc.  
 Cincinnati, Ohio 45215

Date August 28, 1974  
 To Mr. D. R. Lee  
 From H. L. Thomas  
 Subject INTERNATIONAL CHRISTIAN RELIEF  
 Collingswood, N.J.

Pg. 3

Copies to

a Mr. Al Perlman is the owner of Sav Mor Drugs, a Washington, D.C. account we cancelled in 1971 for credit reasons.

JMAnderson's mention of this incident to WMHutchinson is actually what prompted the current investigation of the account.

- On August 8, APSchellinger wrote to JHJenkins (#26000) asking him to clarify the relationship between ICR and Darius since ICR had "a habit of phoning our department direct for a quotation and/or order".
- On August 13, WMH received a letter from Bill Blank thanking us for the DTP and stating that it had been distributed thru the Pan American Health Organization.
- JHJenkins responded to APSchellinger on August 16 stating that further sales to the account had been suspended pending the investigation being conducted into ICR's operation.

Our attempts to get a solid line on ICR's operations have been inconclusive to this point based on a number of indirect contacts which have been made. The Dun & Bradstreet reports on both ICR and Darius are sketchy and give little information as to operations or financial status. The report on Darius does indicate that their sole purpose is to serve as a commissioned buying agent for ICR, however, the Darius letterhead states "Advertising/Business Consultants/Public Relations".

Bill Hutchinson called Interchurch Medical Assistance, a charitable organization we have dealt with for years and asked them if they knew anything about ICR. Interchurch supplied a Wall Street Journal article dated April 1, 1971 wherein ICR was allegedly involved in some questionable dealings related to \$12 million worth of products which had been donated to them because of the ban on the sale of cyclamates in the U.S. Rev. J. T. Shaw, still the Executive Director of ICR, was mentioned in this article several times.

Additional telephone contacts have been made with other manufacturers and, almost universally, they view ICR with suspicion. However, none could cite any specific or substantiated instances of abuse by the organization.

## INTERDEPARTMENT MEMO

Morrell

MERRILL-NATIONAL LABORATORIES  
 Division of Richardson-Merrell Inc.  
 Cincinnati, Ohio 45215

Date August 28, 1974  
 To Mr. D. R. Lee  
 From H. L. Thomas  
 Subject INTERNATIONAL CHRISTIAN RELIEF  
 Collingswood, N.J.

Pg. 4

Copies to

We have been reluctant to press the issue directly with ICR or Darius until the \$23,387 is collected (due September 10) for their last order. It has been agreed internally (you, WMH and I) that we will not ship any further orders to ICR until we can obtain more specific information about their operations. In particular, what assurances do we have that these products are actually being sent outside the U.S. and, if so, are they being sold or donated. \$55,400 is a lot of AVC and Hiprex to an organization of this type in just over two months! It also seems odd ~~that they chose to pickup all of these orders when they could have had them delivered free of charge.~~ Unless we can be assured of the ultimate disposition of the products, my recommendation is that we terminate sales to this organization. However, I don't know if we have legally obligated ourselves to fulfill the contracts as quoted (attached is a summary of contracts versus actual shipments).

In retrospect, the internal handling and control of this entire situation was extremely loose. If JAnderson had not just happened to see the DTP donation shipment by accident, we probably would not yet be aware that this situation exists. While this may have been a unique situation, I think a review of at least the following points is in order.

- International Christian Relief is not a hospital or Federal government account. Is bid pricing authorized under P&P 18 in this case?
- Since this was our first contact with the organization, why were quotations submitted to an organization of this type without first checking their background, etc?
- How were prices offered determined? What approvals were necessary?
- Why were 27/10th prox. terms offered when the bid request from Darius specified "Please quote net prices. No terms required. Certified check will accompany order"? Cash discount given to date is \$795.
- All AVC 4 oz. has been billed at \$1.60 each when APSchellinger's letter quotes \$1.62. Difference represents \$269 on orders to date.

## INTERDEPARTMENT MEMO

**Merrell**

MERRILL-NATIONAL LABORATORIES  
 Division of Richardson-Merrell Inc.  
 Cincinnati, Ohio 45215

Date August 28, 1974  
 To Mr. D. R. Lee  
 from H. L. Thomas  
 Subject INTERNATIONAL CHRISTIAN RELIEF  
 Collingswood, N.J.

Pg. 5

Copies to

- \* ~~Account opening procedure in Customer Service was not followed thoroughly, particularly in view of the potential dollars involved and the type of organization. We really don't even know if the organization is authorized (state and/or Federal) to handle and/or export prescription drugs.~~
- Our financial exposure, currently \$23,387, with an account of virtually unknown financial status could probably have gone significantly higher before being detected.
- Sales credit has been given to the regular territory for sales to date. Is this correct?
- Are we legally obligated to fulfill our contracts with this account?

Assuming no further unexpected developments, investigation of this account will be temporarily suspended pending receipt of payment for the last order. If you want to discuss this situation in the meantime, please let me know. Bill Hutchinson has the complete file on our activities with the organization.

HLT:ghb

INTERNATIONAL CHRISTIAN RELIEF  
Collingswood, N.J.

I. Contract Quantities versus Ordered Quantities

<u>Contract Quantity</u>	<u>Size</u>	<u>Product</u>	<u>Bid Price</u>	<u>Hospital Net</u>	<u>% Discount</u>	<u>Quantity Ordered</u>	<u>Value @ Bid Price</u>	<u>Value @ Hosp. Net</u>
5,000	4 oz.	AVC Cream	\$1.62	\$ 2.89	43.9	13,440	\$21,504.00	\$38,841.60
5,000	16's	AVC Suppos.	2.05	3.44	40.4	11,328	23,222.40	38,968.32
3,000	100's	Bendectin	8.03	8.46	5.1	-	-	-
500	100's	Hiprex	6.65	8.06	17.5	-	-	-
500	500's	Hiprex	28.75	38.25	24.8	372	10,695.00	14,229.00
None Specified	250's	Tenuate Dospan	21.17	28.86	26.6	-	-	-
All of above contracts for one year							\$55,421.40	\$92,038.92

II. Donation of DTP Products - Shipped 7/31/74

<u>Quantity</u>	<u>Size</u>	<u>Product</u>	<u>Catalog Number</u>	<u>1,000 Price</u>	<u>Value @ 1,000 Price</u>
1,548	.5 ml.	D.T.P. A.P. U/Dose	280-05	\$2.05	\$3,173.40
2,209	.5 ml.	D.T.P. Plain U/Dose	290-05	1.28	2,827.52
1,914	7.5 ml.	D.T.P. Plain	290-84	2.05	<u>3,923.70</u>
All of the above have an outdate of November, 1974					\$9,924.62

1974		1975		1976		1977		1978	
MIAA		MIAA		MIAA		MIAA		MIAA	
DADE		DADE		DADE		DADE		DADE	
HOSP		HOSP		HOSP		HOSP		HOSP	
CORAL GABLES		CORAL GABLES		CORAL GABLES		CORAL GABLES		CORAL GABLES	
TOTAL		TOTAL		TOTAL		TOTAL		TOTAL	
A/C	510	510	510	510	510	510	510	510	510
VAGINAL	504	504	504	504	504	504	504	504	504
CLINICAL	108	108	108	108	108	108	108	108	108
Supp-105	402	402	402	402	402	402	402	402	402
A/C	396	432	432	432	432	432	432	432	432
VAGINAL	396	432	432	432	432	432	432	432	432
CLINICAL	108	108	108	108	108	108	108	108	108
Supp-105	402	402	402	402	402	402	402	402	402
TOTAL		TOTAL		TOTAL		TOTAL		TOTAL	
12,338		12,338		12,338		12,338		12,338	
12,338		12,338		12,338		12,338		12,338	
12,338		12,338		12,338		12,338		12,338	

Used for VAGINAL INFECTIONS

1 package & usually complete

Treatment - Charged C.G. for Men

M.D.





RARITAN-NEW JERSEY 08869

088708774 3422

ROUTING 6 MERC 81600001520

PAGE NO 1

0884971

NO DAY YEAR  
16 16 74

INVOICE & B/L NO

364771 LOCATION 01

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

13

SPL. NET. CUST. NO. 48822 LOFT 02 67

ORDER NO. (12THS)	BACK ORDER	PRODUCT CODE	CUSTOMER ORDER LESS THAN CASE QUANTITY COL. (12THS)	CHECK	DESCRIPTION	CASES CAL. SET. BY DOZ.	CASES FULFILLED BY DOZ.	NO. OF CASES REQUIRED	QTY.	TOTAL CASES (12THS)
PRODUCT CODES ARE NDC CODES - LABELER CODE IS 0162										
DELIVER LOOSE AT DESTINATION										
		139051	6 M. 3/4		CLINIC 180 21 C NOVUM	10	10	1		7.
		139057	1 OZ		CMG ORTHO NOVUM 500S					
		139051			CLINIC 200 20 C NOVUM	100	10	1		62.
		133151	7 M. 1/4		CLINIC 150 21 C NOVUM	10	10	1		7.
		3170E1			CLINIC GYNGL LARGE	6	3	2		26.
		266701	6 OZ		ORTHO APPL SCC CLINIC					
MANY DISCREPANCY MUST BE REPORTED WITHIN 90 DAYS TO QUALIFY FOR ADJUSTMENT										

CHECKED BY 1088888	TOTAL CASES	NOV 1974		NOV 20 1974		NOV 21 1974		TOTAL CASES 12 78 104	TOTAL PAGES 104	JOB CONTROL 005334
		185	02	185	02	185	02			

15/11/74



*Ortho Pharmaceutical Corporation*

RARITAN, NEW JERSEY 08869  
AREA CODE 201 - 524 - 2393 • CABLE ADDRESS - ORTHO -

MAIL CHECKS TO:  
P. O. BOX 10 NEWARK, N. J. 07101  
MAIL ORDERS AND CORRESPONDENCE TO:  
P. O. BOX 491, RARITAN, N. J. 08869

CUSTOMER PURCHASE ORDER NO  
10725774 200

SHIPMENT DATE  
NO. DAY, YR  
11/14/74

REFER TO INVOICE NO  
AND ORTHO CUSTOMER NO  
ON ALL CORRESPONDENCE

INVOICE & B/L NO.  
200023

SHIP TO  
MIAMI LADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 192ND STREET  
MIAMI, FL 33157

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 192ND STREET  
MIAMI, FL 33157

TERMS 2/10 NET 31 SP. INSL. CR DSK. TERM 02 2027 SWITCH NO. 40522 61

HDC CODE	DESCRIPTION	QUANTITY DOZEN	NET PRICE	EXTENSION
PRODUCT CODES ARE HDC CODES-LABELER CODE IS 062				
SCHEDULE T				
133151	CLINIC 150 21 0 NOVUM	110	6.46	712.80
135151	CL ORTHO NOVUM 2MG 215	310	7.32	2,269.20
134051	CLINIC 180 21 0 NOVUM	110	6.48	712.80
542077	ACE JEL W APP	1	28.15	28.15
543077	MONISTAT CREAM W/A	18	55.04	991.44
544077	SULTRIN CREAM W APP	6	33.50	201.36
545077	DIENESTROL CRM W APP	6	30.17	181.14
547077	SUROSTACIN CREAM W AP	3	33.15	99.45
				5,196.34+

WE ARE HERE TO HELP. CALL 201-524-2399 FOR PERSONALIZED SERVICE.

ANY DISCREPANCY ON THIS INVOICE MUST BE REPORTED IN 90 DAYS TO QUALIFY FOR ADJUSTMENT

TOTAL AMOUNT DUE \$5,196.34+

\$103.93 CASH DISCOUNT MAY BE DEDUCTED IF PAID BY 12/12/74 QU

NO STATEMENT WILL BE RENDERED • KINDLY REMIT FROM THIS INVOICE • NO ANTICIPATION





FILE COPY  
*Ortho Pharmaceutical Corporation*

INVOICE

RARITAN, NEW JERSEY 08869  
AREA CODE 201 - 524 - 2393 • CABLE ADDRESS - ORTHO -

• MAIL CHECKS TO:  
P. O. BOX 10 NEWARK, N. J. 07101  
• MAIL ORDERS AND CORRESPONDENCE TO:  
P. O. BOX 401, RARITAN, N. J. 08869

CUSTOMER PURCHASE ORDER NO.  
11/24/74 248

SHIPMENT DATE  
MO. DAY YR  
12 03 74

REFER TO INVOICE NO.  
AND ORTHO CUSTOMER NO.  
ON ALL CORRESPONDENCE

INVOICE & B/L NO.  
370229

SHIP TO  
MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 192ND STREET  
MIAMI, FL 33157

SHIP TO  
MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 192ND STREET  
MIAMI, FL 33157

TERMS  
2x 30 NET 31

SP. INSL. C/I DIV. YEAR  
02 2027

SWITCH NO. ORTHO CUST. NO.  
40522 6N

NDC CODE	DESCRIPTION	QUANTITY		NET PRICE	EXTENSION
		DOZEN	12THS		
PRODUCT CODES ARE NDC CODES-LABELER CODE IS 062					
131151	U NOVUM 1/50 21 CLINIC	170		6.40	1,101.60
131151	CL ORTHO NOVUM 2MG 21S	150		7.32	1,096.00
139051	ORTH NOVUM 1/80 21 CL	170		6.48	1,101.60
					3,301.20
WE ARE HERE TO HELP. CALL 201-524-2399 FOR PERSONALIZED SERVICE.					

ANY DISCREPANCY ON THIS INVOICE MUST BE REPORTED IN 90 DAYS TO QUALIFY FOR ADJUSTMENT

TOTAL AMOUNT DUE 3,301.20

26.02 CASH DISCOUNT MAY BE DEDUCTED IF PAID BY 01/02/75

NO MERCHANDISE CAN BE RETURNED FOR CREDIT UNLESS IT IS IN ORIGINAL PACKAGING AND UNOPENED. ALL RETURNS MUST BE RECEIVED WITHIN 90 DAYS OF THE DATE OF INVOICE. ALL RETURNS MUST BE ACCOMPANIED BY A RETURN ORDER FROM THE CUSTOMER. ALL RETURNS MUST BE ACCOMPANIED BY A RETURN ORDER FROM THE CUSTOMER. ALL RETURNS MUST BE ACCOMPANIED BY A RETURN ORDER FROM THE CUSTOMER. ALL RETURNS MUST BE ACCOMPANIED BY A RETURN ORDER FROM THE CUSTOMER.

PARITAN-NEW JERSEY 68829

6 MERCURY

PAGE NO

CUSTOMER NO. 228448  
 70229

NO. 12 DAY 02 YEAR 74

INVOICE & B/I NO  
 370229

LOCATION 01

MIAMI DADE GENERAL HOSP  
 ATTN HOSPITAL PHARMACY  
 9333 SH 152ND STREET  
 MIAMI, FL 33157

49

BILL TO

MIAMI DADE GENERAL HOSP  
 ATTN HOSPITAL PHARMACY  
 9333 SH 152ND STREET  
 MIAMI, FL 33157

PL INVT

CUST. NO.

NET

ITEM	BACK ORDER	PRODUCT CODE	CUSTOMER ORDER		CHECK	DESCRIPTION	CUST. ORDER CASE QTY. REQ'D	CUST. ORDER QTY. SHIPPED	NO. OF CASES SHIPPED	UNIT PRICE	TOTAL
			LESS THAN CASE QUANTITY	QTY.							
PRODUCT CODE S. AND INC CODES - LABELER CODE IS 022 DELIVER LOOSE AT DESTINATION											
		19051		673	8	ORTHO NOVUM 1/80 21 CL	170	10	17		127.
		135151		728	16	CI ORTHO NOVUM 2MG 215	150	10	15		112.
		133151		724	17	O NOVUM 1/50 21 CLINIC	170	10	17		127.
ANY DISCREPANCY MUST BE REPORTED WITHIN 90 DAYS TO QUALIFY FOR ADJUSTMENT ***											
(Large section of the table is mostly blank with some faint markings and a large handwritten 'S' or similar mark in the lower right quadrant.)											
ORDER - PACKER		TOTAL CASES									
LOT CONTROL		NO. OF CASES	189	02	NO. OF CASES	189	02	NO. OF CASES	189	02	NO. OF CASES
TOTAL REPACKS SHIPPED		38									



THIRD COPY  
*Ortho Pharmaceutical Corporation*

INVOICE

RARITAN, NEW JERSEY 08869  
AREA CODE 201 - 524 - 2395 • (ABLE ADDRESS - ORTHO)

- MAIL CHECKS TO:  
P. O. BOX 10 NEWARK, N. J. 07101
- MAIL ORDERS AND CORRESPONDENCE TO:  
P. O. BOX 401, RARITAN, N. J. 08869

CUSTOMER PURCHASE ORDER NO.  
01/10/75 315

441915

REFER TO INVOICE NO.  
441915 CUSTOMER NO.  
ON ALL CORRESPONDENCE.

INVOICE & B/L NO.  
373090 1

BILL TO  
MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

SHIP TO  
MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

TERMS: 21 30 NET 31

SP 441 52 2027

SWITCH NO. ORTHO CUST. NO. 46922 6A

NDC CODE	DESCRIPTION	QUANTITY DOZEN	UNITS	NET PRICE	EXTENSION
PRODUCT CODES ARE NDC CODES-LABELER CODE IS 002					
SCHEDULE T					
133151	CLINIC U NOVUM 1/50 21	300		6.48	1,944.00
139051	CL ORTHO NOVUM 1/60 21	400		6.48	2,592.00
153051	CL ORTHO NOVUM 50 21	100		7.32	732.00
					5,268.00
WE ARE HERE TO HELP. CALL 201-524-2395 FOR PERSONALIZED SERVICE.					

ANY DISCREPANCY ON THIS INVOICE MUST BE REPORTED IN 90 DAYS TO QUALIFY FOR ADJUSTMENT

TOTAL AMOUNT DUE \$5,268.00

\$105.36 CASH DISCOUNT MAY BE DEDUCTED IF PAID BY 02/10/75

NO OTHER PHARMACEUTICALS ARE COVERED BY THIS PLAN. THE PLAN IS NOT A CONTRACT AND IS SUBJECT TO CHANGE WITHOUT NOTICE. THE PLAN IS NOT A CONTRACT AND IS SUBJECT TO CHANGE WITHOUT NOTICE. THE PLAN IS NOT A CONTRACT AND IS SUBJECT TO CHANGE WITHOUT NOTICE.

NO CLAIMS WILL BE DENIED • VARIOUS AGENTS OFFER THIS INSURANCE • NO AMBIPARTION

Pharmaceutical Corporation

CR 200 18

RARIFAN-NEW JERSEY 08069

ROUTING 6 MERC

PAGE NO 1

3731140

NO. DAY YEAR  
21 13 75

INVOICE & B/L NO.

3731140

LOCATION 01

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

80

BILL TO

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

SPL. INST. CUST. NO. 48522 COPT 02

ITEM NO. (1215)	BACK ORDER	PRODUCT CODE	CUSTOMER QUOTE LESS THAN CASE QUANT. (11)	DOZ.	CHECK	DESCRIPTION	CUST. ORDER CASE QTY IN DOZ.	CASE SIZE REQUESTED IN DOZ.	NO. OF CASES REQUESTED	CHECK	TOTAL CASES
						LEBELIN CLGE IS 062					
		138251		28		S.L. LEFTH NOVUM SW 20	100	10	16		63
		138251		40		S.L. CRITH NOVUM 17/50 21	400	10	40		300
		138251		30		CLINIC L NOVUM 17/50 21	300	10	30		225

ANY DISCREPANCY MUST BE RETURNED WITHIN 90 DAYS TO QUALIFY FOR ADJUSTMENT\*\*

CHECKER - PACKER	TOTAL CASES						TIME CHECKER
	NO. OF CASES	ISS.	QTY.	NO. OF CASES	ISS.	QTY.	
LOT CONTROL							
TOTAL REPACKS SHIPPED							

BK-13-75  
 TOTAL CASES SHIPPED  
 801156/1





FILE COPY  
*Orlho Pharmaceutical Corporation*

INVOICE

RARITAN, NEW JERSEY 08869  
AREA CODE 201 - 524 - 2393 • CABLE ADDRESS - ORLHO -

\* MAIL CHECKS TO:  
P. O. BOX 10 NEWARK, N.J. 07101  
\* MAIL ORDERS AND CORRESPONDENCE TO:  
P. O. BOX 401, RARITAN, N. J. 08869

CUSTOMER PURCHASE ORDER NO.  
02/11/75 255

SHIPMENT DATE  
MO. DAY, YR  
02 13 75

REFER TO INVOICE NO.  
AND ORLHO CUSTOMER NO.  
ON ALL CORRESPONDENCE

INVOICE & B/L NO.  
377183

1

SHIP TO  
MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
5333 SW 152ND STREET  
MIAMI, FL 33157

SHIP TO  
MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
4333 SW 152ND STREET  
MIAMI, FL 33157

TERMS: 2/10 NET 31

SP. INST. 02 DIV. IER 2027

SWITCH NO. 48522

611

NDC CODE	DESCRIPTION	QUANTITY		NET PRICE	EXTENSION
		DOZEN	21'S		
PRODUCT CODES ARE NDC CODES-LABELLER CODE IS 062					
SCHEDULE 1					
133151	CLINIC O NOVUM 1/90 21	200		6.48	1,296.00
133151	CL ORTHO NOVUM 2MG 21'S	100		7.32	732.00
133051	CL ORTHO NOVUM 1/90 21	200		6.48	1,296.00
					3,324.00

WE ARE HERE TO HELP. CALL 201-524-2393 FOR PERSONALIZED SERVICE.

ANY DISCREPANCY ON THIS INVOICE MUST BE REPORTED IN 90 DAYS TO QUALIFY FOR ADJUSTMENT

TOTAL AMOUNT DUE \$3,324.00

100.00 CASH DISCOUNT MAY BE DEDUCTED IF PAID BY 03/19/75

NO MERCHANDISE CAN BE ACCEPTED FOR CREDIT UNLESS THE RETURN HAS AN INDIVIDUAL AUTHENTICITY LABEL AND IS RETURNED WITHIN 90 DAYS OF THE DATE OF THE ORIGINAL INVOICE. ALL RETURNS MUST BE ACCOMPANIED BY A RETURN ORDER FROM THE ORIGINAL PURCHASER. ALL RETURNS MUST BE RETURNED TO THE ORIGINAL PURCHASER. ALL RETURNS MUST BE RETURNED TO THE ORIGINAL PURCHASER. ALL RETURNS MUST BE RETURNED TO THE ORIGINAL PURCHASER.

NO STATEMENT WILL BE RENDERED • KINDLY REMIT FROM THIS INVOICE • NO ANTICIPATION

*Ortho Pharmaceutical Corporation*

OR 200 Y8

RARITAN NEW JERSEY 08869

ROUTING 6 MERCURY

PAGE NO

1

VO22112 10/24 255

NOV 1983

MO. DAY YEAR  
02 12 75

INVOICE & B/L NO.

377183

LOCATION 01

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

50

BILL TO

MIAMI DADE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

SPL INSE

CUST. NO.

48522

COPI

02

64

REF NO	BACK ORDER	PRODUCT CODE	CUSTOMER ORDER QTY	LESS THAN CASE QTY	CHECK	DESCRIPTION	CUST ORDER CASE QTY IN DOZ	CASE QTY FIGS. 40 IN DOZ	NO OF CASES RECEIVED	CHECK	TOTAL IN CASES
						PRODUCT CODES ARE NIC CODES - LABELER CODE IS 062					
						CELLULR LOOSE AT DESTINATION					
		135091				CL CRTHG NOVUM 1/80 21	200	10	20		150.
		135151				CL CRTHG NOVUM 2MG 21S	100	10	10		75.
		135151				CLINIC O NOVUM 1/50 21	200	10	20		150.
						DISCREPANCY MUST BE REPORTED WITHIN 90 DAYS TO QUALIFY FOR ADJUSTMENT					

UNFILED

STATFEB 13 PM 8

RECEIVED  
FEB 13 1975

CHECKER - PACKER	TOTAL CASES				TOTAL CHECKER			
NO. OF CASES	1RS	QZ	1RS	QZ	NO. OF CASES	1RS	QZ	NO. OF CASES
LOT CONTROL	20	375	14	11	20	375	14	11
TOTAL REPACKS SHIPPED			374					

TIME CHECKER  
LOT CONTROL  
TOTAL PAGES SHIPPED



*Ortho Pharmaceutical Corporation*

INVOICE

RARITAN, NEW JERSEY 08869  
 AREA CODE 201 - 524 - 2393 • CABLE ADDRESS - ORTHO -

• MAIL CHECKS TO:  
 P. O. BOX 10 NEWARK, N. J. 07101  
 • MAIL ORDERS AND CORRESPONDENCE TO:  
 P. O. BOX 401, RARITAN, N. J. 08869

CUSTOMER PURCHASE ORDER NO  
 03/28/75 4216  
 BILL TO

SHIPMENT DATE  
 MO DAY YR  
 04 01 75

REFER TO INVOICE NO  
 AND ORTHO CUSTOMER NO  
 ON ALL CORRESPONDENCE

INVOICE & B/L NO.  
 J61041 1

MIAMI DADE GENERAL HOSP  
 ATTN HOSPITAL PHARMACY  
 5233 SW 152ND STREET  
 MIAMI, FL 33157

MIAMI DADE GENERAL HOSP  
 ATTN HOSPITAL PHARMACY  
 9333 SW 152ND STREET  
 MIAMI, FL 33157

TERMS 2 & 30 NET 31 SP. INST. C/I DIV. TERR. SWITCH NO. ORTHO CUST. NO.  
 02 2027 48524

NDC CODE	DESCRIPTION	QUANTITY DOZEN	12HS	NET PRICE	EXTENSION
PRODUCT CODES ARE NDC CODES-LABELER CODE 15 002					
SCHEDULE I					
123151	CLINIC D NOVUM 1750 21	210		6.48	1,360.
135151	CL ORTHO NOVUM 2PG 215	110		7.32	805.
139051	CL ORTHO NOVUM 1780 21	200		6.48	1,296.
313078	CLINIC DELFEN FOAM KIT	3		13.51	40. 3,502
WE ARE HERE TO HELP. CALL 201-524-2393 FOR PERSONALIZED SERVICE.					

ANY DISCREPANCY ON THIS INVOICE MUST BE REPORTED IN 90 DAYS TO QUALIFY FOR ADJUSTM

TOTAL AMOUNT DUE 537.50

370.00 CASH DISCOUNT MAY BE DEDUCTED IF PAID BY 05/01/75

NON-MERCHANDISE CANNOT BE ACCEPTED FOR CREDIT UNLESS THE PURCHASER HAS RECEIVED A QUANTITY DISCOUNT FROM THE MANUFACTURER. THIS POLICY IS SUBJECT TO CHANGE WITHOUT NOTICE. THE MANUFACTURER'S POLICY IS THE FINAL AUTHORITY. THE MANUFACTURER'S POLICY IS THE FINAL AUTHORITY. THE MANUFACTURER'S POLICY IS THE FINAL AUTHORITY.

Pharmaceutical Corporation

OR 200 18

RARITAN-NEW JERSEY 08869

CUSTOMER P.O. NUMBER

03/26/75 4216

INVOICE NO.

381041

NO. DAY YEAR  
03 31 75

FORMING

0 0 JSP

INVOICE & B/L NO.

381041

LOCATION 01

PAGE NO.

1

MIAMI LACE GENERAL HOSP  
ATTN: HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

BILL TO

MIAMI LACE GENERAL HOSP  
ATTN: HOSPITAL PHARMACY  
9333 SW 152ND STREET  
MIAMI, FL 33157

PL. NO.

CUST. NO.  
48522

COPY

02 EN

LT	BACK ORDER	PRODUCT CODE	CUSTOMER ORDER LESS THAN CASE QUANTITY DOZ	QTY	CHECK	DESCRIPTION	CUST. ORDER CASE QTY IN DOZ	CASE SIZE IN DOZ	NO. OF CASES REQUIRED	CHECK	TOTAL STOCK CASE WEIGHT	ISS	DE
						PRODUCT CODES ARE NOT SHIPPED - LABELER GLD. IS 002							
						DELIVER LOOSE AT DESTINATION							
		135651		30		CL CRTHC NOVUM 1/80 ZL	200	10	20				
		135153		11		CL CRTHC NOVUM 2MG 21S	110	10	11				
		133151		21		CLINIC O NOVUM 1/50 ZL	210	10	21				
		213C76		1		CLINIC DELFER PEAR KIT	3	3	1				
<p>ANY DISCREPANCY MUST BE REPORTED WITHIN 90 DAYS TO QUALIFY FOR ADJUSTMENT***</p>													

SHIPPED

CHECKS - PACKS	TOTAL SALES				TOTAL PRICE INVOICE
	NO. OF CASES	ISS	DE	NO. OF CASES	
TOT CORRECT				52	360
TOTAL REPLACES SHIPPED				53	400
				92	

ONE CHECK  
011.11  
5361.8



*Schering-Plough Pharmaceutical Corporation*

144V01C

RARITAN, NEW JERSEY 08869.  
 AREA CODE 201-524-2393 • CABLE ADDRESS - ORITHO •

• MAIL CHECKS TO:  
 P. O. BOX 10 NEWARK, N. J. 07101  
 • MAIL ORDERS AND CORRESPONDENCE TO:  
 P. O. BOX 401, RARITAN, N. J. 08869

CUSTOMER PURCHASE ORDER NO  
 04/28/75 4282

SHIPMENT DATE  
 NO. DAY YR.  
 64/24/75

REFER TO INVOICE NO  
 AND ORITHO CUSTOMER NO  
 ON ALL CORRESPONDENCE

INVOICE & B/L NO.  
 384000 1

BILL TO  
 MIAMI DADE GENERAL HOSP  
 ATTN HOSPITAL PHARMACY  
 9333 SW 182ND STREET  
 MIAMI, FL 33157

SRP ID  
 MIAMI FACE GENERAL HOSP  
 ATTN HOSPITAL PHARMACY  
 9333 SW 182ND STREET  
 MIAMI, FL 33157

TERMS 2% 30 NET 31

SP. INSI. C/L U2 DIV. YERS 2027

SWITCH NO. ORITHO CUST. NO. 48522 04

NDC CODE	DESCRIPTION	QUANTITY		NET PRICE	EXTENSION
		DOZEN	UNITS		
PRODUCT CODES ARE NDC CODES-LABELER CODE IS 062					
SCHEDULE T					
133151	CLINIC O NOVUM 1/50 21	210		6.40	1,360.80
135151	CL ORTHO NOVUM 2MG 21S	100		7.32	732.00
139051	CL ORTHO NOVUM 1/00 21	210		6.40	1,360.80
					3,453.60*
WE ARE HERE TO HELP. CALL 201-524-2393 FOR PERSONALIZED SERVICE.					

ANY DISCREPANCY ON THIS INVOICE MUST BE REPORTED IN 90 DAYS TO QUALIFY FOR ADJUSTMENT

TOTAL AMOUNT DUE 33,453.60\*\*

3.69% CASH DISCOUNT MAY BE DEDUCTED IF PAID BY 05/29/75 00

NO MECHANICALLY ACCEPTED CHECKS OR UNUSUAL DISCOUNTS AUTHORITY AT ALL TIMES IS RESERVED BY THE COMPANY

NO STATEMENT WILL BE RENDERED

KINDLY REMIT FROM THIS INVOICE

NO ANTICIPATION

RANTAN-NEW JERSEY 08849

ROUTING 6 JSP 428XXX428

PAGE NO 1

108828744 4254

MO. DAY YEAR  
09 29 73

INVOICE & B/L NO.

384008

LOCATION 01

384008

MIAMI DACE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 15TH STREET  
MIAMI, FL 33157

MIAMI DACE GENERAL HOSP  
ATTN HOSPITAL PHARMACY  
9333 SW 15TH STREET  
MIAMI, FL 33157

BILL TO

57

LINE

CUST NO.

COPI

38526

112

LINE	BACK ORDER	PRODUCT CODE	CUSTOMER ORDER LESS THAN CASE QUANTITY QTY	QUANTITY	CHECK	DESCRIPTION	CASE QTY IN CASE	CASE SIZE REQ'D IN CASE	NO OF CASES REQUIRED	CHECK	TOTAL QTY CASES
1		154031	1	1		ORTHO NOVUM 1/50 21	210	10	21		157.0
2		154031	1	1		ORTHO NOVUM 2MG 21S	100	10	10		75.0
3		154031	1	1		CLINIC 4 NOVUM 1/50 21	210	10	21		157.0
<p>IF DELIVERED BY AIR MAIL TO BE DELIVERED WITHIN 90 DAYS TO QUALIFY FOR ADJUSTMENT</p>											

CHECKED - PACKER	
LOT CONTROL	
TOTAL PACKETS SHIPPED	

TOTAL CASES		TOTAL QTY		TOTAL CASES		TOTAL QTY	
NO OF CASES	QTY	NO OF CASES	QTY	NO OF CASES	QTY	NO OF CASES	QTY
19		19					
409		409					

88  
BK-116 SW  
TOTAL PACKETS SHIPPED  
52008

INQUIRE

	\$/14	\$/16	\$/17			
1000 CAPS PAURSID	100	500	297			
100's NITROSID 2.5%	2500					
100's DUMATE 75	<del>1000</del>	1000				
<u>TOTALS</u>						
PAURSID =	897,000	CAPS	IN 1 MONTH	at 2 per day = 5 year caps		
NITROSID	250,000	CAPS				
DUMATE	100,000	CAPS				



**MARION LABORATORIES, INC.**  
**PHARMACEUTICAL DIVISION**

10236 BUNKER RIDGE ROAD KANSAS CITY, MISSOURI 64137  
 PLEASE REMIT TO: P.O. BOX 972 KANSAS CITY, MISSOURI 64141

DUNS # 00-711-9355  
 NEW REG # 19-13298

*8/9.7 98*



**MARION LABORATORIES, INC.**  
 P.O. BOX 972  
 KANSAS CITY  
 MISSOURI 64141

To  
 MIAMI-DADE GENERAL  
 HOSPITAL  
 ATTN: ACCOUNTS PAYABLE  
 9333 S.W. 152ND STREET  
 MIAMI FLA 33157

TERMS- 1% 20 NET 30

YOUR ORDER NO.	CUSTOMER NO.	DATE	PO#	INVOICE NO.	PAGE	1	S.O. NO.	X9468
8955	56930	5/09/74	4301	396345	1			

CUSTOMER NO.	INVOICE NO.
56930	396345

QUANTITY	UNIT	DESCRIPTION	NET PRICE	EXTENSION
100	1000	PAVABID CAPS S3053		6200.00
		IN PATIENT USE ONLY BID 74-316		6200.00

PAY THE LAST AMOUNT IN THIS COLUMN IF PAID BY	IF PAID AFTER THE DATE IN COLUMN 1, THIS AMOUNT IS DUE BY
5/29/74	6/08/74
6138.00	6200.00

INVOICE





**MARION LABORATORIES INC  
PHARMACEUTICAL DIVISION**

DUNS # 02-711-9555  
NEW REG # 19-13296

10236 BUNKER RIDGE ROAD KANSAS CITY, MISSOURI 64137  
PLEASE REMIT TO: P.O. BOX 972 KANSAS CITY, MISSOURI 64141



**MARION LABORATORIES INC**  
P.O. BOX 972  
KANSAS CITY  
MISSOURI 64141

To  
MIAMI-DADE GENERAL  
HOSPITAL  
ATTN ACCOUNTS PAYABLE  
9333 S W 152ND STREET  
MIAMI FLA 33157

TERMS- 1% 20 NET 30

YOUR CHECK NO.	CUSTOMER NO.	DATE	POOR	INVOICE NO.	PAGE
8978	56930	5/10/74	4301	396999	1
S.O. NO. L1163					

PAY THE LAST AMOUNT IN THIS COLUMN IF PAID BY	IF PAID AFTER THE DATE IN COLUMN 1, THIS AMOUNT IS DUE BY
5/30/74	6/09/74

QUANTITY	UNIT	DESCRIPTION	NET PRICE	EXTENSION
2500	100	NITRO-BID 2-5 CAPS IN PATIENT USE ONLY BID 74-316	53101	10625.00 10625.00

10518.75	10625.00
----------	----------

93293  
**PHARMACEUTICAL DIVISION**  
**W. MARION**  
**LABORATORIES, INC.**  
 10236 BUNKER RIDGE ROAD - 761-2500  
 KANSAS CITY, MISSOURI 64137  
 BNDD No. PM 0037071  
 HEW Reg. No. 19-13298

CHARLES L. RICE CO., 213 EAST 117TH STREET, KANSAS CITY, MISSOURI 64114

**SHIPPING ORDER** | DATE 5-7-77 | CUSTOMER ACCT. NO. 56930 | POOL NO. | CLASS ORDER NUMBER L 1163

BILL TO: *Miami* | ADDRESS: *9333 SW 152nd St* | CITY: *Miami* | STATE: *Fla* | ZIP: *33157*

SHIP TO: | ADDRESS: | CITY: | STATE: | ZIP:

CODE	SHIP VIA	PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #	PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #	PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #
			100	PAYABID	155547				15CM	FLU .01 CR			101115						
			250	PAYABID	155551				80CM	FLU .01 CR			101150						
			300	PAYABID UDIP	155554				15CM	FLU .01 CR			101175						
			1000	PAYABID	155558				15CM	FLU .025 CR			101215						
			5000	PAYABID	155570				80CM	FLU .025 CR			101260						
			100	CAPRE	162047				15CM	FLU .025 CR			101275						
			1000	CAPRE	162058				15CM	FLU .025 OINT			101315						
			1200	OS CAL OTC	164592				10CM	FLU .025 OINT			101330						
			100	OS CAL	165047				20CC	FLU .01 SOL.			101400						
			500	OS CAL	165055				60CC	FLU .01 SOL.			101460						
			1000	OS CAL	165058				4 OZ	METASEP			102615						
			150	OS CALFORTE	165347														
			500	OS CALFORTE	165355														
			1000	OS CALFORTE	165358														
			100	OS CALGESIC	165647														
			500	OS CALGESIC	165655														
			1000	OS CALGESIC	165658														
			100	OS CALMONE	166047														
			500	OS CALMONE	166055														
			1000	OS CALMONE	166058														
			100	OS FEO CAL	166547														
			1000	OS FEO CAL	166558														
			100	OS FEO VIM	166847														
			100	OS VIM	167247														
			500	OS VIM	167255														
			1000	OS VIM	167258														
			100	SAL PHENESIN	167547														
			500	SAL PHENESIN	167555														
			1000	SAL PHENESIN	167558														

RETURNED - DO NOT SHIP

CR

CR

CR

CR

CR

CR

CR

CR

CR

CR

EXPLANATION - 20 POSITIONS

DLVD BY SALESMAN

QNT. #

SHIPPED

IN PATIENT USE ONLY

REG. #

BID # 20-216

NET

898

SALES TAX

AMOUNT

CODE

DNAI

P & H CHGS

CUSTOMER P.O. NO. 898

ORDER PER. 898

102500

33101



**MARION LABORATORIES, INC.**  
**PHARMACEUTICAL DIVISION**

DUNS # 00-711-9555  
 NEW REG # 19-13298

10230 BUNKER RIDGE ROAD KANSAS CITY, MISSOURI 64137  
 PLEASE REMIT TO: P.O. BOX 972 KANSAS CITY, MISSOURI 64141

To MIAMI-DADE GENERAL  
 HOSPITAL  
 ATTN ACCOUNTS PAYABLE  
 9333 S W 152ND STREET  
 MIAMI FLA 33157

TERMS- 1% 20 NET 30

YOUR ORDER NO	CUSTOMER NO	DATE	POOL	INVOICE NO	PAGE
8999	56930	5/16/74	4301	398786	1

S.O.NO. L1679

QUANTITY	UNIT	DESCRIPTION	NET PRICE	EXTENSION
1000	100	MIAMI DADE GENL HOSP 9333 SW 152ND ST MIAMI FL 33157		
		DUOTRATE 45 CAPS A4103		475.00
500	1000	PAVABID CAPS B4051		31000.00
		IN PATIENT USE ONLY BIC 74-316		31475.00

FORM NO. 3903 REV. 11-73

48.745



**MARION LABORATORIES, INC.**  
 P.O. BOX 972  
 KANSAS CITY  
 MISSOURI 64141

CUSTOMER NO	INVOICE NO.
56930	398786

PAY THE LAST AMOUNT IN THIS COLUMN IF PAID BY	IF PAID AFTER THE DATE IN COLUMN 1, THIS AMOUNT IS DUE BY
6/05/74	6/15/74

31160.25	31475.00
----------	----------

32097 PHARMACEUTICAL DIVISION  
**MARION**  
 LABORATORIES, INC.  
 10236 BUNKER RIDGE ROAD - 761-2500  
 KANSAS CITY, MISSOURI 64137  
 BNDD No. PM 0037071  
 HEW Reg. No. 19-13298

CHARLES L. RICE CO., 213 EAST 117TH STREET, KANSAS CITY, MISSOURI 64114

REF 4 6 11 1 12

**SHIPPING ORDER** 1500 DATE: 5-12-74 CUSTOMER ACCT. NO. 56930 POOL NO. CLASS ORDER NUMBER L 1679

BILL TO: *M/S* ADDRESS: *117th Miami Road, Shiole* SHIP TO: *9333 SW 152nd St*

CITY: *MIAMI* STATE: *FLA* ZIP: *331*

CODE	SHIP	DESCRIPTION	QNTY.	CODE	LOT #	PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #	PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #	
400A	SILVADENE		105072				100	PAYABID	155547				15CM	FLU .01 CR			101115	
2432	GAVISCON OTC		112502				250	PAYABID	155551				80CM	FLU .01 CR			101140	
100	GAVISCON		112547				500	PAYABID UDIP	255554				125CM	FLU .01 CR			101175	
100	PRETTS		112742				1000	PAYABID	155558				15CM	FLU .025 CR			101215	
100	FUMASORB		121547				5000	PAYABID	155590				80CM	FLU .025 CR			101240	
1002	FUMASORB		121554				150	CAPRE	162347				125CM	FLU .025 CR			101275	
50	NAPRIL CAPS		134039				1000	CAPRE	162058				15CM	FLU .025 OINT			101315	
250	NAPRIL CAPS		134051				1200	OS CAL OTC	164592				80CM	FLU .025 OINT			101340	
1000	NAPRIL CAPS		134058				160	OS CAL	165047				20CC	FLU .01 SOL.			101410	
100	TRITEN 1.0		134847				500	OS CAL	165055				50CC	FLU .01 SOL.			101460	
100	TRITEN 2.5		135047				1020	OS CAL	165058				4 OZ	NETASEP			102011	
100	DUOTR 30		152547				100	OS CALFORTE	165347									
500	DUOTR 30		152555				500	OS CALFORTE	165355					12	BLUBORO			119012
1000	DUOTR 30		152558				1000	OS CALFORTE	165358					100	BLUBORO			119047
100	DUOTR 45		151247				100	OS CALGESIC	165647									
500	DUOTR 45		151255				500	OS CALGESIC	165655									
1000	DUOTR 45		151058				1000	OS CALGESIC	165658									
100	DUOTR 30 PB		152547				100	OS CALMONE	166047									
500	DUOTR 30 PB		152555				500	OS CALMONE	166055									
1000	DUOTR 30 PB		152558				1000	OS CALMONE	166058									
100	DUOTR 45 PB		154047				100	OS FED CAL	165547									
500	DUOTR 45 PB		154055				1000	OS FED CAL	166550									
1000	DUOTR 45 PB		154058				100	OS FED VIM	164847									
40	NITROBID 2.5		155041				500	OS VIM	167247									
100	NITROBID 2.5		155047				500	OS VIM	167255									
40	NITROBID 4.5		155141				1000	OS VIM	167258									
100	NITROBID 4.5		155147				100	SAL PHENESIN	162547									
100	NICO ADD		152547				500	SAL PHENESIN	162555									
100	VENTAIRE		142047				1000	SAL PHENESIN	162558									
100	VENTAIRE .5		141047															

RETURNED - DO NOT SHIP

EXPLANATION - 20 POSITIONS

DLVD. BY SALESMAN

CONT. #

SHIPPED

IN PATIENT USE ONLY

REQ #

BID # 24-316

1% NET



**MARION LABORATORIES, INC.**  
**PHARMACEUTICAL DIVISION**

10236 BUNKER RIDGE ROAD KANSAS CITY, MISSOURI 64137  
 PLEASE REMIT TO: P.O. BOX 972 KANSAS CITY, MISSOURI 64141

DUNS # 00-711-9555  
 NEW REG # 19-13298

*c/19-7/81*



**MARION**  
 P.O. BOX 972  
 KANSAS CITY  
 MISSOURI 64141

To  
 MIAMI-DADE GENERAL  
 HOSPITAL  
 ATTN ACCOUNTS PAYABLE  
 9333 S W 152ND STREET  
 MIAMI FLA 33157

TERMS- 1% 20 NET 30

YOUR ORDER NO.	CUSTOMER NO.	DATE	POSK	INVOICE NO.	PAGE	S.O. NO.	L2416
8977	56930	5/17/74	4301	398991	1		

CUSTOMER NO.	INVOICE NO.
56930	398991

PAY THE LAST AMOUNT IN THIS COLUMN IF PAID BY	IF PAID AFTER THE DATE IN COLUMN 1, THIS AMOUNT IS DUE BY
6/06/74	6/16/74

QUANTITY	UNIT	DESCRIPTION	NET PRICE	EXTENSION
297	1000	PAVABID CAPS	84048	18408.00
		ADJUST S/O L1052 BALANCE OF ORDER		18408.00

18223.92	18408.00
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PHARMACEUTICAL DIVISION  
**IV MARION**  
 LABORATORIES, INC.  
 10236 BUNKER RIDGE ROAD - 761-2500  
 KANSAS CITY, MISSOURI 64137  
 BNDD No. PM 0037071  
 HEW Reg. No. 19-13258

CHARLES L. RICK CO., 313 EAST 117TH STREET, KANSAS CITY, MISSOURI 64114

SHIPPING ORDER

DATE: 297 5-16-74

CUSTOMER ACCT. NO. 56930

SHIP TO ORDER NUMBER L2416

BILL TO: *MB* *Miami Dade Hospital*  
 ADDRESS: *9333 SW 152nd St*  
 CITY: *Miami* STATE: *FL* ZIP: *33157*

CODE	SHIP	DESCRIPTION	QNTY.	CODE	SALES TAX	AMOUNT	CODE	DMAT	P & H CHGS.	CUSTOMER P.O. NO.	ORDER PER		
65	RYLA									8977			
PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #	PRICE	SIZE	DESCRIPTION	QNTY.	CODE	LOT #		
	500G	SILVADENE		105072			100	PAYABID		155547	15GW FLU .01 CR	101115	
	243Z	CAVICON OTC		117502			250	PAYABID		155551	20GW FLU .01 CR	101160	
	100	CAVICON		117547			500	PAYABID UOIP		155554	42GW FLU .01 CR	101175	
	100	PRETTS		117742			3000	PAYABID	297	155558	15GW FLU .025 CR	101215	
	100	FUMASORB		121547			5000	PAYABID		155590	60GW FLU .025 CR	101260	
	1000	FUMASORB		121558			100	CAPRE		162047	42GW FLU .025 CR	101275	
	50	NAPRIL CAPS		134039			1000	CAPRE		162058	15GW FLU .025 OINT	101315	
	250	NAPRIL CAPS		134051			1200	OS CAL OTC		164592	60GW FLU .025 OINT	101360	
	1000	NAPRIL CAPS		134058			100	OS CAL		165047	20CC FLU .01 SOL.	101420	
	100	TRITEN 1.0		134847			500	OS CAL		165055	60CC FLU .01 SOL.	101450	
	100	TRITEN 2.5		135047			1000	OS CAL		165058	4.0Z METASEP	106011	
	100	DUOTR 30		152547			100	OS CALFORTE		165247			
	500	DUOTR 30		152555			500	OS CALFORTE		165355	12	BLUBORO	119212
	1000	DUOTR 30		152558			1000	OS CALFORTE		165356	100	BLUBORO	119347
	100	DUOTR 45		153247			100	OS CALGESIC		165647			
	500	DUOTR 45		153255			500	OS CALGESIC		165658			
	1000	DUOTR 45		153258			1000	OS CALGESIC		165658			
	100	DUOTR 30 PB		153547			100	OS CALMONE		166047			
	500	DUOTR 30 PB		153555			500	OS CALMONE		166058			
	1000	DUOTR 30 PB		153558			1000	OS CALMONE		166058			
	100	DUOTR 45 PB		154047			100	OS FED CAL		166547			
	500	DUOTR 45 PB		154055			1000	OS FED CAL		166558			
	1000	DUOTR 45 PB		154058			100	OS FED VIM		166847			
	60	NITROBID 2.5		155041			100	OS VIM		167247			
	100	NITROBID 2.5		155047			500	OS VIM		167255			
	60	NITROBID 6.5		155-11			1000	OS VIM		167258			
	100	NITROBID 6.5		155147			100	SAL PHENESIN		167547			
	100	NICO 400		157547			500	SAL PHENESIN		157555			
	100	VENTAIRE		142147			1000	SAL PHENESIN		157558			
	100	VENTAIRE-5		147347									

RETURNED - DO NOT SHIP

CR	
CR	
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CR	

EXPLANATION - 20 POSITIONS

DLVD. BY SALESMAN  
 CONT. # \_\_\_\_\_  
 SHIPPED \_\_\_\_\_  
 IN PATIENT USE ONLY  
 REQ. # \_\_\_\_\_  
 BID # \_\_\_\_\_  
 IS \_\_\_\_\_ NET  
*Ady par 8/10/74*  
*Robert L. O.*

DOCUMENT # 22181  
1002

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

CABLE ADDRESS: NYFDOPRUS

NEW YORK DISTRICT  
350 THIRD AVENUE  
3RD FLOOR, NEW YORK 10022  
TELEPHONE: (212) 962-5300

FOI Services Inc.  
12315 Wilkins Avenue  
Rockville, MD 20852-1877

May 28, 1982

IN REPLY REFER TO: F82-13220

Dear Requestor:

In response to your request (copy attached) for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act:

  X   We are enclosing the requested record(s). 3 page of the EIR of 5/11, 16, 18/78 are enclosed.

       This is a partial response. Further response will be made at an early date.

  X   As you will note, minor deletions of material have been made in the record(s) furnished to you. In the judgement of the Food and Drug Administration the information deleted does not fall within the scope of your request and, in any case, is not required to be disclosed under the Freedom of Information Act. If, however, you do desire to review the deleted material, please make an additional request. If the Agency should then deny you this information, you would have the right to appeal such denial to the Department of Health, Education and Welfare. Any letter of denial will tell you how to make this appeal.

       Other:

       By copy of this letter a reproduction charge of        and/or a charge of        for search time is being reported to FOI Staff for inclusion in your monthly billing statement.

       Please pay enclosed invoice.        No Charges.

/rb  
Enclosure(s)  
Copy of Request Letter

Sincerely yours,  
*Gary G. Lloyd*  
Gary G. Lloyd  
Compliance Officer  
Compliance Branch  
New York District



12315 Wilkins Avenue  
Rockville MD 20852-1877  
301 861-0410

*Sc*

FEDERAL BUREAU OF INVESTIGATION  
FEDERAL DRUG ADMINISTRATION HFI-35  
ROCKVILLE, MD 20857

05-18-82

CONTROL NUMBER 22181

IN ACCORDANCE WITH THE PROVISIONS OF THE FREEDOM OF INFORMATION ACT, PLEASE  
FURNISH US WITH A COPY OF THE FOLLOWING DOCUMENTS. PAYMENT WILL BE  
REQUIRED UPON RECEIPT OF AN INVOICE FOR THE CHARGES. PLEASE REFER TO OUR  
CONTROL NUMBER IN YOUR REPLY.

COPIES OF EIRS AND 4838 FOR THE PERIOD 1/1/76 THROUGH 12/31/78 FOR HERBERT  
MAY, INC., FLUSHING, NEW YORK.

RECEIVED  
MAY 20 1982  
COMPLIANCE BRANCH

*E92-13220*  
RECEIVED  
MAY 19 1982  
FBI FOI STATE (HPT:SS)

FREEDOM OF INFORMATION  
DATE REC'D 5/18  
DATE ASSGN 5/20  
COMPL. EXT. H. Lloyd  
AGGREGATE



Herbert Henry Inc.  
146-02 45th Ave.  
Flushing, NY 11355  
EI: 5/11,16,18/78

#### Summary of Findings:

This establishment inspection was done according to the New-York District May 1978 workplans which listed the establishment as a Drug-Repacker. The firm, located in the back room of a retail pharmacy, from which it rents space, does no repacking. The firm deals in wholesale pharmaceuticals and ships merchandise as received.

Drug defect report 30563 was followed up during this inspection. Report cites possible mislabeling of Nitro-Bid 6.5 capsules, lot #A7072 manufactured by ~~Herbert Henry Inc.~~. Defect was reported to be an improper caution statement on the bottle. Of the five lots noted on the firm's premises (including A7072) only one appeared to have the proper caution statement. On the first visit, no samples were taken. Information regarding the importer (~~Herbert Henry Inc.~~) was obtained along with some background information on the product.

Inspection of the storage facilities revealed that the firm was keeping all the stock it had on shelves along one wall of the building. Most stock was of Nitro-Bid. Mr. Herbert H. Lewson, president of the firm, explained that most merchandise is shipped directly from supplier to purchaser.

The second visit to the firm was made to collect samples of the lots of Nitro-Bid. Either a physical or documentary sample was taken for each lot. Affidavits were obtained.

#### History of Business:

Herbert Henry Inc. is located in the rear of a retail pharmacy at 146-02 45th Ave., Flushing, NY 11355. This firm rents space but has no relation to the pharmacy. This wholesaler of pharmaceuticals was incorporated in New York in 1972. Mr. Herbert H. Lewson is president of the firm and his wife Myra Z. Lewson is the secretary.

Herbert Henry Inc. does not handle controlled drugs. Merchandise is sold exactly as received. Products are received interstate, both ~~from~~ and ~~is~~ sold interstate. All products are branded.

#### Persons Interviewed and Administrative Procedures:

Upon entering the premises at 146-02 45th Ave. credentials were presented to the manager of the pharmacy. He directed us to an office in the back room where we presented our credentials to Herbert Henry Lewson, president of the firm, and issued him a Notice of Inspection. No samples were taken on this first visit and no List of Observations was issued. Subsequent visits were made to collect samples and affidavits. Receipt for sample was issued.

Mr. Lewson provided information regarding his firm and supplied background on the Nitro-Bid being sold by his firm which is the subject of Drug Defect Report 30563.

Herbert Henry Inc.  
146-02 45th Ave.  
Flushing, NY 11355  
EI: 5/11,16,18/78

I was accompanied on the first day of this inspection (5/11/78) by Investigator George A. Prager.

#### Individual Responsibility and Authority:

Mr. Herbert H. Lewson, president, claimed to be responsible for all operations of the firm. Except for an accountant present on the first day of inspection, no employees were apparent. During the inspection Mr. Lewson said that he had arranged with ~~XXXXXXXXXXXXXXXXXXXX~~ to distribute Nitro-Bid and he showed letters of agreement addressed to himself. He also said that he travels to Afro American to pick up stock personally.

#### Guarantees and Labeling Agreements:

The firm does not do any labeling and gives no written guarantees. They do receive some guarantee on incoming merchandise such as that on the ~~XXXXXXXXXXXX~~ invoice stating that ~~XXXXXXXXXXXX~~ takes full responsibility for the product. No Food and Drug type guarantees are received.

#### Firm's Training Program:

This firm has no employees other than Mr. Lewson, his wife, and one secretary, none of whom require training.

#### Operations:

Since Mr. Lewson is semi-retired, the firm is open only between 9 a.m. and 1 p.m. After 1 p.m. phone calls are monitored by a secretary (who was on vacation at the time of this inspection).

This firm deals in wholesale pharmaceuticals. They are only a dealer. No repacking, labeling or manufacturing is done. The firm does not have its own label.

This firm handles all domestic trade for ~~XXXXXXXXXXXXXXXXXXXX~~. Mr. Lewson arranged with ~~XXXXXXXXXXXX~~ for Herbert Henry Inc. to distribute two shipments of Nitro-Bid capsules manufactured by ~~XXXXXXXXXXXX~~ and ~~XXXXXXXXXXXX~~ from ~~XXXXXXXXXXXX~~ where they had been sent by ~~XXXXXXXXXXXX~~. The merchandise is mainly stored at ~~XXXXXXXXXXXX~~ with a small amount of stock kept at Herbert Henry. As an order comes in Mr. Lewson will pick up a shipment from the garage at ~~XXXXXXXXXXXX~~, where it is stored, using his own key.

#### Consumer Complaints:

The firm does not receive complaints because it does not deal directly with the public. Returns on merchandise are occasionally received by the firm.

#### Recall Procedures:

The firm has no established procedure for recalling defective merchandise.

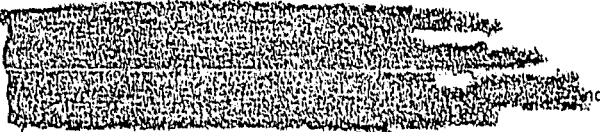
Herbert Henry Inc.  
 746-02 45th Ave.  
 Flushing, NY 11355  
 EI: 5/11,16,18/78

Lot numbers are not recorded on invoices. Mr. Lewson indicated that he would recall all lots distributed of a particular product if necessary.

Promotion and Distribution:

Herbert Henry Inc. does no advertising. Most of their business is done over the telephone. ~~Most~~ of their business is done interstate.

Consignees include:



Refusals:

All information requested was provided by Mr. Lewson. When asked, he said he would voluntarily hold the Nitro-Bid which was sampled, but refused to hold it longer than ten days.

Manufacturing Codes:

This firm does no coding of their own. Any code already on the product will remain there. Code numbers are not recorded by the firm.

Samples Submitted:

Samples of Nitro-Bid were taken as follow-up to Drug Defect Report 30563 (0178-184-424, 425) and documentary samples were taken of the other three lots of Nitro-Bid on the premises. (DOC. 78-184-426/428).

Exhibits: #1. Drug Defect Report 30563

*George A. Prager*

George A. Prager  
 Investigator 700  
 New York District

*Nancy B. Goldstein*

Nancy B. Goldstein  
 Investigator 938  
 New York District



MARION LABORATORIES, INC.  
PHARMACEUTICAL DIVISION

10236 BUNKER RIDGE ROAD • KANSAS CITY, MISSOURI 64137

June 24, 1977

Dear Pharmacist:

~~On a separate page, this letter contains the purpose of the shipment you are receiving. This shipment consists of Nitro-BID, Nitroglycerin, sustained release capsules of 2.5 mg. and 6.5 mg. strengths, which were manufactured and labeled for consumption in and export to the Republic of Bulgaria. This product has been through some device or subterfuge, returned to the United States, and is currently being sold in the United States. The purpose of this letter is to advise you of this situation. In the opinion of our counsel, the sale of Bulgarian Nitro-BID in the United States is not in compliance with the Food and Drug Administration regulations of the Food and Drug Administration.~~

You will be able to recognize this foreign NITRO-BID through the difference in the labels. The regular labels used for the United States are lavender for NITRO-BID 2.5 mg. and yellow for NITRO-BID 6.5 mg., with the color in the center of the label, with wide white margins. The labels for Bulgarian NITRO-BID are orange for the 2.5 mg. strength, with the orange covering the margins of the label and the center of the label being white; and green for the 6.5 mg. strength, again with the color being around the margins of the label with white in the center.

The Bulgarian NITRO-BID does not contain NDC numbers, as are used on domestic labeling, and the caution does not comply with U.S. law.

This shipment was exported from the United States to Bulgaria. We have been advised that a substantial part of this shipment has been subject to rough handling and a number of glass containers were damaged. We have no knowledge of the temperature and other conditions under which this shipment of NITRO-BID was stored. Therefore, in the event any claim is made against wholesalers or retailers selling this Bulgarian NITRO-BID, we wish to advise you that no protection will be afforded

page two

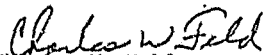
to such persons under Marion's standard policy, which affords Marion's bona fide vendors liability insurance protection. These re-entered Bulgarian products would be sold at the sole risk of the vendors.

We trust that you have not sold any such Bulgarian NITRO-BID but in the event the same might be offered to you, we wanted to advise you of the above risks. We would also appreciate your informing us of any such attempted sale.

Thank you for your usual fine cooperation.

Sincerely,

MARION LABORATORIES, INC.

  
Charles W. Feld  
Vice President-Sales

CWF:jt

att: Herb Walter

FORM 446 (REV. 11-15-66)

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE  
FOOD AND DRUG ADMINISTRATION

ENTRY DATE: 7/19/77  
X  
9036446

MAY PROCEED NOTICE

12060493	Port Sheridan	HOLLAND	NEW YORK	NEW YORK
493701	303			
FOR THE Shipper/Consignee		IMPORTER RECORD		DATE OF ENTRY 7/19/77
Name & Address		Name & Address		MANUFACTURER/SHIPPER (Name & Address)
		ECON AS CONSIGNEE		Excelsior International Inc. 514 North Michigan Avenue Chicago, Illinois 60607
		SILVER SHIPPING CO. INC.		Address 2108 St. Lawrence N.Y.
LEAD SAMPLE				PHONE NO 212-1658

NOTICE

(FOR BROKER'S USE)

GENERAL DESCRIPTION OF SHIPMENT

**THIS IMPORTATION**  
**MAY PROCEED**  
**Without FDA Examination**

This notice does not preclude action should the merchandise later be found violative.

VALID ONLY IF SIGNED

SIGNED: [Signature] DATE: [Date]  
FDA Representative

QTY	PACKAGED	ITEMS
3		Cartons Containing: Pharmaceuticals, Cereals 1, Attached

**IMPORTANT NOTICE** - An import shipment must be accompanied by a copy of this notice to the FDA. The date of arrival of the shipment must be reported to the FDA within 15 days of the date of arrival.

The date of arrival of the shipment will be a factor in determining the date of arrival for the purpose of this notice.


**MARION INTERNATIONAL, INC.**

 A SUBSIDIARY OF MARION LABORATORIES, INC.  
 DEPT. OF EXPORT ADMINISTRATION

 SIX NORTH MICHIGAN AVE (505) • CHICAGO ILLINOIS 60607 U.S.A.  
 • (312) 231-1111 • 06-16-64

 INVOICE # (No pedido)  
 DCE NO (Número)

 # ORDER NO (Número pedido no)  
 1-1-22

INVOICE (Cuenta)

DATE OF INVOICE (Fecha de factura)

 SHIPPING MARKS (MARCAS DE EMPAQUE)  
 Standard Export International, Inc. USA

NAME (Cargador)

 TYPE OF Methodo de Seguro:  
 INSURANCE

TERMS (Cond. ones de pago)

AS SHIPPED (Medido de embarque)

WITNESING SHIPMENT OF:

Q OF UNITS (Cantidad)	DESCRIPTION (Descripción)	PRICE PER UNIT (Precio por Unidad)	TOTAL IN U.S. DOLLARS
1000 BOT.	PACKETS 100's NITROGEN O.S. NON SUSTAINED RELEASE CAPSULES AT THE PRICE OF		
1000 BOT.	PACKETS 100's NITROGEN O.S. NON SUSTAINED RELEASE CAPSULES AT THE PRICE OF		

DOUBLE INVOICE

EXPORTED FROM 1986 U.S.A.

EXPORTED FROM 1986 U.S.A.

 PACKING IN PLASTIC 100's PER BOTTLE.  
 LABELS TO BE BEFORE ACCEPTED.

TOTAL GROSS WT.: 1986.8 Eqs. (4336 Lbs.)

TOTAL NET WT.: 1876.8

TOTAL CARRIER: 232.8 Cu. Ft.

ALL NITROGENS ARE OF USA MANUFACTURE

I hereby certify that all export carbons  
 are marked with Contract Number  
 I also certify that this invoice is true and correct  
 and that the country of origin of the goods is  
 USA U.S.A.

MARION INTERNATIONAL, INC.

L. KAT, Export Secretary.

CERTIFICATE OF ORIGIN

FOR GENERAL USE AND FOR THE FOLLOWING COUNTRIES

BRAZIL EGYPT GREECE IRAH IRAQ ITALY LEBANON NETHERLANDS POLAND SYRIA

SHIPPER'S NAME MARION INTERNATIONAL INC. 6 NORTH MICHIGAN AVENUE CHICAGO, ILLINOIS 60602		SHIPPER'S REF. NO.	
TO ORDER:		3/4/77	
SHIPPER'S PRIVATE COMMUNICATIONS		REMARKS-SPECIAL INSTRUCTIONS	
PORT OF ORIGIN		PORT OF DESTINATION	
ONLINE CARRIER (Vessel/Airline)		PORT OF LOADING	
DATE OF DEPARTURE (Vessel/Airline)		FOR TRANSPORTATION TO	

PARTICULARS FURNISHED BY SHIPPER				
UNIT AND NUMBER	NO. OF PCKGS.	DESCRIPTION OF PACKAGES AND GOODS	GROSS WEIGHT	MEASUREMENT
MR. MARION INTERNATIONAL, INC. 4.	8	CARTONS: PHARMACEUTICALS ( 12000 BOT. PACKING 100'S NITROBID 2.5 MM SUSTAINED RELEASE CAPSULES; 4000 BOT. PACKING 100'S NITROBID 6.4 MM SUSTAINED RELEASE CAPSULES. )	4,386 #	239' D
1.7020		IN ALL TRANSPORT CONTAINER NO. _____ ALL NITROBID ARE OF USA MANUFACTURE PACKING IN PLASTIC 100'S PER BOTTLE, LABELLING AS BEFORE ACCEPTED		G-dont

undersigned E.A. Meinardus (Recognized Agent), does hereby declare for the above named shipper, the goods described above were shipped on the above date and consigned as indicated and are products of the United States of America and at Chicago, Ill on the 15th day of March 1977  
 info before me this 16th day of March 1977  
 E.A. Meinardus  
 PUBLIC  
 WILLMETT CHAMBER OF COMMERCE, INC. a recognized Chamber of Commerce  
 of the laws of the State of ILLINOIS, has examined the manufacturer's invoice or shipper's affidavit concerning the origin of the merchandise, and, according to the best of its knowledge and belief finds that the products named are of the United States of North America.  
 Mar. 21 1977



PFIZER LABORATORIES  
INTRA-DIVISIONAL COMMUNICATION

DATE 15 Apr 1974  
PAGE 1 of 2

HOSPITAL AFFILIATES Miami-Dade Hosp ; Coral Gables Hosp.

TO: Mike Logan

PREFACE: I have conducted an investigation into large orders being received from the above accounts and have the following information:  
THREE SOURCES: Chief Pharmacist of the Hospitals Involved,  
A Detail Man from Reid Provident Company, who is a former U.S.V. and Roerig Representative,  
A Manager of a large Drug Store who is involved as a "Middle-Man"

THIS WAS DONE

CONCLUSION: To Open a "special account to be called "Hospital Affiliates Miami-Dade Hospital" and to pool the account within the District.

REMARKS: The business develops from two sources:  
1. 14 Nursing Homes and an E.M.O involving 45 local Doctors.  
2. Export to the Bahamas and to some extent Nicaragua.

The business here in Miami develops as a result of recently formed H.M.O. (Health Maint. Organization) from 45 doctors who are in the process of signing up some 4500 patients, all working for two local establishments; this is just a beginning as they will continue to expand with a goal of havin. 50,000 persons signed up within a year. This H.M.O. may use this source of supply exclusively or may also have an agreement with other suppliers at a later date. The 14 Nursing Homes are scattered about the entire Miami-St. Laurende to area and I would estimate we are talking in terms of about 1400 beds.

The business on the Bahamas develops in an interesting manner. Up until recently the Bahamas purchased most of their drugs through direct sources in Canada, with the exception of a few drugs only available in England. They picked up "shorts" from Miami wholesaler. Now, an Importer-Exporter who has offices in Miami and Nassau has "gained favour" with Sir L. Pindling, Prime Minister and has been appointed to obtain all drugs and foods F.O.B. Miami. It is reported by our sources that this total business, FOOD & Drugs is about \$1.5 million per quarter. No break-down was obtained on Drugs alone. However these two facts are available. There are about 200,000 persons on the Bahamas and most of the Drugs are handled through hospitals operated by the Government. In addition to the above, the unusually heavy demand at present is due at least partly to the fact that Nicaragua Hospitals are being re-stocked and this same "broker" has secured this business also (the monies having been kept in Miami Bank which was obtained from various charity organizations, etc). This would explain the Atarax orders being in excess of Vistaril orders.

( see page two)

REPRESENTATIVE	TELEPHONE NO.	MANAGER'S COMMENTS
ADDRESS		<i>Mike Logan</i> <i>5/15/74</i>
CITY	STATE	
CC		

PFIZER LABORATORIES  
INTRA-DIVISIONAL COMMUNICATION

DATE

15 Apr 76

PAGE

2 of 2

SUBJECT

Cont'd from page 1

TO:

Jerry Weinstein, R.Ph Chief Pharmacist of Mia-Dade Hospital, Coral Gables Hospital, Abbey General Hospital, and Miami International Hospital (soon to open) also has an export license and has a company called TARUS for this purpose.

L.Harris, manager of a very large Drug Store is involved to this extent. He represents the financing of the orders and is the "middle" man between the Hospital and the Exporter here in Miami. He would work under the TARUS firm name in this respect and is also the source of the monies represented by the Cashier's Checks being received.

(This information must be held in confidence, as it is unlikely that his present employer knows about his outside business interests)

L.Harris has been in the drug business for many years and has sources all over the city of New York for bringing in any merchandise not available in Miami. This is the reason they are only dealing with the top 10 or 12 companies here in Miami. He are one of these 12.

Already shipped through this source are :

100,000 Adoril Tablets  
1,000 x 500s Valium Tablets  
1,000 x 500 Orinase Tablets  
500,000 Reid Provident Equivalent of Premarin  
10,000 Vials Provaghan (Reid Provident's rbernaghan)  
1,000x 1M Refet (Tetracyclines)  
288 x 100 NEENESE Tablets (obtained outside Miami ???)

Orders already mailed in to Pfizer includes over \$35,000 made up of Vistaril Caps and Terramycin Caps. and over \$35,000 in Atarax Tabs.

Sp.Note: At times they will use part of this merchandise to swap out locally for specified items from small firms:

Finemol Supp 2 x 100 Reflex caps with a local hospital for a specified drug from the Endo Company.

CONCLUSION: It is my hope that we will handle these orders through a special account requested to be called "Hospital Affiliates Mia-Dade Hospital, accepting only pre-paid orders (Cashier's Checks) and to pool the account. Estimation of \$150,000 per year are not unrealistic.

REPRESENTATIVE M Gill Pulzner	TERRITORY NO. DH 14	MANAGER'S COMMENTS
ADDRESS		
CITY	STATE	
CC		

OPM 61251 (REV. 11/75)

SYNTEX (U.S.A.) INC. STANFORD INC. ... PALO ALTO, CALIFORNIA 94304.

SOUTHERN REGIONAL OFFICE  
P. O. Box 1-7  
Tucker, Georgia 30084  
(404) 932-1110

May 14, 1974.

Mr. J. Weinstein,  
Miami Dade General Hospital,  
9333 S. W. 152 Street,  
Miami, Florida. 33157

Dear Mr. Weinstein:

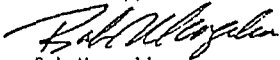
Our representative Mr. Sandy Mendez, has forwarded your request for bid quotation on specific Syntex products. Based upon your estimated usage rates, our quotations are as specified on the attached.

The prices quoted are net 30 days, f. o. b. destination and are effective for a period of twelve months - May 15, 1974 through May 14, 1975. Delivery can be made within ten (10) days after receipt of your order. When placing orders against this bid, please refer to bid quote #2-43. All inquiries should be mailed to the address listed above. Minimum opening order is \$250.00.

This bid is conditioned on the purchaser being a charitable institution or hospital not operated for profit and on the condition that the products covered by this bid shall be purchased as supplies solely for use by such hospital or other non-profit institution.

We look forward to fulfilling your needs in the near future and if you have any further questions, please do not hesitate to let me know.

Sincerely,



Bob Margolin,  
Special Accounts Manager.

RM;mbs

Encl.

cc: J. Koenig - Sales Services  
D. Schwartz - Manager, CSS  
P. Starkman  
S. Mendez

SIGMA WORKING  
TELEX 859650

12.1.76

ATTN. MR T HOFFMEISTER (COPY MR PAUL FREIMAN)

THANK YOU VERY MUCH FOR YOUR VALUABLE HELP. HERE FOLLOWS THE TEXT OF THE TELEX WHICH WE SENT TO GABAR/MR. RICHMAN YESTERDAY.

RATHER THAN ACCEPTING THE LARGE DISCOUNTS REQUESTED IMMEDIATELY I AM TRYING TO GET HIM TO ACCEPT THOSE DISCOUNTS ON A CUMULATIVE BASIS FOR FOUR SHIPMENTS TALLING U.S. DOLLARS 800,000 IN THE NEXT SIX MONTHS OR SO. WE WILL SEE IF THEY ACCEPT OR NOT.

I WILL KEEP YOU POSTED.

QUOTE:

OEMS 859650

11.33.76

ATTN. MR. RICHMAN

THANK YOU FOR YOUR TELEXES OF NOVEMBER 23, 24 AND 26. I AM AFRAID WE CANNOT MEET, FOR THIS FIRST SHIPMENT, YOUR REQUEST FOR A 60 PCT DISCOUNT ON THE U.S. WHOLESALE PRICE FOR THE FOUR NORINYL PRODUCTS AND FOR A 35 PCT DISCOUNT FOR THE REMAINING PRODUCTS, BUT BECAUSE OF THE VERY SPECIAL CIRCUMSTANCES WE ARE PREPARED TO GIVE YOU A DISCOUNT OF 35 PCT ON THE NORINYL PRODUCTS AND 20 PCT FOR THEIR PRODUCTS FOR THE FIRST SHIPMENT OF U.S. DOLLARS 250,000 OR MORE, FOLLOWED BY RESPECTIVELY 40 PCT AND 25 PCT DISCOUNT CUMULATIVE (REPEAT: CUMULATIVE) FOR THE FIRST TWO SHIPMENTS 45 PCT AND 30 PCT CUMULATIVE FOR THE FIRST THREE SHIPMENTS AND 50 PCT AND 35 PCT CUMULATIVE FOR THE FIRST FOUR SHIPMENTS OF U.S DOLLARS 250,000 EACH.

IN OTHER WORDS IF YOU WOULD ORDER A TOTAL OF OVER U.S. DOLLARS 1,000,000 DURING THE NEXT SIX MONTHS OR SO YOU WOULD INDEED PURCHASE THE FOUR NORINYL PRODUCTS AT A TOTAL 50 PCT DISCOUNT AND ALL OTHER PRODUCTS AT A TOTAL 35 PCT DISCOUNT WITH RESPECT TO THE U.S. PRICE TO THE WHOLESALE.

CONSEQUENTLY, WE CONFIRM CODE NUMBERS, P, , PRODUCT DESCRIPTION, QUANTITY, UNIT PRICE AND TOTAL AMOUNT FOR THE FIRST SHIPMENT AS FOLLOWS:

GROUP 'A'  
-----

0101-25	NORINYL 1"50 REF	6X21	8016	6.48	51.943.68
0102-25	NORINYL 1"80	6X21	8016	6.48	51.943.68
0101-24	NORINYL 1"50	6X28	5016	6.48	32.503.68
0102-24	NORINYL 1"80	6X28	5016	6.48	32.503.68
0272-42	NAPROSYN	250 MG 104S	2400	12.79	30.696.00
-----					

TOTAL GROUP 'A'

199.590.72

GROUP 'B'

	MEMORETTE NORINYL 1"80	12.000	0.15	1.800.00
0102-69	MEMORETTE NORINYL 1"80	12.000	0.15	1.800.00
2506-46	SYNALAR SOL. 60 CC 0.01 PCT	1.200	3.30	3.960.00
2506-44	SYNALAR SOL. 20 CC 0.01 PCT	2.400	1.68	4.032.00
2502-13	SYNALAR CRM. 15 GM 0.01 PCT	3.600	1.12	4.032.00
2501-13	SYNALAR CRM. 15 GM 0.025 "	4.800	1.60	7.680.00
2504-13	SYNALAR QINT. 15 GM	360	1.60	576.00
2511-13	LIBEX CRM. 15 GM 0.05 PCT	3.600	1.83	6.588.00
2201-42	EVEK .625 100S	1.800	2.62	4.716.00
2202-42	EVEK 1.25 100S	1.800	4.64	8.352.00
2203-42	EVEK 2.50 100S	1.800	8.28	14.904.00
2271-21	VAGITROL 4 OZ.	1.800	2.30	4.140.00
2274-16	VAGITROL SUPP.	1.800	3.16	5.688.00

TOTAL GROUP 'B' 68.628.00

TOTAL SHIPMENT 268.218.72

THE TOTAL INVOICE OF 268.218.72 IS MORE THAN 30 PCT UNDER OUR PRICE TO THE U.S. WHOLESALER, NOT COUNTING CUMULATIVE DISCOUNTS TO BE OBTAINED BY SUBSEQUENT SHIPMENTS WHICH WOULD RAISE YOUR SPECIAL DISCOUNT TO ABOUT 45 PCT. THIS IS THE MAXIMUM WE CAN DO.

PLEASE NOTE THAT QUANTITIES HAVE BEEN ADJUSTED TO MULTIPLES OF 12, 24 OR 48 IN VIEW OF PACKAGING AND THAT THE TOTAL SHIPMENT HAS BEEN SUBDIVIDED INTO A GROUP 'A' AND A GROUP 'B'.

GROUP 'A' IS TO BE DELIVERED TO YOU F.O.B. AT JOHN F. KENNEDY AIRPORT - NEW YORK (BECAUSE SHIPMENT IS FLOWN IN FROM PUERTO RICO) AND GROUP 'B' IS TO BE DELIVERED F.O.B. SYNTEX LABS., EAST BRUNSWICK, NEW JERSEY.

WE ALSO CONFIRM ITEMS 2, 3 AND 4 OF YOUR TELEX OF NOVEMBER 23 AND WE ASK YOU TO CONFIRM THAT PAYMENT WILL BE DONE BY AN IRREVOCABLE LETTER OF CREDIT BETWEEN OUR BANK IN THE U.S. AND YOURS. DELIVERY IS APPROXIMATELY ONE WEEK FROM RECEIPT OF YOUR ORDER AND A FEW DAYS FOR TRANSMITTAL TO AND CONFIRMATION BY THE U.S. SO IN TOTAL ABOUT 10 DAYS MAXIMUM.

LOOKING FORWARD TO YOUR ORDER.

SINCERELY,

ROBERT RADEMAKER""""

CORRECTION: LAST WORDS - SEVENTH LINE SHOULD READ: THE OTHER.

UNQUOTE

REGARDS,

ROBERT

SIGMA WORKING

SYNTEX PLA

LA PUERTO RICO INC.  
L.U.C. 2050  
AACAO, PUERTO RICO 00681

14

November 20, 1976

Dr. Robert Rademaker  
SIGMA  
Syntex House  
Woking, Surrey GU22 7UY  
England

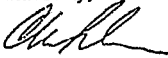
Dear Dr. Rademaker:

This will confirm our agreement in our telephone discussion that Syntex Puerto Rico, Inc. will accept an order from the Belgium purchasing agent for the Zaire government which will be subject to the following discounts from wholesale prices based upon total purchases from Syntex (Syntex Laboratories, Inc., Syntex (F.P.), Inc. and Syntex Puerto Rico, Inc.) during the period ended October 31, 1977:

<del>Combined sales in excess of \$1,000,000</del>		
Combined sales between \$500,000 and \$1,000,000		30%
Combined sales between \$250,000 and \$500,000		25%
Combined sales up to \$250,000		20%

It is further agreed that we will invoice on the assumption that the purchaser will meet his commitment to place orders in excess of \$1,000,000 during the period and will, therefore, invoice at the 35% discount price, providing that it is clearly understood by the customer that we have the right to a retrospective adjustment if they fail to meet the \$1 million value.

Sincerely,



Clifford Mahler  
President  
CM:ws

cc: Mr. R. Rogers  
Mr. R. Schwartz

TEX IP, I INC.  
 BOX 7010  
 ACAO, PUERTO RICO 00611

November 20, 1976

Dr. Robert Rademaker  
 SIGMA  
 Syntex House  
 Woking, Surrey GU22 7UY  
 England

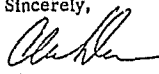
Dear Dr. Rademaker:

This will confirm our agreement in our telephone discussion that Syntex (F.P.), Inc. will accept an order from the Belgium purchasing agent for the Zaire government which will be subject to the following discounts from wholesale prices based upon total purchases from Syntex (Syntex Laboratories, Inc., Syntex (F.P.), Inc. and Syntex Puerto Rico, Inc.) during the period ended October 31, 1977.

Combined sales between \$500,000 and \$1,000,000	45%
Combined sales between \$250,000 and \$500,000	40%
Combined sales up to \$250,000	35%

It is further agreed that we will invoice on the assumption that the purchaser will meet his commitment to place orders in excess of \$1,000,000 during the period and will, therefore, invoice at the 50% discount price, providing that it is clearly understood by the customer that we have the right to a retrospective adjustment if they fail to meet the \$1 million value.

Sincerely,



Clifford Mahler  
 President

CM:ws

cc: Mr. R. Rogers  
 Mr. R. Schwartz

**SYNTEX**

SYNTEX LABORATORIES, INC.  
P.O. BOX 44125-SAN FRANCISCO, CALIFORNIA 94144  
DUNS #00-923-8411

MIAMI-CADE GENERAL HOSPITAL  
ITH: HOSP PHARMACY  
333 SW 132ND ST  
MIAMI FL 33157

MIAMI-LWDE GENERAL HOSPITAL  
ATH: PCSP PHARMACY  
9333 SW 132ND ST  
MIAMI FL 33157

LINE NO.	INVOICE DATE	CUSTOMER'S ORDER NUMBER	CUST CODE	SHIPPED VIA	NET	TERMS	PAID DATE
171-01	02/14/75	0135	02	WELF			
DUCT CODE	DESCRIPTION	QUAN. ORDER	QUAN. SHIP	UNIT PRICE	AMOUNT		
271-21	VAGITROL 4 OZ.	144	144	1.5600	224.64		
501-13	SYNALAN CREAM .025 15GM	600	600	1.2000	720.00		
502-13	SYNALAN CREAM .01 15GM	210	210	6.7300	1422.00		
905-33	AKANE 60'S	456	456	6.7000	3073.20		
<small>STANDARD YOUR ORDER TO MINIMUM SHIPMENT QUANTITY TO AVOID DELAY. IF AVAILABLE AT THIS TIME - PLACE ON BACK ORDER FINAL QUANTITY SHIPPED - REMAINDER TO FOLLOW ACCORDANCE WITH INSTRUCTIONS OUT OF STOCK ITEMS HAVE NOT BEEN CL-ORDERED - PLEASE RE-ORDER.</small>					<small>DISC. ALLOWED WITHIN MONTHLY TERM PERIOD</small>	<small>TOTAL AMOUNT</small>	<small>DUPLICATE</small>
					00.00	02	4,181.84
<small>PLEASE PAY FROM THIS INVOICE ENCLOSE DUPLICATE INVOICE WITH REMITTANCE. REFER TO INVOICE NUMBER SHOWN ON ALL RELATING CORRESPONDENCE.</small>							ACCOUNTING DEPT.

NY 8/71



NOTE

MIAMI DADE BOOGYTT. FOR <sup>ST</sup> IN HOUSE MUSEUM?

6000 pc. AARONC CAPS - 60'S (281 <sup>AMPHES</sup>)  
FOR ASTHMA

NO. SMOGOTS

same  
dms

17,063 pc. SWACAR <sup>Chemical for 0.5/</sup>

NO. M/K

3,253 pc. Signal. <sup>Chemical for 1/10</sup>

NO. M/K

3,226. Signal. <sup>Solution 60cc</sup>

NO. SMOGOTS

32,542. Customs pup for 30

2,760  
3304  
15040

Cyelles <sup>Marine</sup> / FOR INSTIT. MK }  
" " " / S.D. INSTIT. MK }  
" " " 2MG. stock }  
" " " <sup>Marine</sup> in 1 YR }

13  
1/100'S

11,104

cc: Hector Arlotta  
Bill Lederman

Keith Moore

Claud Mallory

File ✓

June 19, 1975

Mr. Lionel Harris  
Miami Dade General Hospital  
9333 S. W. 152nd Street  
Miami, Florida 33157

Dear Lionel:

I would like to thank you for the time and courtesy which you extended to me during my visit of June 12. To summarize our discussion, we reviewed your original bid quantities and a number of items you indicated you could use. Your projected figures amounted to \$250,000.00 on 19 separate items. Through 8 months you have purchased \$25,692.00 worth of merchandise. The bulk of this amount has come from the purchase of four (4) items. This is not the type of performance that we anticipated on entering into our contract with you; therefore, we increased the prices on January 29, 1975. As I pointed out during our conversation, the contract ends in September at which time there will be further increases in price.

We discussed the potential purchase of 1000-1000 Modane Regular Tablets. At the time of our telephone conversation I indicated that the figure for 1000-1000's would be \$55.70. If you are prepared to take two shipments of 500-1000's each, we can drop the price to \$51.50. Currently your \$4.34 price for Modane 100's, based on your restated contract, is the best price in this country. In September it will be necessary to increase this price considerably. Certainly the price of the 100's will far exceed that quoted on the 1000-1000's.

You requested information on our new product, Kaon-CI Tabs<sup>TM</sup>. You will find this attached.

Please call me if you are interested in the 1000 price.

Sincerely,

Peter F. Nillos  
Director of Sales

PPN/ga  
Enclosure

MIAMI DADE - SALES & UNITS

(SEPTEMBER 1974 THRU APRIL 1975)

<u>BID QUANTITY</u>	<u>PRODUCT</u>	<u>SIZE</u>	<u>QUOTE</u>	<u>UNITS PURCHASED</u>	<u>(ROUNDED) DOLLAR PURCHASE</u>
100,000	Kaochlor 10% SF	15ml	\$15.00/C	200	\$ 30.00
14,400	"	4 oz.	0.63		
15,000	"	Pints	1.19	323	384.00
5,000	"	Gal.	10.70	28	295.00
10,000	Kaochlor 20%	Pints	1.89	10	19.00
5,000	" 20%	Gal.	12.61	54	684.00
50,000	Kaon Elixir	15ml	21.00/C	20	427.00
12,000	"	4 oz.	1.00		
1,000	"	Pints	2.80	1,472	4,121.00
5,000	"	Gal.	23.06	135	3,109.00
1,000	Kaon Tabs	100	2.61	1,575	4,111.00
3,000	Modane	100	4.34	1,069	4,640.00
3,000	Modane Mild	100	3.74	76	283.00
1,000	Chymolase	48	7.49		
500	Ilozyme	250	11.64		
1,000	Ilopan-Choline	100	6.75	11	74.00
200	Ilopan Stat-Pak	25	31.74	8	239.00
7,500	Kaochlor 10%	Pint	1.19	5,505	6,551.00
No Quantity (Part of 10% SF Qty.)	Kaochlor 10%	Gal.	10.70	43	<u>461.00</u>
				8 months total	\$25,692.00

*B. Lederman*

MEMO

WARREN-TEED PHARMACEUTICALS INC.

Date: September 11, 1974

To: Mr. Hal Denis

From: William J. Lederman

cc:

DATE STAMP

Subject: Miami Dade General Hospital — MIAMI DAD GENERAL HOSPITAL NON PROFIT

~~CONFIDENTIAL - NOT TO BE DISCLOSED TO THE PUBLIC~~  
 (Approved February 1974)  
 (Approved February 1974)

The initial approach from this customer was made over a month ago. Order was received on August 3. Most recent call to account was yesterday, September 10. Quantities were confirmed and an immediate order (see attachment #1) was obtained. The following procedure was used for this account:

1. 1973 purchases were reviewed. Total = ~~424,100~~
2. 1974 purchases to date = \$1730
3. Annual Estimated Needs were projected using full price and exception prices. (see attachment #3) Checked (✓) items indicate exception prices.
4. Purchase orders using competitive pricing by Cooper Labs were obtained and were added. Indicate base price of Kay Ciel \$.74/pint; \$4.80/gal.
5. Competitive information on other bids was reviewed to determine prices used for similar quantities or lesser quantities. (price sheets attached)
6. ~~Doctor Anloca originally developed this account. The regional manager, Keith Moore, has personally called on this account. Both of these gentlemen would like to have the business and feel that this will not affect the current distribution in an adverse manner.~~  
~~(Claude Mallory feels that this is a legitimate business offer and should be accepted.)~~
7. Final attachment will be bid request authorization computed to gross profit line. The estimated value of this contract, assuming all contracts purchased, would be \$290,137.

1473 = 377<sup>00</sup>  
 1474 = 1730<sup>00</sup>  
 1475 = 211  
 290,137

NOTE: Denis  
 Date 6/24/74

NOTE: On June 6, 1974, Mr. Mallory informed this hospital of their right to bid.

8. GRAND TOTAL: Gross Net Cost + G.P.

## WARREN-TEED PHARMACEUTICALS, INCORPORATED

619 WEST BROADWAY STREET, COLUMBUS, OHIO 43215  
 (614) 291-6574



September 12, 1974

Mr. Gerald M. Weinstein  
 Director of Pharmaceutical Services  
 Abbey Hospital Pharmacy  
 Coral Gables Hospital Pharmacy  
 Miami Dade Hospital Pharmacy

Abbey Foundation Hospitals, Inc.  
 NON-PROFIT TAX NUMBER 06017970523

Dear Mr. Weinstein:

We at Warren-Teed appreciate the opportunity to bid on your estimated annual needs contract. Prices quoted are firm for a one year period unless the quantities are substantially below those estimated. Prices will be renegotiated if substantially below those estimated.

Force  
 from the  
 Buy Bill

Warren-Teed will bill to:

Miami Dade General Hospital  
 9333 S.W. 152nd St.  
 Miami, Florida 33156

Ship to:

R.C.W. Associates Inc.  
 8768 S.W. 131st St.  
 Miami, Florida 33156

know all was not being  
 shipped to hospital + still  
 shipped

Warren-Teed's terms are 2% 10 Prox. Minimum order \$50.00.

Sincerely,

*W. J. Lederman*  
 Wm. J. Lederman  
 Sales Planning Manager

EJL/nm

City Miami State Florida Zip 33157 Title Director of Purchases  
 Representative H. Arlotta Terr. 6103 Date Sept. 12, 1974

PRODUCT	PACKAGE SIZE	ESTIMATED ANNUAL QUANTITY	UNIT PRICE
Bar-Don Elixir	Pints		
Bar-Don Elixir	Gallons		
Bar-Don Tablets	1,000's		
Chymolase Tablets	48's	1,000	@ 4.78/48
Chymolase Tablets	250's		
Chymolase Tablets	1,000's		
Chymolase Tablets	Boxes of 100 (Unit Dose)		
Ilopan Injection	10 cc.		
Ilopan Injection	2 cc.		
Ilopan Injection Stat-Pak	2 cc.	200	@ 34.81/25
Ilopan-Choline Tablets	100's	1,000	@ 6.20/100
Ilopan-Choline Tablets	500's		
Ilozoff Capsules	100's		
Ilozyme Tablets	250's	500	@ 9.37/250
Kaochlor Liquid (10%) S.F.	15 ml. (Unit Dose)	100,000	@ 0.0970/15
Kaochlor Liquid (10%) S.F.	4 oz.	14,400	@ 0.45/4 oz
Kaochlor Liquid (10%)	Pints	15,000	@ 0.80/pt.
Kaochlor Liquid (10%)	Gallons	5,000	@ 5.90/gal.
Kaochlor-Def Tablets	60's		
Kaochlor <del>44444444444444444444</del> 10% Pts.	<del>44444</del>	7,500	@ 0.80/pt.
Kaochlor Concentrate (20%)	Pints	10,000	@ 1.60/pt.
Kaochlor Concentrate (20%)	Gallons	5,000	@ 8.50/gal.
Kaon Elixir	15 ml. (Unit Dose)	50,000	@ 0.18/15ml
Kaon Elixir	4 oz.	12,000	@ 0.72/4oz.
Kaon Elixir	Pints	1,000	@ 2.90/pt.
Kaon Elixir	Gallons	5,000	@ 21.73/gal
Kaon Tablets	Boxes of 100 (Unit Dose)		
Kaon Tablets	100's	1,000	@ 2.30/100
Kaon Tablets	500's		
Modane Liquid	Pints		
Modane Mild Tablets	100's	3,000	@ 2.95/100
Modane Mild Tablets	1,000's		
Modane Regular Tablets	100's	3,000	@ 4.23/100
Modane Regular Tablets	1,000's		
Modane "	of 100 (Unit Dose)		
	2 oz.		
	1 lb.		
	Pints		
	100's		
	2 oz.		
	100's		
	1,000's		
	8 oz.		
	Gallons		
	80 gm. Packets		
	80 gm. Packets		
	90 gm. Packets		
	28 - 10th Prox.		

QUANTITIES SHOWN ARE UNLESS OTHERWISE SPECIFIED.  
 \*REQUEST FOR QUANTITY PRICE QUOTATION BASED ON ESTIMATED ANNUAL QUANTITY.

*INCOMPLETE*  
*QUANTITIES*  
*15,000 PINTS*  
*5000 GALLON*  
*OF SAME ITEM*

*2,636,600 OUNCES OF*  
*POTASSIUM-LIQUID IN 1 YR*  
*FOR 260 BED HOSPITAL*  
*--- TAKES 27 1/2 EZ EVERY DAY*

William J. Lederman  
 Sales Planning Manager

## MEMO

WARREN-TEED PHARMACEUTICALS INC.

Date: September 11, 1974

To: Mr. Hal Denis

From: William J. Lederman

DATE STAMP

cc:

Subject: Miami Dade General Hospital

~~Non-profit~~ Tax Certificate - Number 06017970823, ~~ISSUED~~ Issued: February 6, 1963

The initial approach from this customer was made over a month ago. Order was received on August 3. Most recent call to account was yesterday, September 10. Quantities were confirmed and an immediate order (see attachment #1) was obtained. The following procedure was used for this account:

1. 1973 purchases were reviewed. Total = \$577.
2. 1974 purchases to date = \$1730.
3. Annual Estimated Needs were projected using full price and exception prices. (see attachment #3) Checked (✓) items indicate exception prices.
4. Purchase orders using competitive pricing by Cooper Labs were obtained and were added. Indicate base price of Kay Ciel \$.74/pint; \$4.90/gal.
5. Competitive information on other bids was reviewed to determine prices used for similar quantities or lesser quantities. (price sheets attached)
6. Hector Ariotta originally developed this account. The regional manager, Keith Moore, has personally called on this account. Both of these gentlemen would like to have the business, and feel that it will not affect their current distribution in an adverse manner.

Claud Mallory feels that this is a legitimate business offer and should be accepted.

7. Final attachment will be bid request authorization computed to gross profit line. The estimated value of this contract, assuming all contracts purchased, would be \$290,137.

NOTE: On June 5, 1974, Mr. Mallory informed this hospital of their right to bid.

8. GRAND TOTAL: Gross Net Cost G.P.

## MEMO

WARREN-TEED PHARMACEUTICALS INC.

cc:

Date: September 11, 1974

To: Mr. Hal Denis

From: William J. Lederman

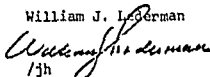
DATE STAMP

Subject: Miami Dade General Hospital - Page 2

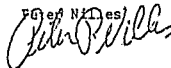
I have personally reviewed this particular account, and while I do not have personal knowledge of the people there, I feel we have delayed making an offer as long as possible.

Mr. Weinstein has cancelled an order with Cooper. At the earliest possible moment, either Claud Mallory and the regional manager or Peter Milles will visit the account.

William J. Lederman


  
/jh

Peter Milles


 approved disapproved

September 11, 1974



## WARREN-TEED PHARMACEUTICALS INCORPORATED



12 WEST GODDALE STREET, COLUMBUS, OHIO 43215  
 (614) 221-5574

Ship To: R.C.W. Associates Inc.  
 876B S.W. 131st St.  
 Miami, Florida 33156

Bill To: Miami Dade General Hospital  
 9333 S. W. 152 St.  
 Miami, Florida 33157

Copy to: Hector Arlotta  
 Keith Moore  
 Claud Mallory  
 Chattanooga  
 Order Dept.  
 fil

Attention: Gerald Weinstein, Director of Pharmacies

Thank you for your recent statement indicating your Estimated Annual Needs of the following product(s).

1,000	Kaon Tablets	100's	@ 2.30/100	1
3,000	Modane Tablets	100's	@ 4.23/100	
3,000	Modane Mild	100's	@ 2.95/100	
1,000	Chymolase	48's	@ 4.78/48	
500	Ilozyme	250's	9.77 @ 9.77/250	
1,000	Ilopan Choline	100's	@ 6.20/100	
200	Ilopan Stat Pak (25 x 2ml)		@ 24.81/25	
7,500	Kaochlor 10%	Pts.	@ .80/pt.	

We will be pleased to provide the above product(s) at the unit price(s) specified, based on the estimated annual quantities indicated in your signed statement.

The unit prices are effective from Sept. 12, 1974 through Sept. 12, 1975.

These products may be ordered as needed, providing each order meets our minimum requirement of \$50.00.

Thank you for your interest in this purchasing arrangement. Should you desire additional information, please consult our medical service representative or write to this office.

Very cordially yours,

WARREN-TEED PHARMACEUTICALS INC.

*William J. Lederman*  
 William J. Lederman  
 Sales Planning Manager

SUBSIDIARY OF ROHM AND HAAS COMPANY

## WARREN-TEED PHARMACEUTICALS INCORPORATED



12 WEST GOODALE STREET, COLUMBUS, OHIO 43215  
 6141-221-5574

Ship To: R.C.W. Associates Inc.  
 8768 S.W. 131st St.  
 Miami, Florida 33156

Bill To: Miami Dade General Hospital  
 9333 S. W. 152 St.  
 Miami, Florida 33157

Copy to: Hector Arlotta  
 Keith Moore  
 Claud Mallory  
 Chattanooga  
 Order Dept.  
 file

Attention: Gerald Weinstein, Director of Pharmacies

Thank you for your recent statement indicating your Estimated Annual Needs of the following product(s).

100,000	Kaochlor 10% S.F.	15ml	@ 0.0975/15ml
14,400	Kaochlor 10% S.F.	4 oz.	@ 0.45/4 Oz.
15,000	Kaochlor 10% S.F.	Pts.	@ 0.80/pt.
5,000	Kaochlor 10% S.F.	Gal.	@ 5.90/gal.
10,000	Kaochlor 20%	Pts.	@ 1.60/pt.
5,000	Kaochlor 20%	Gal.	@ 8.50/gal
50,000	Kaon Elixir	15ml	@ 0.18/15ml
12,000	Kaon Elixir	4 oz.	@ 0.72/4 oz.
1,000	Kaon Elixir	Pts.	@ 2.90/pt.
5,000	Kaon Elixir	Gal.	@ 21.73/gal.

We will be pleased to provide the above product(s) at the unit price(s) specified, based on the estimated annual quantities indicated in your signed statement.

The unit prices are effective from Sept. 12, 1974 through Sept. 12, 1975.

These products may be ordered as needed, providing each order meets our minimum requirement of \$50.00.

Thank you for your interest in this purchasing arrangement. Should you desire additional information, please consult our medical service representative or write to this office.

Very cordially yours,

WARREN-TEED PHARMACEUTICALS INC.

*William J. Lederman*  
 William J. Lederman  
 Sales Planning Manager

June 4, 1976

Mr. Lionel Harris  
Miami Dade General Hospital  
~~DMA Southern Hospital Enterprises~~  
9333 S.W. 152nd Street  
Miami, Florida 33157

Dear Mr. Harris,

In a letter dated May 3, 1976 we listed the quotation prices for 1976 based on your estimated usage of specific Warren-Teed products. Two products, Kaochlor Liquid S-F 10% and Kaon-Cl 20 were excluded because of non-usage in 1975. We now wish to add these products as well as Kaochlor Liquid 10% (with sugar) to our quotation based on a request from our representative, Mr. Hector Arlotta. Mr. Arlotta said you do plan to purchase these products, and this was confirmed by a recent order which included two of these products.

Enclosed is an amended quotation which lists the prices for these products in pints and gallons. Based on estimated usage, we are pleased to quote a price for Kaochlor 10% pints that is lower than our previous estimate (\$1.67 vs. \$1.61).

We appreciate this opportunity to expand the potential for use of Warren-Teed products by your organization.

Sincerely yours,

Donald F. Crooke  
Sales Planning Manager

DFC:tpc

5-27-76

## Miami Dade EAN:

<u>PRODUCT</u>	<u>SIZE</u>	<u>EAN</u>	<u>COST</u>
Kaochlor 10% S-F	Pints	100	\$1.61
Kaochlor 10% w/sug.	Pints	3864	\$1.61
Kaon-C1 20	Pints	1000	\$2.45
Kaon Elixir	Pints	<u>5000</u>	\$3.35
		9964	

Gallons:


Kaon Elixir	Gallon	500	\$24.90
Kaochlor 10% w/sug.	Gallon	500	\$10.60
Kaon C1 20	Gallon	500	\$16.34
Kaochlor 10% S-F	Gallon	400	\$10.60

Add to EAN Contract:

Kaochlor 10% S-F	Pint	100	\$ 1.61
Kaochlor 10% S-F	Gallon	400	\$10.60
Kaochlor 10% w/sug.	Pint	3864	\$ 1.61
Kaochlor 10% w/sug.	Gallon	500	\$10.60
Kaon-C1 20	Pint	1000	\$ 2.45
Kaon-C1 20	Gallon	500	\$16.34

Ronald Clark, of W.T.  
 explains that there are  
 drawings to help in making  
 large sales which they pass  
 along to customer

IMPORTANT



cc: H. Arlotta/6105  
JPC FILE

May 3, 1976

Mr. Lionel Harris  
Miami Dade General Hospital  
9333 S.W. 152nd Street  
Miami, FL 33157

Dear Mr. Harris:

I have recently assumed responsibility for the Bids and Contracts Department of Warren-Teed Pharmaceuticals Inc. Mr. Lederman, who formerly managed this department, is now a Sales Manager in our St. Louis region. My department remains under the direction of Mr. Peter Nilles, Director of Sales.

I appreciate the fine relationship that has existed between Miami Dade General Hospital and Warren-Teed, and hope it will continue.

The objective of the Bids and Contracts Department is to increase usage of Warren-Teed products at prices favorable to the customer and our company. ~~We cannot offer these prices to customers who purchase large quantities during a one year period. Those customers who purchase with these large quantities that we are going to pay along~~

Our representative in your area, Mr. Hector Arlotta, recently sent us your estimated annual needs for the coming year. We have reviewed your purchases for the past twelve months compared with your estimated needs for the period. We are pleased to submit new quotations for those products which have come close to your last year's estimate. In each case they are the same as submitted by Mr. Arlotta. We are not bidding on the following products because our records indicate that you have made no purchases during the past year:

Kaochlor Liquid S-Y 10X, pints and gallons  
Kaon-CL 20X, pints and gallons (This product was formerly called Kaochlor Concentrate 20X.)

If your non-usage of these products is due to dissatisfaction in any respect, please let me know. We would like the opportunity to discuss your reasons and submit new prices.

I look forward to the opportunity to meet with you in the near future.

Sincerely yours,

Donald F. Crooks  
Sales Planning Manager

DFC:nc

*Don't care  
what hospital  
needs - require  
them to buy big  
(Don't you want them  
to buy big?)*

REQUEST FOR QUANTITY PRICE QUOTATION  
(Based Upon Estimated Annual Needs)

Institution: MIAMI DADES GEN HOSP  
(print clearly)

Rep. H. Carlin

Address: 2549377 SW 15th St.

Terr. # 6105

Miami FL 331  
City State Zip

Branch chest

Authorized Signature: [Signature]

Date Request 4/2/76

Title: Pres. LANEY HARRELL

Date for Close 4/2/76

National Drug Code Number	Product	Size	Number of Units	Quota Per Unit
0013-1201-17	Axonal Tablets C.T.	100		
-23		1000		
0013-1233-51	Bar-Don Elixir	pint		
-53		gal.		
0013-1291-17	Bar-Don Tablets C.T.	100		
-23		1000		
0013-1611-14	Chymolase Tablets RGT	48		
-19		250		
-23		1000		
-18		100		
0013-2311-17	Stat-Pak	100		
831	Liopan-Choline	100		
0013-2357-86	Liopan Injection	100		
-97		500		
0013-2966-85	Liopan Injection	100		
0013-6701-17	Liozof Capsules	100		
0013-3103-51	Kaochlor 10%	pint		1.01
-53		gal.		
-56		4 oz		
-58	Stat-Pak	15ml		13.8
0013-3093-51	Kaochlor 10% SF	pint	100	
-53		gal.		
-56		4 oz		
-58	Stat-Pak	15ml		
0013-3113-51	Kaochlor Concentrate 20%	pint	7000	3.45
-53		gal.		14.4
-56		4 oz		
0013-3051-16	Kaochlor EFF Tablets	60		
0013-3121-17	Kaon Tablets SCT	100	5900	3.54
-21		500		
-18	Stat-Pak	100		
0013-3203-51	Kaon Elixir Grape	pint	7000	3.24
-53		gal.		14.4
-56		4 oz		
-58	Stat-Pak	15ml		
0013-3303-51	Kaon Elixir Lemon-Lime	pint		
-53		gal.		
-58	Stat-Pak	15ml		
0013-3071-19	Kaon-CI Tabs	250	500	5.25
-21		1000	1000	14.86

National Drug Code Number	Product	Size	Number of Units	Quote Per Unit	
0013-5033-51	Modane Liquid	pint			
0013-5011-17	Modane Tablets SCT	100	5460	3.20	5.20
-23		1000			
-18		Stat-Pak	100		
0013-5011-07	Modane OTC	10's			
-13		30's			
0013-5021-17	Modane Mild Tablets SCT	100	1000	3.50	3.50
-23		1000			
0013-5054-61	Myoflex Cream	2 oz			
-74		lb.			
0013-6083-51	Pektamalt	pint			
0013-6221-17	Ratio	100			
0013-6501-17	Salrin Tablets CT Scored	100			
-23		1000			
0013-6806-86	Secretin-Boots	10ml			
0013-7074-61	Taloin Ointment	2 oz			
-74		lb.			
0013-7101-17	Teeds Lozenges	100			
-23		1000			
0013-7363-39	Tympagesic	13ml			
0013-8083-51	Ventilade Syrup	pint			
-53		gal.			
0013-8333-48	W-T Lotion	8 oz			
-53		gal.			

COMMENTS: *None of the figures used as a basis for estimating annual consumption are based on usage. The figures are based on a significant increase in business for 1976 for the product.*  
*Heute Schmitt*

Thank you for your statement indicating your estimated annual needs for the above products. Upon review and acceptance, you shall be notified within 10 days.

Very cordially yours,  
 WARREN-TEED PHARMACEUTICALS INC.  
 William J. Lederman, R.Ph.  
 Sales Planning Manager

Subsidiary of:  
 Rohm and Haas Company

~~QUANTITY PRICES AVAILABLE ONLY TO HOSPITALS AND CONSUMING INSTITUTIONS  
 BASED ON QUANTITY, PRICE, QUANTITY BASED ON ESTIMATED ANNUAL NEEDS.~~



*Bell Teleman*

FROM: *Walt Gilbert*  
WARREN-TEED PHARMACEUTICALS, INC.  
582 WEST GOODALE STREET  
COLUMBUS, OHIO 43215

SUBJECT

*Miami Dade Gen Hosp Bud # 1576*

DATE *4/4/56*

MESSAGE

*The attached E. A. C. for Miami Dade  
Gen Hosp is based on last years consumption.  
It will advise suitability, so please do not delay.  
Best regards  
Please do find the standard catalogue.*

*P.S. Please explain the unusual caution remarks - *Hygiene?**

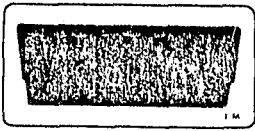
REPLY TO

DATE

[Empty lines for reply]

SIGNED

ANSWER NOW! KEEP WHITE - RETURN PINK



1. white hall checks out OPUS  
Christie + Weinstein —  
get lousy replies but  
ship anyway —
2. Inter office memo (Kowitz 58)  
says products could be  
diverted but 85,74% profit  
on 109,058 orders worth it —
3. 60% profit to "charity" not good  
enough — they raised prices.



XC-SSM  
ESP

OPUS CHRISTI AMERICA, INC.

P. O. BOX 540592  
MIAMI, FLORIDA 33154  
TELEX 312490-Symic MSPG  
TELEPHONE (305) 233-3222  
DÉLÉGATION GÉNÉRALE  
34, VIA DI PORTA PINCIANA  
00187 ROMA - TELEX 62352  
TEL 479 346-479.103

19 January, 1976

WHITEHALL INTERNATIONAL  
685 Third Avenue  
New York, N.Y. 10017

Attention Mr. Bill De Mucci, Treasurer

	<u>PRODUCT</u>	<u>SIZE</u>	<u>QUANTITY</u>	<u>GUIDE LINE PRICE</u>
1.	Anacin	50's	1,000 Doz.	\$ .34
2.	"	100's	1,000 Doz.	.52
3.	"	200's	1,000 Doz.	.92
4.	Amberol	1/3 oz.	200 Doz.	.35
5.	Arthritis Pain Formula	40,s	500 Doz	.32
6.	Bisodol Mints	100,s	100 Doz	.40
7.	Dristan Tablets	24,s	1,200 Doz	.41
8.	"	50,s	1,400 Doz	.78
9.	"	100,s	1,200 Doz	1.23
10.	" Nasal Spray	15 cc	1,200 Doz	.40
11.	" " "	30 cc	1,000 Doz	.66
12.	Freezone	1/3 oz.	300 Doz	.23
13.	Heat Linament	2-1/3 oz.	250 Doz	.41
14.	" Cream	2 oz.	300 Doz	.43
15.	Outgrow	.31 oz.	100 Doz	.46
16.	Preparation H Oint.	1 oz.	2,000 Doz	.44
17.	" " "	2 oz.	2,000 Doz	.74
18.	" " Supp.	12's	1,800 Doz	.58
19.	" " "	24,s	1,600 Doz	1.01
20.	Primatine Mist w Mouthpiece	15 cc	200 Doz	1.10
21.	" " Refill	15 cc	200 Doz	.98
22.	" Formula M Tablets	24,s	250 Doz	.43
23.	Sleep Eye	26,s	100 Doz	.55

00042

OPUS CHRISTI: SECRETARIAT GÉNÉRAL 1711 GENÈVE CASE POSTALE 107  
OPUS CHRISTI DEUTSCHLAND & FRANKFURT/MAIN, ROCKENHEIMER ANLAGE 30



CHRIST AMERICA, INC.  
 P. O. BOX 560572  
 MIAMI, FLORIDA 33156  
 TELEX 312490  
 TELEPHONE 1-305-332-3332  
 TELEVISION GENERALE  
 AVENUE DE LA REPUBLICA  
 287 ALGERIE - TELER 425147  
 TEL 021 246-475 603

19 January, 1976

WHITEHALL INTERNATIONAL  
 685 Third Avenue  
 New York, N.Y. 10017

Attention Mr. Bill De Mucci, Treasurer

PRODUCT	SIZE	QUANTITY	GUIDE LINE PRICE	PRICE	PRICE	PRICE	PRICE
1. Anacin	50's	1,000 Doz.	.34	1.65	1.53	4.250	5.50
2. "	100's	1,000 Doz.	.32	6.24	2.56	11.00	2.50
3. "	200's	1,000 Doz.	.32	11.24	5.16	1.950	3.50
4. Ambsol	1/3 oz.	300 Doz.	.35	2.20	1.63	1.400	1.50
5. Arthritis Pain Formula	40's	100 Doz.	.32	3.54	5.60	5.754	2.126
6. Bisodol Mints	100's	100 Doz.	.40	4.80	1.78	13.100	4.242
7. Ditatan Tablets	24's	1,200 Doz.	.41	4.72	3.63	17.712	6.504
8. " " "	50's	1,200 Doz.	.78	14.76	5.32	5.000	1.880
9. " " "	100's	1,200 Doz.	1.23	2.80	1.77	7.920	2.010
10. " Nasal Spray	15 cc	1,200 Doz.	.40	7.22	2.68	5.571	5.571
11. " " "	30 cc	1,000 Doz.	.66	2.76	1.97	1.320	9.520
12. " " "	1/3 oz.	300 Doz.	.23	4.72	3.81	5.571	5.571
13. Heat Linament	2-1/3 oz.	250 Doz.	.43	5.16	7.00	16.560	5.500
14. Cream	2 oz.	300 Doz.	.44	5.22	2.89	17.760	5.500
15. Gummy	31 oz.	100 Doz.	.44	5.22	1.25	12.528	3.580
16. Preparation H Oint.	1 oz.	2,000 Doz.	.74	1.89	2.38	2.670	2.180
17. " " "	2 oz.	2,000 Doz.	.58	6.16	3.10	2.352	1.402
18. " " Supp.	12's	1,800 Doz.	1.01	12.12	3.88	1.700	8.020
19. " " "	24's	1,800 Doz.	1.10	13.20	11.61	1.250	2.14
20. Peppermint Mist w Mouthpiece	15 cc	200 Doz.	.98	11.76	6.54	6.60	5.025
21. " " Refill	15 cc	200 Doz.	.43	5.16	2.41	2.41	2.41
22. " Formula M Tablets	24's	250 Doz.	.55	6.60	2.18	2.41	2.41
23. Sleep Etc	26's	100 Doz.					

00016

199

Whitehall Co. products project to sell out products in 1976  
 They have a lot of products to sell in 1976 and they are  
 looking for a distributor to sell their products in 1976

406.000  
 607.000 + 406.000

ARPC

12

FEBRUARY 10, 1976  
~~W.F. DE MUCCI~~

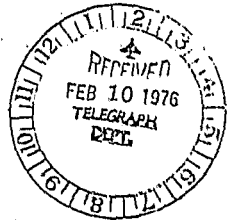
W I I  
32478

TELEX NO. 32478

BRAXTON

MILAN (ITALY)

*N.Y.*  
RINALDI OUR EXPORT DIVISION HAS RECEIVED A TENTATIVE ORDER FROM A CUSTOMER  
NAMED OPUS CHRISTI STOP WE WOULD LIKE TO CHECK ON THIS CUSTOMER CONCERNING  
CREDIT AND REPUTATION STOP THEY CLAIM THEY ARE HEADQUARTERED IN ROME AT THE  
FOLLOWING ADDRESS : DELEGATION GENERALE, 34 VIA DI PORTA PINCIANA, 00187  
ROME, TELEX 62352, TELEPHONE 479.346-479.103 STOP WE WOULD BE MOST GRATEFUL  
IF YOU COULD PROVIDE US WITH ANY INFORMATION ABOUT THIS ORGANIZATION STOP  
A TELEX REPLY WOULD BE APPRECIATED DEMUCCI



cc: Mr. S.S. Mazarin

00041

RCA0559-12#  
- 223214 AMERHOME  
- 223214 AMERHOM  
32478 BRACON

MR. DEMUCCI

RE OPUS CHRISTI YOUR TELEX IS IN THE HANDS OF MY PARTNER LUIGI MACCHI  
DI CELLERE OF OUR ROME OFFICE WHO WILL CONTACT YOU UPON COMPLETION  
OF INVESTIGATION.

REGARDS  
RINALDI, #  
223214 AMERHOM  
32478 BRACON.....

00017

Reply via RCA: call 212-363-4141

February 10, 1976

MEMO TO FILE

RE: MR. PHILLIP WEINSTEIN  
OPUS CHRISTI AMERICA, INC.

In reference to the interest of Mr. Phillip Weinstein, from OPUS CHRISTI AMERICA, INC. Miami, in buying certain quantities of Whitehall products to be exported to ~~CARTMAS, charitable operations~~ overseas, we contacted over the telephone Dr. Juan Gasso, of J. GASSO GASSO, in the Dominican Republic and who Mr. Weinstein offered as a reference.

Dr. Gasso informed that he knows Mr. Weinstein personally and he has had some business dealings in the past which included the manufacturing through Mr. Weinstein of certain pharmaceutical products for the Dominican Republic.

Dr. Gasso further added that as far as he understands, Mr. Weinstein is semi-retired and has a distribution of pharmaceutical products to hospitals throughout the D.R. He appears to be well connected with pharmaceutical companies such as UPJOHN and PFIZER.

Early this year, Mr. Weinstein visited the Dominican Republic to explore with Gasso the opportunities to export pharmaceutical products to this market. He was advised by Dr. Gasso that because of the distributors' protective law in the Dominican Republic, the importation of any pharmaceutical products having exclusive distributorship arrangements in the island would be outlawed.

~~Dr. Gasso somehow finds it illogical that Mr. Weinstein is involved in a non-profitable organization.~~

ESP/ef

cc: S. S. Mazarin  
 W. F. DeMucci

00019

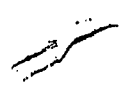
## WHITEHALL INTERNATIONAL INC.

685 THIRD AVENUE  
NEW YORK, N. Y. 10017 U. S. A.

Telephone  
Yukon 6-1000

Cable Address  
INTERWHITE, NEW YORK

February 13, 1976



Mr. Phillip Weinstein  
Opus Christi America, Inc.  
P.O. Box 560592  
Miami, Florida 33156

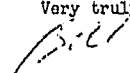
Dear Mr. Weinstein:

Enclosed please find a list of Whitehall International products, quantities and prices at which we would be willing to sell to Opus Christi America. While the prices quoted are higher than your guideline prices, I think you will see that they are quite reasonable and, in fact, are the lowest export prices which we sell at.

If you agree to place an order for the attached prices and quantities, our terms, as we had agreed, would be cash with order. I am also attaching a price list which you can use as a guide for any future orders you might want to enter with us.

I hope the above is satisfactory and look forward to receiving confirmation of this order in the near future. I would also like to say it was a pleasure meeting with you during your recent trip to New York and I hope we can establish a long business relationship.

Very truly yours,



William F. DeMucci  
Treasurer

WFD:mcg

bcc: Messrs: S.S. Mazarin  
E.S. Parapar  
C. de Hegedus

00014



February 13, 1976

SUGGESTED EXPORT ORDER FOR OPUS CHRISTI AMERICA, INC.NET EXPORT PRICES C.I.F. MIAMI, FLA.TERMS: CASH WITH ORDER

<u>CODE</u>	<u>PRODUCT</u>	<u>SIZE</u>	(DOZENS) <u>QUANTITY</u>	<u>PRICE</u> <u>PER DOZ.</u>	<u>AMOUNT</u>
0200-35	ANACIN	50's	500	\$ 7.72	\$ 3,860.00
0200-45	ANACIN	100's	500	11.89	5,945.00
0200-55	ANACIN	200's	200	22.11	4,422.00
0220-10	ANBESOL	.31 fl. oz.	200	7.50	1,500.00
0270-10	A.P.F.	40's	500	7.20	3,600.00
1240-20	DRISTAN TABLETS	24's	500	9.61	4,800.00
1240-30	DRISTAN TABLETS	50's	500	16.89	8,445.00
1240-40	DRISTAN TABLETS	100's	500	25.44	12,720.00
1200-20	DRISTAN NASAL MIST	15 cc.	500	9.61	4,805.00
1200-30	DRISTAN NASAL MIST	30 cc.	500	14.83	7,415.00
1520-10	FREEZONE	.31 fl. oz.	300	4.72	1,416.00
1700-10	HRET LINIMENT	2 1/3 oz.	250	7.64	1,910.00
2530-10	OUTGRO	.31 fl. oz.	100	9.85	985.00
2870-10	PREP H OINTMENT	1 oz.	500	10.77	5,385.00
2870-20	PREP H OINTMENT	2 oz.	500	18.22	9,110.00
2880-10	PREP H SUPPOSITORIES	12's	500	13.33	6,665.00
2880-20	PREP H SUPPOSITORIES	24's	500	24.22	12,110.00
2910-20	PRIMATENE MIST Complete				
	Unit	15 cc.	200	27.00	5,400.00
2910-30	PRIMATENE MIST Refill	15 cc.	200	24.12	4,824.00
2930-10	PRIMATENE TABS. (M)	24's	250	9.88	2,470.00
3410-20	SLEEP-EZE	26's	100	12.71	1,271.00
<u>TOTAL NET AMOUNT:</u>					<u>\$109,058.00</u>

ABOVE PRICES ARE QUOTED IN U.S. DOLLARS AND COVER PRODUCT LICENSED FOR EXPORT ONLY. DIVERSION CONTRARY TO U.S. LAW PROHIBITED. PRICES SUBJECT TO CHANGE WITHOUT NOTICE. ANY ORDER SUBJECT TO ACCEPTANCE BY WHITEHALL INTERNATIONAL, INC.

00020



OPUS CHRISTI AMERICA, INC.  
 WAREHOUSE NO. 2  
 P.O. BOX 560592  
 8766 Southwest 129th Terrace  
 MIAMI, FLORIDA 33176

DÉLEGATION GÉNÉRALE  
 34, VIA DI PORTA PINCIANA  
 00187 ROME - TELEX 62352  
 TEL. 479.316-479.103

TELEX 512490 SONIC MSPG  
 TELEPHONE (305) 233-3222

3 March, 1976

W. F. D.

MAR 05 1976

Mr. William F. DeMucci  
 Treasurer  
 Whitehall International, Inc.  
 685 Third Avenue  
 New York, N.Y. 10017  
 U.S.A.

Dear Mr. DeMucci,

Your suggested export order for Opus Christi America, Inc. had been forwarded for comment and approval.

Our return response was general dissatisfaction with the price structuring which was almost double the guide lines set for us and based upon similiar products currently being purchased in Switzerland and in Italy.

There is no question however, that interest is high in U.S. Brandnames and U.S. labels. We have therefore been instructed to place an order for the quantities shown on our enclosed Purchase Order No. 76015 (for which we have been funded), together with the following provisos.

1. We are to open discussions within the next month or two to discuss a bid price within the area of our earlier guide line price.
2. Clarification of entitlement to free goods (1 per 11) when offered by Whitehall.
3. Cash discounts for pre-payment (note the usual 2% was taken on this initial order). Other discounts on quantity purchase, special deals, allowances for freight and duty payment.

We will normally anticipate placing a second order within a week of the receipt of our initial order, or as soon as we are aware of your delivery cycle and our shipping dates.

00032



OPUS CHRISTI AMERICA, INC.  
WAREHOUSE NO. 2  
P.O. BOX 560592  
8766 Southwest 129th Terrace  
MIAMI, FLORIDA 33176

DÉLÉGATION GÉNÉRALE  
34, VIA DI PORTA PINCIANA  
00187 ROME - TELEX 62352  
TEL. 479.346-479.103

3 March, 1976

Page 2- cont'd

Our export manager Mr. Weinstein will probably be in communication with you, or you may call him if there are any questions.

For the time being let me also convey my hope that we can establish a satisfactory working relationship within the next few months and for a long time thereafter.

Very sincerely yours,

OPUS CHRISTI AMERICA, INC.

00033

  
Pablo Ortega T.  
Director General

POT/Lp

Encl/ Cashier's Check

OPUS CHRISTI AMERICA, INC.  
P.O. BOX 860582  
8766 SOUTHWEST 129TH TERRACE  
MIAMI, FLORIDA 33176  
TELEX 912490-SONIC MSPG  
TELEPHONE (305) 233-3222



DÉLEGATION GÉNÉRALE  
3A, MA D'ORTA PINCIANA  
00487 POMÉ - TÉLÉX 42352  
TL. 479.344-479.103

CERTIFIED PURCHASE ORDER

7601E

GOODS REQUESTED FROM

SHIP GOODS TO

WHITEHALL INTERNATIONAL, INC.  
685 THIRD AVENUE  
NEW YORK, N.Y. 10017  
U.S.A.

OPUS CHRISTI AMERICA, INC.  
8766 SOUTHWEST 129 TERRACE  
MIAMI, FLORIDA 33176

DATE OF ORDER March 3, 1976  
YOUR QUOTATION # 2-13-76  
SHIP VIA:  
Carolina Freight Carriers

GOODS ARE FOR EXPORT ONLY  
TERMS OF PAYMENT:  
Pre-Paid

NO.	QUANTITY		DESCRIPTION	DOZ. UNIT	PRICE
	ORDERED	SHIPPED			
1.	200	0200-35	ANACIN 50's	7.72	1544
2.	200	0200-45	ANACIN 100's	11.89	2378
3.	100	0200-55	ANACIN 200's	22.11	2211
4.	200	0220-10	ANBESOL .31 fl. oz.	7.50	1500
5.	250	0270-10	A.P.F. 40's	7.20	1800
6.	200	1240-20	DRISTAN TABLETS 24's	9.61	1922
7.	200	1240-30	DRISTAN TABLETS 50's	16.89	3378
8.	300	1240-40	DRISTAN TABLETS 100's	25.44	7632
9.	100	1200-20	DRISTAN NASAL MIST 15 cc	9.61	961
10.	200	1200-30	DRISTAN NASAL MIST 30 cc	14.83	2966
11.	200	1520-10	FREBZONE .31 fl. oz.	4.72	944
12.	150	1700-10	HEET LINTMENT 2 1/3 oz.	7.64	1146
13.	50	2530-10	OUTGRO .31 fl. oz.	9.85	492
14.	100	2870-10	PREP H OINTMENT 1 oz.	10.77	1077
15.	100	2870-20	PREP H OINTMENT 2 oz.	18.22	1822
16.	200	2880-20	PREP H SUPPOSITORIES 12's	13.33	2666
				00038	
				SUBTOTAL.....	\$ 34,439
				LESS 2%.....	688
				TOTAL.....	\$ 33,750

APPROVED BY

CERTIFIED BY:

*Charles Ortega*

TITLE DIRECTOR GENERAL

OPUS CHRISTI AMERICA, INC.

DIXIE NATIONAL BANK of DADE COUNTY <sup>1211</sup>/<sub>476</sub> C 62428

MIAMI, FLORIDA Mar. 3, 1976

Pay to the order of \*\*\*Whitehall International, Inc.\*\*\*

\*33,750.71\*

DIXIE NAT'L BANK \$33,750 AND 71 CTS

DOLLARS

CASHIER'S CHECK remitter: Opus Christi America, Inc.

*[Handwritten Signature]*  
AUTHORIZED SIGNATURE

⑆0670⑉0158⑆

⑈92 001 0⑈

00031

When payment in advance  
 MDSE FOR HOSPITAL USE ONLY

	10cc Talwin injectable	15cc Suppl. Mastometer		
1/24/74	3000	432		
1/16/75	<del>3500</del>	1440		
4/11/75	3500	1728		
3/21/75	2500	1440		
5/15/75	100	100		
6/8/75	1500	1240		
10/22/75	2500	1872		

Note on 5/1/75 New York limits his purchases to 100 per month on above 2 items - This lasts 1 month - Sure etc back to normal

In 4 MONTHS, ordered 12,500 - 10cc VIALS - Talwin  
 or 12,000 DOSES - other 5040 Suppl  
 Mastometer - 15cc

LOOK at other items in the order

W. F. FARMER  
 W. YORK, N. Y. 10016

OFFICE COPY

MIAMI CASE GEN HOSP PCY  
 9332 S W 152ND ST  
 MIAMI FL 33157

A DISCOUNT OF 2% WILL BE ALLOWED  
 IF PAID BY 10TH OF MONTH  
 FOLLOWING INVOICE DATE. NET  
 AMOUNT DUE END OF DISCOUNT MONTH

WINTHROP LABORATORIES  
 P.O. BOX 100515  
 ATLANTA, GEORGIA 30348

5 01-71-017 WF 4 1-244845-000-3 10-22-75 30974

HTA 10-22-75 HOSPITAL TRANSPORT CO

			PRICE		GROSS	
10	C-430	CARBOCCAINE VIAL 1.5% 30CC	1.08	C	10.80	10.80
20	H-581	HYPACUE MEG 603 50ML VIALS 10	19.60	I	392.00	392.00
456	I-241	ISUPREL SOLUTION 1-200 10CC	1.45	B	661.20	661.20
456	I-245	ISUPREL SOLUTION 1-100 10CC	1.54	B	702.24	702.24
1,872	I-350	ISUPREL MISTMETER 15CC	1.94	B	3,631.68	3,631.68
20	P-216	PHISCHEX PLASTIC GAL	5.41	B	108.20	108.20
12	P-200	PENICILLINE SOL 1/24 N-D 15CC	1.01	B	12.12	12.12
2,500	T-490	TALWIN VIALS 30MG/1ML 10ML 15	1.33	B	3,325.00	3,325.00
2	T-555	TALWIN UNI-AMP 45MG 1.5ML 5X5	8.02	T	16.04	16.04
4	T-565	TALWIN UNI-AMP 60MG 2ML 5X5	9.44	T	37.76	37.76
4	Z-462	ZEPHIRAN AC SOL 1-750 4X1 GAL	4.64	Z	18.56	18.56
GROSS TOTAL					8,915.60	8,915.60

OUT OF STOCK-SHIPMENT WILL FOLLOW

10	C-400	CARBOCCAINE VIAL 1% 30CC
1	H-170	HYTAKEROL CAP 5G
300	H-664	HYPACUE MEG 303 300ML WYSET
5	I-330	ISUPREL AMP 1-500 5CC 10
5	L-660	LEVOPHEG 0.2% AMP 4CC 10

QUANTITY-PRICED ITEMS FOR HOSPITAL USE ONLY

L CASES SHIPPED 53 TOTAL WEIGHT 507 LBS.

A CASH DISCOUNT OF 176.31 WILL BE ALLOWED  
 IF PAID BY 11/10/75. NET AMOUNT DUE 11/30/75 8,915.60

MIAMI, FLA. 33157

OFFICE COPY

MIAMI CASE GEN HOSP PCY  
 9332 S W 157ND ST  
 MIAMI FL 33157

A DISCOUNT OF 2% WILL BE ALLOWED  
 IF PAID BY 10TH OF MONTH  
 FOLLOWING INVOICE DATE. NET  
 AMOUNT DUE END OF DISCOUNT MONTH

WINTHROP LABORATORIES  
 P.O. BOX 100515  
 ATLANTA, GEORGIA 30348

CI-71-G17 HF 4 1-244845-000-3 05-08-75 16874

TA 05-08-75 UNITED PARCEL SERVICE ZONE 4

			PRICE	GRSS	
100	I-350	ISLAPREL MISTMETER 15CC	1.94 3	194.00	194.00
100	T-490	TALBIN VIALS 30MG/14L 10ML 15	1.33 3	133.00	133.00
GRSS TOTAL				327.00	327.00

QUANTITY-PRICED ITEMS FOR HOSPITAL USE ONLY

CASES SHIPPED 2 TOTAL WEIGHT 27 LBS.

A CASH DISCOUNT OF 2% WILL BE ALLOWED  
 IF PAID BY 06/10/75. NET AMOUNT DUE 06/30/75 327.00



PHONE INSTRUCTIONS FROM MR TORRELL 5-1-75

#1. Atlanta Call Mr Harris

CAN ONLY SHIP (per month)

100 - T490 TALWIN

100 - I350 MISTOMETERS

PER MONTH - PER N.Y.

#2. - WILL REFUND OVER PAYMENTS  
Wants Atlanta to handle  
with N.Y. Credit Dept

#3 DIVISION MANAGER WILL  
CALL ON HOSPITAL  
& EXPLAIN.

#4 N.Y. CREDIT DEPT. (DEE NICKY)  
SAID LET HER KNOW IN AM,  
IF HOSP WANTED ABOVE SHIPPE  
NOW (TO APPLY AGAINST CREDIT BALANCE  
N.Y. will plan phone me  
Harris & make the Refund Be

Page  
2



Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. KOWITT, again in the same line of questioning, now you were in the business of diversion for many years.

Mr. KOWITT. I was a wholesaler that specialized in products that came through the diversion market, but I don't consider myself a diverter. To me, a diverter is the hospital or the entity that does the ordering, and then sells it to a wholesaler.

Mr. BILIRAKIS. All right. We have—apparently our investigation has indicated that there is an awful lot of instances of expired drugs, knowingly being purchased somewhere in the scheme of things, and ultimately by a drugstore or by a pharmacist.

Mr. KOWITT. My experience is that—I know I certainly never bought anything like that. It was never even offered to me. I don't know of any wholesalers that do, and I don't know of any of my customers that would buy that product. Certainly not an Eckerd Drug.

Mr. BILIRAKIS. Certainly not an Eckerd Drug?

Mr. KOWITT. Certainly not, in my opinion.

Mr. BILIRAKIS. OK. Who would be the people that might tend to, with a pair of scissors or whatever, cut off the labeling, the expiration date? Would that be maybe the independent?

Mr. KOWITT. I think he would be the only one that really stood to profit from it, because he can use it in his own drugstore and nobody might find out about it.

Mr. BILIRAKIS. Are you aware that salesmen sometimes do not return expired drugs?

Mr. KOWITT. No, I am not.

Mr. BILIRAKIS. You are not aware of that.

All right. Thank you, Mr. Chairman.

I have taken, I guess, more than my time.

Mr. SLATTERY [presiding]. Mr. Kowitt, I understand that in your case in Florida, sales or donations by pharmaceutical manufacturers to several allegedly charitable organizations were involved. Did you find anything strange about the products that were being sold?

Mr. KOWITT. Yes, I did.

Mr. SLATTERY. Can you elaborate on what you learned?

Mr. KOWITT. Sure. Parke-Davis, for example, sold hundreds of thousands of cycles, again which is a month's supply of birth control pills, in no less than 12 different styles to a charity by the name of Opus Christi, headquartered in Rome, and which most people believed was affiliated with the Catholic Church. Even an internal memo that was provided to me refers to Opus Christi as the Catholic organization. So I believed that they felt that it was affiliated with the Catholic Church.

Mr. SLATTERY. And who did you say sold the hundreds of thousands of birth control pills?

Mr. KOWITT. That is Parke-Davis Laboratories.

Now Ortho also sold very large quantities of birth control pills to this charity.

Mr. SLATTERY. Do you have any other interesting cases of sales to alleged charitable organizations?

Mr. KOWITT. Well, in another case, as I mentioned earlier, Whitehall Laboratories either sold or bid on products such as Neet, which is a depilatory used to remove hair from ladies' legs.

Mr. SLATTERY. Could you repeat that?

Mr. KOWITT. It's a depilatory, a product used to remove hair from ladies' legs. Outgro, a medication for ingrown toenails, and Freezezone, used as a liquid corn and callous remover, to a charity for alleged use in the Caribbean.

Mr. SLATTERY. Why would a company ship such goods for alleged use by a charity in the Caribbean? Don't you believe they knew the goods were ultimately for resale?

Mr. KOWITT. Yes. In an exhibit that I introduced at my trial, there was an internal memo from the company which made clear the fact that they definitely were aware of the possibility of this merchandise being diverted. They discussed it in the memo, but decided to ship, because they were earning an \$85,000 profit on the sale of \$109,000 to this charity.

Mr. SLATTERY. A 79-percent return?

Mr. KOWITT. A 79-percent gross profit, that is correct.

Mr. SLATTERY. Without objection, I would like to introduce exhibit 10, an October 25, 1976 interoffice memorandum between the employees of the Ortho Pharmaceutical Corp. Ortho sold to the bogus charities established by Mr. Berkey, et al., is that correct?

Mr. KOWITT. Yes, sir, it is.

Mr. SLATTERY. Let me enter the exhibit 10 into the record.  
[The exhibit referred to follows:]



# Ortho Pharmaceutical Corporation

Exhibit 10

INTER-OFFICE MEMORANDUM

C O N F I D E N T I A L

To:	Mr. W. B. Anderson	Date:	October 25, 1976
From:	John D. Feike	cc:	Mr. F. Lusky Mr. G. V. Parlin Mr. R. N. Wilson Mr. R. Gelbman
Subject:	<u>SOURCES OF DIVERSION</u>		

As we have discussed, it appears at this point that we have effectively cut off the major sources of ORTHO-NOVUM diversion. Retail drugstores which purchased diverted ORTHO-NOVUM in the past are now advising that they can no longer get merchandise.

This, of course, does not mean that we are letting our guard down nor does it mean that our investigations are complete. Frank Lusky and I continue to pursue the likes of Opus Christi, Interchurch Medical Assistance (IMA), International Christian Relief (ICR), Church of God, and other apparently involved organizations to determine the extent of involvement and to make sure that, through organizational and personal name changes, the people running these programs do not obtain our merchandise through alternate, devious methods.

~~It is felt that our new program, LUSKY's and my efforts, on the part of some of the few retail authorities on pharmaceutical products, diversion, what we ran into with Opus Christi was just the tip of the iceberg. Our investigations show that almost all pharmaceutical companies are involved in some way or another, and in most cases to a much greater degree than Ortho. It has been very interesting to find that many of these companies express very little concern over diversion events when they know their product is involved. There are exceptions to this rule, however; and based on information obtained from other drug companies plus what we have found out on our own, we can now anticipate and chart diversion efforts in advance.~~

A good case in point is the ongoing efforts of John Berkey of Opus Christi in his dealings with Merrill National. When Merrill first agreed to do business with Opus Christi, they were advised to bill Opus Christi and ship to Dulles International Airport in care of the president of the airport facility, Admiral Gardiner (Retired). Here the drugs were to be consolidated and shipped to missions overseas.

After a short time, Berkey advised that Admiral Gardiner was having financial problems; and through an agreement with Arthur Wilde of IMA, they should bill to and ship to IMA at the Church of the Brethren warehouse in New Windsor, Maryland. It wasn't long before IMA and

*Book*  
*Ortho*  
*etc.*

the Brethern (thanks to our efforts) decided they did not want to do any more business with John Berkey of Opus Christi. At this point, Berkey advised Merrill to "bill to" Opus Christi and "ship to" American Medicinal International in Miami. Merrill investigated American Medicinal and found, as we have found, that this account had a history of diversion. They advised John Berkey of this and said this account was not acceptable. John Berkey then told Merrill to ship the order to the Church of God warehouse in Fairfax, Virginia. At this point in time, Merrill National is not sure what is going on . . . . but we do.

We know that Opus Christi is a diverter and that they, through John Berkey, will go to any length to get the merchandise they need. IMA appears to be involved. IMA not only did business with Opus (for a 5% commission) but also secured product for International Christian Relief (for a 5% commission) who has a history of diversion by way of its tie in with Darius Associates. Even though IMA may not be diverting the products they purchase, the fact that they purchased for ICR without advising us is enough justification for us to no longer do business with them.


American Medicinal, as you may recall, is the organization which wrote to Arnold Cronk asking if an arrangement could be made to ship sizable quantities of Ortho merchandise to Belgium for resale to iron curtain countries. This inquiry was made by a Mr. Solomon Huriash to Dr. Cronk on behalf of American Medicinal. The initial order alone was for approximately \$300,000 with repeat orders to follow. Under no circumstances should we consider doing business with these people.

Church of God has written and phoned me several times. They claim to have a strong demand for our products in their missions overseas. It is obvious to us that a definite tie in exists between Bob Murphy and Reverend Willets of Church of God and John Berkey of Opus Christi. We definitely should not sell or donate any of our products to this organization.

We, Frank Lusky and myself, are continuing to correspond with both American Medicinal and Church of God in order to become better informed regarding possible diversion activities, contacts, and secondary sources of distribution of diverted merchandise. At a certain point in the near future, however, we will have to let them know that we will not do business with them.

We continue to have contact with Arthur Wilde of IMA in an effort to better determine the activities of his association and his involvement with International Christian Relief and other organizations.

Insofar as Opus Christi is concerned, we have made several appointments with John Berkey only to have them cancelled at the last moment. During our latest phone call to John Berkey, he advised that he was willing to "blow the lid" off of the total diversion program, but wanted some sort of "protection" in return. We think we have put the total program together on our own, however, we look forward to discussing the issue with Berkey if and when he elects to keep his appointment.



John D. Felke

Mr. SLATTERY. And after discovering that the products were being diverted, Ortho investigated, as stated in the first sentence of the letter, and I quote:

As we have discussed, it appears at this point that we have effectively cut off the major sources of Ortho-Novum diversion,

and then the memo continues, and I quote again from the memo;

Ortho has become one of the few real authorities on pharmaceutical product diversion. What we ran into with Opus Christi was just the tip of the iceberg. Our investigations show that almost all pharmaceutical companies are involved in some way or another, and in most cases to a much greater degree than Ortho. It has been very interesting to note that many of these companies expressed very little concern over diversion, even when they know their products are involved.

Now, again, that's a direct quote from an interoffice memorandum between two employees of the Ortho Pharmaceutical Corp.

Mr. Kowitt, Ortho appears to have reached the same conclusion that you have reached. Many pharmaceutical companies are not concerned over diversion, or at least Ortho does not appear to be, based on this interoffice memorandum. Would you agree?

Mr. KOWITT. Well, I think Ortho at this point became very interested, and that is the reason for their investigating. But the prior year, for example, they too sold 45,800 cycles of their birth control pills to Miami Dade in a 6-month period.

So I think in 1974, 1975, they were not particularly concerned, but I think, as this memo indicates, they were one of the few that really did take an interest in diversion, and probably were responsible for prosecution in my trial.

Mr. SLATTERY. Mr. Kowitt, how do you think Ortho got their information about diversion?

Mr. KOWITT. Well, one of the ways that they got information, I learned, was when I was given this memo as part of my pretrial discovery. It is a confidential memo from Ortho Laboratories dealing with diversion. It is dated April 6, 1976, and I would like to read just a very brief part of it.

Mr. SLATTERY. Without objection, that will be entered in the record.

[The memorandum follows:]

Mr. J. Feike

April 6, 1976

Mr. F. Lusky

Messrs: W. B. Anderson  
I. L. Holzman  
R. P. RooneyCONFIDENTIALORTHO-NOVUM DIVERSION

John:

~~Concerning the rumor that Majestic Sales was offering a large quantity of ORTHO-NOVUM (with "Opus Christi" batch numbers) I have been unable to verify.~~ FDA

On 3/29/76, a confidential source interviewed people at Majestic and they denied having any ORTHO-NOVUM. The premises were checked and there was no ORTHO-NOVUM in sight. Majestic claimed they have been unable to get this product since their source, Southern Trading, was cut off by Ortho. But it was noted the last paper work they had was dated during 4/75 showing Ortho shipment to Miami-Dade Hospital (which is tied in with Southern Trading).

One interesting note is that Majestic Sales is not located at Miami, but in West Hollywood, Florida. This puts Majestic near Ft. Lauderdale, the base of one D. Pollard and friend.

Among the options we have are:

1. Majestic could have merchandise at another point.
2. Pollard could be more deeply involved than we suspect.
3. Some of our information could have been exaggerated.
4. Some combination of above.
5. None of the above.

I have done most of this investigation through my own sources. Still working on Euro-Export in Ft. Lauderdale, and Opus Christi, Herrifield Industrial Park, Fairfax, Va., but time demands I use private agencies for this.

FBI →  
4  
FDA

Frank Lusky

FJL:bh



Mr. KOWITT. On March 29, 1976, a confidential source interviewed people at Majestic, which is my company, and they denied having any Ortho-Novum. The premises were checked and there was no Ortho-Novum in sight. Majestic claimed that they had been unable to get this product since their source, Southern Trading, was cut off by Ortho, but it was noted the last paperwork they had was dated April 1975, showing Ortho's shipment to Miami Dade Hospital. In the last sentence it says:

"I have done most of the investigation through my own sources, still working on other people, but time demands that I use private agencies for this."

Now what they are referring to is on March 29, 1976, I had a knock on my door and a Food and Drug Administration inspector walked in, showed me his badge, and I opened all my books and records and my warehouse to this inspector, thinking it was a routine FDA investigation or inspection, and I had no idea that 8 or 9 days later this entire—all the information that I turned over to the Food and Drug Administration would be in the files of Ortho Laboratories.

So that's one of their sources of information about diversion.

Mr. SLATTERY. I would like to explore another facet of the relations between manufacturers and charities. A donation to a charity would in all probability give the donating company a tax deduction, I would assume. Would you agree?

Mr. KOWITT. I would assume so, sure.

Mr. SLATTERY. Now in the course of your trial, was there some discussion of a donation of pharmaceuticals made by Ciba-Geigy to Interchurch Medical Assistance?

Mr. KOWITT. Yes, there was.

Mr. SLATTERY. What value did Ciba-Geigy put on the donation?

Mr. KOWITT. According to a letter that they wrote to Interchurch Medical Assistance, the value that they put on one shipment was \$154,754.82.

Mr. SLATTERY. I would like to enter exhibit 13, which is a letter to Mr. Wilde with the Interchurch Medical Assistance Corp. in New York from the director of distribution of Ciba-Geigy, Mr. Nievergelt.

[The exhibit referred to follows:]

September 30, 1975

Exhibit 13

Mr. Arthur D. Wilde  
 Interchurch Medical Assistance, Inc.  
 Room 246  
 475 Riverside Drive  
 New York, New York 10027

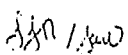
Dear Mr. Wilde:

Please be informed that the drug donation referred to in my letter of August 11, 1975 has been shipped to your warehouse in New Windsor, Maryland on September 26, 1975 via Halls Motor Transit. The shipment consisted of 43 cartons with a total weight of 1,572 lbs. The total value of the donation is \$154,754.02. Our "no charge" invoice is enclosed.

We would like you to confirm the receipt of this shipment not only with respect to the quantity received of each product but also to the number of cartons contained in the shipment. If everything arrives in line with the shipping papers, your confirmation by mail is adequate. In case of any discrepancy, however, we would like to be advised by phone without delay. We are pleased to make this contribution to your fine organization.

Very truly yours,

GEIGY PHARMACEUTICALS  
 Div. of CIBA-GEIGY Corp.

  
 J. J. Nievergelt  
 Director of Distribution

Jaw  
 Enclosure

cc: Mr. C. Rotondella

GENERAL PURPOSE DISPOSAL AUTHORIZATION (All initiation of this Form will be in Accounting NO. A 2228)

QUANTITY & DESCRIPTION	SIZE OR MODEL NO.	PROD. ORDER & DATE OR ASSET #	ORIGINAL COST	BOOK VALUE	LOCATION
See Supply Request No. 75028				\$6,555.21	Suffern

ACCOUNTING TO BE CREDITED

ADJUSTMENTS: SHIPPING & RECEIVED

Donations - According to Distribution Policy EXPECTED COMPLETION DATE: September 19, 1975

APPROVAL UNIT: **Inventory Control** (Div. 656 GEIGY) **Pharma SB2312** **N. Migliorato, Manager**  
 AUTHORITY: **Not Required**  
 DATE: *9/15/75*

**EVALUATION AND APPROVAL**

RECOMMENDED ACTION AND REASON: TRANSFER TO ANOTHER DIVISION, SELL, TRADE, DONATE, DESTROY, RETURN FOR CREDIT, SUNK, SCRAPPING REQUIRES THE RECOMMENDATION OF PURCHASING.

VALUATION BY: **Medialized Staff**

AUTHORIZATION BY AUTHORIZED MANAGER: **Donations - According to Distribution Policy**  
 BY: **Distribution** **J. J. Neveeralt, Director** *9/15/75*

**DISPOSAL ACTIONS (Check one below)**

TRANSFER TO OTHER DIV.

SELL

TRADE-IN (Requires Purchase Requisition)

RETURN FOR CREDIT

SCRAP (Requires Requisition)

DONATION

DESTROY ON PREMISES

DESTROY OFF PREMISES (Determine if Purchase Requisition is Required)

TERMS: \$ Sales Price \$ Trade-In Allow. \$ Credit Amt. Payment Terms: Collect, Prepaid, Pick-up

DONATION TO: **Interchurch Medical Assistance, Inc., New York, New York**  
 NAME OF RECEIVING DEPT. OR AGENCY: **Interchurch Medical Assistance, Inc., New York, New York**  
 NAME OF DESTROYED: **583311005122**  
 DATE DESTROYED: **9/15/75**

**CORD OF TRANSFERS**

BY NAME	DEPT. & COMPANY	SIGNATURE & DATE

Mr. SLATTERY. And in that letter he states that the total value of the donation is \$154,754 I will enter that in the record.

And what do you think was Ciba-Geigy's cost for this alleged donation of \$154,000?

Mr. KOWITT. They indicated that the cost was \$6,555.

Mr. SLATTERY. I would just note for the record that this is attached to exhibit 13 which I just referenced. A general purpose disposal authorization, which indicates the book value of this particular charitable contribution was, in fact, the \$6,555.

Now if my arithmetic is correct, the claimed value exceeded the cost in this case by \$147,445, giving Ciba-Geigy a pretty nice tax deduction, I would say.

Why do you think the discrepancy was so large?

Mr. KOWITT. Well, possibly because the merchandise which they donated were sample products which lacked the necessary childproof safety caps. I believe there was a new law that went into effect around that time, requiring all products to be distributed—and having childproof safety caps, and these apparently didn't.

Mr. SLATTERY. Were those products basically worth \$6,000 on the U.S. market or \$6,500; and was Ciba-Geigy, in effect, claiming a value of substantially more? Is that what you're saying?

Mr. KOWITT. Well, I don't think they could even be sold in their existing form, because they lacked the safety caps, and they were samples.

Mr. SLATTERY. Are you saying they were basically worthless?

Mr. KOWITT. Well, I think if they tried to sell them, it would be worthless, but, I think, perhaps their cost of manufacturing or some way they arrive at a value, put it at the \$6,555.

Mr. SLATTERY. Does the \$6,555, what they call book value, represent the actual cost of production?

Mr. KOWITT. I really can't answer that. I don't know.

Mr. SLATTERY. Are you familiar with a large sale of insulin syringes by Becton-Dickinson & Co. to Zaire?

Mr. KOWITT. Yes, I am. The order was for 13.5 million U-100 disposable insulin syringes with a value of \$1 million. Now that was the largest order in the history of Becton-Dickinson up until that point in time, and over 9 million of them were actually shipped to Zaire before the company realized they were being diverted, and they were coming back into the United States.

Mr. SLATTERY. Let me show you exhibit 11, which is a Becton-Dickinson internal memorandum entitled, "International Diverting Problem."

[The memorandum referred to follows:]

~~MEMORANDUM~~

August 25, 1978

Exhibit 11

MEMO TO: R. F. CAREY  
 FROM: A. F. Kelley  
 SUBJECT: ~~INTERNATIONAL DIVERTING ROBERT~~

Recent History of Problem

1. Zaire order for 13½ million units (#8409)
  - A. 4½, 4½, 4½ separate shipments ✓
  - B. First and second orders have been shipped (#8409)
  - C. Then came a request for change to MICRO-FINE, #8410.
2. Case being forwarded to office from Florida, re Lawrence Pharmaceuticals, Inc., 6100 Phillips Highway, Jacksonville with lot control #8D039, which is a lot number for ZAIRE shipment. Account was advised by source "We have approximately 10 million syringes."  
 Case being forwarded from an ECKERD DRUG STORE, Clearwater, Florida with lot control #8D042, which is a lot number for ZAIRE shipment. This huge chain has not purchased normal quantities of #8409 since May. Account (once again) advised our salesperson, Ray Watts, that they can buy our merchandise at a lower price than our best promotional offer.
3. Ketchum Dists., New York City advised us that they purchased a minimum of 100,000 #8409 from another source.
4. End of May (28) field reports were received of chains being offered a special price on 8409 (\$8.75/100 from H. L. Moore to Rea & Darick (Penna.) - Rite Aid (Penna.) (approximately \$8.00). Dart Drug (Maryland) (Ben Kawalowski) was offered special price (low \$8.00/100 range).
5. H. L. Moore (wholesaler) - New Britain, Connecticut offering \$9.50 (?) price on 8409--yet their purchases of PL 86 are down \$54,981 (-60%) y-t-d June. Buyer at Moore expressed concern of high inventories of 8409 with the release of 8410.

...continued

BECTON  
DICKINSON

August 25, 1978  
Page Two

*BECTON DICKINSON SUMMARY*

Personal Experience/Observations

One must be extremely naive not to realize that even without further proof that BDCF is being "ripped off."

No customer will ever divulge their source of supply, why should they? They are buying our product in original cases at a lower cost.

In my previous employment I lived with these situations also. For example:

- A. SURINAM orders. The International Department advised that this small (tiny) country would buy a \$250,000 order of English Becton products because they were recognized names in South America. However, the merchandise was smuggled in. We laughed at this statement, but were overruled. The goods showed up in metro.
- B. A Toronto "agent" for the Yugoslavian government wanted to buy \$400,000 worth of products. I advised the International Manager to tell him yes, and in consideration of the order size that we would print the packages in the local language (?) Croatian-Slavic(?). The agent called back in two days and advised "not necessary." We did not ship any goods.
- C. BDCF has already had previous "lousy" experience with Puerto Rico shipments coming back to the mainland. And now again. Merchandise showed up in a drugstore in upstate New York. Last month traced this to Dolphin Dists. of Puerto Rico, which has a forwarding depot in New Jersey.
- D. How many diabetics in Cuba? Is U-100 available there? Regardless, the 12 million syringes are relative to a total population of 25 million people.

*Art*

A. F. Kelley

/amn

Mr. SLATTERY. The memo describes a market essentially flooded with Becton-Dickinson syringes. The August 1978 memo notes that Eckerd Drug Stores had not purchased normal quantities since May. At the very end of the memo, some key questions are also raised.

For example, and I quote, "How many diabetics are in Zaire? And is U-100 available there? Regardless, the 13.5 million syringes are relative to a population of 25 million people," end quote.

Are these questions that the company should have asked before the sale?

Mr. KOWITT. Of course.

Mr. SLATTERY. What percentage of the U.S. population are diabetics?

Mr. KOWITT. I believe it's about 1.5 percent.

Mr. SLATTERY. So if the population of Zaire was, say, 25 million and 1.5 percent were diabetic, that would be 375,000 cases, if my math is correct.

Mr. KOWITT. That's correct. Except Random House Encyclopedia only gives the population of Zaire, as of 1977, at 16,685,000, which is almost 40 percent less than the Becton-Dickinson memo.

Mr. SLATTERY. What is U-100?

Mr. KOWITT. U-100 is a type of insulin which was new to the market at that time, and it is unclear as to whether this new form of insulin was even available in a country like Zaire at the time these syringes were shipped.

Mr. SLATTERY. Why would English-labeled products be desirable in Zaire?

Mr. KOWITT. I really couldn't tell you. I know that Zaire was a former French Colony, and I believe the primary language spoken is French.

Mr. SLATTERY. What, in your judgment, happened to the syringes? Why would a company sell 13.5 million syringes to Zaire?

Mr. KOWITT. You want my opinion?

Mr. SLATTERY. Yes.

Mr. KOWITT. Well, I think the International Sales manager that got credit for this \$1 million sale couldn't care less where that merchandise wound up. He got his million dollars worth of credit, and he took the order, and closed his eyes to what happened to the rest of it.

Mr. SLATTERY. Are you personally knowledgeable about this particular incident, and if so, can you shed any light on what ultimately happened to these 13.5 million syringes?

Mr. KOWITT. Well, as I indicated, from what I've read and the documents that I've seen, 9 million of them were diverted back into the U.S. market and sold to chains and wholesalers.

Mr. SLATTERY. What documents have you seen?

Mr. KOWITT. Well, there was a company—a memo that indicated that 9 million of them did come back. There was documentation to that effect.

Mr. SLATTERY. What documentation are you referring to?

Mr. KOWITT. I believe it's part of the memo.

Mr. SLATTERY. That 9 million approximately came back to the United States?

Mr. KOWITT. I gave the exhibit to counsel. I just don't remember which one it was.

Mr. SLATTERY. Do you know where they were returned?

Mr. KOWITT. What point of entry, you mean? No, I don't.

Mr. SLATTERY. And you don't know who actually received them in this country.

Mr. KOWITT. Nine million syringes must have gone to a lot of people.

[Pause.]

Mr. SLATTERY. According to the "International Diverting Problem" memo that I referred to a few minutes ago, exhibit 11, in that memo it indicates that near the end of May, field reports were received of chains being offered a special price on 8,409, \$8.75 per 100, from H.L. Moore to Rea & Derrick in Pennsylvania, Rite-Aid in Pennsylvania, approximately \$8. Dart Drug in Maryland was offered a special price, the low \$8 per 100 range, for these syringes coming back from Zaire.

Mr. KOWITT. I don't believe they were the same syringes, sir, because the syringes shipped to Zaire were only the U-100 style of syringe. What he's referring to is the U-40 and U-80, the other style of insulin syringe, the older type of syringe.

Becton-Dickinson syringes have been in the diversion market for many years.

Mr. SLATTERY. Mr. Kowitt, the examples that we have been talking about all occurred during the period between 1974 and 1978, which is the timeframe covered in your trial.

When did you sell your company and go out of the wholesale pharmaceutical business?

Mr. KOWITT. I sold my interest in my company in June 1984.

Mr. SLATTERY. Based on your experiences up to the time you sold out, did occurrences like this change fundamentally between 1974 and 1984? Or would you say these occurrences are continuing to this day.

Mr. KOWITT. As far as my end of it was concerned, I kept getting the same basic types of merchandise from the same types of sources, sure.

Mr. SLATTERY. So what you're saying is that the companies that you have mentioned are companies that you are testifying were involved in the various diversion programs right up through and including 1984. Is that your testimony?

Mr. KOWITT. What I'm saying is that my recent suppliers, I don't know where they got their merchandise. I wasn't privileged, as I was with—the information I provided to the committee, to have all these documentations.

But in recent years, as before, I bought my merchandise from licensed wholesalers. I don't know which hospital or which clinic or which doctor or which exporter or where they got their product from. I really don't know.

Mr. SLATTERY. Of course, the key is, which manufacturer it was coming from, correct?

Mr. KOWITT. Right. That I can tell you, as I indicated, that basically the same companies' products were in the marketplace over that period of time. Some came and went. Some stayed all the time. Some were never there.



Mr. SLATTERY. Just to clear up the record, can you once again state the names of the manufacturers that are involved in this activity or were involved in this activity during the time that you were in business.

Mr. KOWITT. I'll be glad to go over again the companies whose products I found to be most available in the marketplace.

Mr. SLATTERY. Please review those.

Mr. KOWITT. They included Allergan, Abbott Laboratories, Bristol Laboratories, Cooper Laboratories, Lederle Laboratories, Squibb-Smith, Miller & Patch, which is now Coopervision—Syntex, Wallace, and Warren-Teed.

Mr. SLATTERY. Are there any others that you had any contact with?

Mr. KOWITT. Oh, there are many, many others, but they were on a spot basis. They may be available for a year, and then not be available for a year, and that's why I said they came and went intermittently.

Mr. SLATTERY. Those that you indicated were frequently available, were they available almost all the time?

Mr. KOWITT. Almost all the time.

Mr. SLATTERY. Why do you think that some companies had little or no diversion, while others tended to be in the market a lot in that respect?

Mr. KOWITT. Well as I indicated, I think it's their philosophy, really, those that didn't want their product diverted just kept tight reins on their sales personnel and ordering institutions, and others that enjoyed the benefits of diversion used the diversion industry as a means of selling large quantities of competitive items and controlling their inventory and making a nice profit.

Mr. SLATTERY. Mr. Kowitt, thank you very much. We appreciate your time. I don't believe we have any further questions today. Thank you very much.

Our next witness today will be Mr. Eddie R. Burklow from Atlanta, GA.

Do you have any objection to being sworn in, Mr. Burklow?

[Witness sworn.]

The record will show that Mr. Burklow is represented by counsel, and if counsel will identify himself.

Mr. DAVIS. Guy Davis from Atlanta.

Mr. SLATTERY. Mr. Burklow, your full statement will be entered in the record. If you would care to summarize your statement, I would appreciate it.

**TESTIMONY OF EDDIE RONALD BURKLOW, SOUTHEAST REGIONAL SALES DIRECTOR, BARR LABORATORIES, ACCOMPANIED BY GUY E. DAVIS, JR., COUNSEL**

Mr. BURKLOW. Thank you, Mr. Chairman. My name is Ed Burklow. I've been in the pharmaceutical business for 18 years. I have worked in sales and marketing capacities for Pfizer Laboratories and Lederle Laboratories, and I am presently southeast regional sales director for Barr Laboratories, a generic drug manufacturer. From 1976 until March 22, 1982, I was Special Accounts manager for Lederle.

While working for Lederle and being in a pharmaceutical supply contract with Pharmacy Resources Corp., an Atlanta, GA, hospital purchasing group, during several discussions with the president of Pharmacy Resources, Mr. William E. Cash, Jr., he said that his member hospitals had excess supplies of certain pharmaceuticals and discussed this problem with a Lederle salesman, who I know had disposed of excess Lederle merchandise through clinics in his area. He suggested that I talk with Larkin Wholesale, a Glasgow, KY, pharmaceutical wholesaler.

I spoke with an official of that company and asked him if Larkin was interested in the purchase of excess pharmaceutical inventory. He immediately agreed, as long as the expiration dates of the products were good and the merchandise was not stolen. He was not otherwise concerned as to the source from which Pharmacy Resources would obtain the pharmaceuticals.

This information was relayed to Mr. Bill Cash, and within a short period of time, Pharmacy Resources was reselling excess hospital inventory of several manufacturers to Larkin, pharmaceutical diversion.

The idea to become involved in drug diversion evolved because we could buy it well below wholesale prices through Pharmacy Resources approximately 55 member hospitals, including both non-profit and for-profit institutions and sell the products through wholesalers at a good profit. The hospital purchasing group increased the quantity of certain products ordered from the manufacturers, ostensibly for the use of about five member hospitals, thereby creating excess inventories.

We would either pay the invoices directly or would reimburse the hospital for our purchases. We sold the products to licensed wholesalers and paid by check. This proved to be a profitable but small side business activity.

Mr. Cash and I operate our business as a partnership under the name of Benchmark Medical Services. Mr. Cash obtained a Federal ID number, a DeKalb County business license, and on several occasions advertised regionally. In no way did we attempt to hide this business. I was still employed at Lederle, and this side venture remained a small-scale activity with little time or effort expended by me.

In late 1981 or early 1982, Mr. Cash contacted me at Lederle and asked me to inquire of Lederle management as to the possibility of Pharmacy Resources Corp. purchasing merchandise for export. I referred his inquiry to the regional manager, Mr. Pat Rizzotto, who contacted the Lederle national sales manager, Mr. Larry Tilton, together with John Kelly, chief of prices and quotations. They decided to proceed with direct sales to Pharmacy Resources, even though Lederle had an international division which was responsible for export sales.

The Lederle domestic division did not want to pass its sales leads to the international division and thereby lose sales credit for the ensuing transactions. Even though Pharmacy Resources obviously did not fit any trade class for opening such an account, particularly since Pharmacy Resources had no warehouse, Lederle expedited the opening of the account without any concern as to the eventual destination of their product. On more than one occasion, the re-

gional manager told Cash that they were elated to have the account and that on several occasions the account had helped them make their budget on the products sold.

Benchmark Medical, of which I was a part, was not involved in these transactions.

On March 22, 1982, I resigned from Lederle to assume my present position with Barr Labs. In August 1982, Pharmacy Resources and Benchmark Medical moved their offices to Roswell, GA, to obtain warehouse space. I also rented an office at the location from Barr Labs. After moving to these new quarters, Pharmacy Resources opened accounts with Pfizer and Wyeth Labs with no more difficulty than experienced earlier with Lederle.

Again, no misrepresentations or false statements were made in order to make direct purchases from these manufacturers. The goods obtained were sold through Benchmark Medical to several licensed wholesalers, including Durr Drug Co. of Montgomery, AL; Lawrence Drug Co. of Jacksonville, FL; Med Sales Co. of Miami, FL; Larkin of Glasgow, KY; and Chapin Medical of Anaheim, CA.

In August 1982, the member hospitals of Pharmacy Resources Corp., began a new program in which all purchase contracts were to be honored through it, one wholesaler, Owens & Minor, of Wilson, NC. In November 1982, we began purchasing larger quantities of pharmaceuticals via Owens/Minor through two of our hospitals. At all times, we maintained proper records so that in the event of recall or other action, proper notification could be given. In all cases, we properly stored and packed the merchandise. Broken, mislabeled, or otherwise less-than-perfect products were discarded.

In September 1982, Mr. Cash and I traveled to Costa Rica in an effort to develop the export market. We met with the vice president of the company that organizes and awards bids for the social security health system there. We hired two individuals to represent us there and formed a Costa Rican company called Implemed, S.A.

We submitted bids to several large orders. We contacted the domestic sales representatives of several other pharmaceutical vendors, including Bristol, Upjohn, and Cutter, and they all agreed to sell to us if we should win the Costa Rican bids. In mid-1983, the bid process stalled, after we had spent several thousand dollars in cash, and I decided to call the project off.

In mid-1983, because of a decline in the pharmacy management business and certain reimbursement limitations, Cash decided to either get out of the pharmacy management business or sell Pharmacy Resources Corp. Benchmark would cease to exist. Mr. Cash had come in contact with Ronald Rivers, president of another small management firm in Middle, GA, who had purchased two contracts from Pharmacy Resources and was severely in default of payments for the purchase.

On one occasion Cash had discussed with Rivers the possibility of buying excess pharmaceuticals through five accounts. Over the phone Cash told Rivers that Pharmacy Resources was being sold and that he was getting out of the business altogether.

Within 1 day Rivers called back and told Cash he wanted to do some business, and that he and his associate, Mr. Billy Scott, wanted to visit him. Subsequent to that meeting, Pharmacy Re-

sources did purchase pharmaceuticals through the hospital operated by Rivers. The system worked as follows:

They had a list of products made in unit dose products for which we knew there was a market. We would place orders through prime vendor Owens/Minor and the products would be shipped to the respective hospitals and held for Rivers and Scott.

Rivers and Scott would deliver the products to our warehouse where they would be inventoried, checked, boxed, and shipped.

We would sell the products to the companies previously named, the invoices for the Owens Minor products would be paid by Benchmark. The profit on this arrangement would be shared 50-50.

Pharmaceutical diversion has grown enormously in the past years for several reasons. The principal cause is discriminatory or multitiered pricing. Most manufacturers have different prices for the same product for different market categories. These prices vary tremendously depending upon competition, marketing strategy, product age, company financial posture, and product demand.

Most companies give the best prices to the hospital and Government levels, and in descending order come the clinics, wholesalers, chain drug outlets, and independent retailers. Chains and independent pharmacists will usually buy at the same level unless through bulk purchases they may benefit from quantity pricing levels.

The difference in the lower tier level costs and the higher tier level costs can vary as much as a multiple of 50. Tier pricing multiples that vary from 3 to 50 are going to promote diversion, whether it be pharmaceuticals or automobile tires.

The revision of State antisubstitution laws and the growing acceptance of generic pharmaceuticals have caused many manufacturers to raise prices to the retailers and lower them to the institutional market. Such multiple tier pricing schemes by the manufacturers are as varied as the schemes by the diverters to circumvent these pricing practices. Institutions where the designated nonprofit or otherwise dispense pharmaceuticals to the patients at a profit. A possibility of a product dispensed by these hospitals, nursing homes, and clinics is directly related to the product's average wholesale price or AWP.

The AWP of a product is an artificial price established by the manufacturer on a given product and it is a price standard utilized by the wholesaler in price-bargaining with the chains, pharmacies, and institutions which fully expect to obtain the drugs at a price less than the AWP. The AWP is set by the manufacturer as his wholesale price to any licensed purchaser. The AWP is considered by institutions as a standard markup device.

It is my understanding that on every product, institutions such as hospitals charge a patient a price based upon AWP, multiplied by a low of 3 to a high of 6. Although  $3\frac{1}{2}$  to 4 is the common multiple.

Almost every hospital has a minimum charge of about 75 cents and \$1 per tablet per capsule dispensed. If a whole bottle of tablets or capsules costs them \$2, they charge the patient \$1 per tablet. Thus the revenue produces \$198 per bottle of pills at this price.

On injectable products, the minimum charge is \$5 to \$8 per injection. Many ampules cost the hospital only 11 cents, and the hospital charges a minimum of \$5 to \$7 to administer it.

The circumstances are different with expensive pharmaceutical items. The cost of pharmaceutical is directly related to the length of time it has been on the market. The competition experienced by the product and whether or not here is a generic substitute. It is these products which are targeted for diversion.

Referring to exhibit 1, is a product analysis by tier pricing. The third item listed is Omnipin, injection, 1 gram, which comes 10 to a package and carries an AWP of \$148.69, or \$14.87 per injectable. The typical markup by the institution is a multiple of four. Thus each injectable is billed to the patient at \$14.87 multiplied by 4 plus \$5 to administer it, or \$64.48.

Under hospital purchasing programs, this injectable can be purchased at a contract price of \$35.70 for the same package of 10, or \$3.57 per injectable. However, the hospital does not afford the patient the savings realized by the contract purchase price. Patients are charged the AWP, multiplied by 4, regardless of the contract purchase price paid by the hospital.

Medicare expenses are paid based upon the diagnosis of the illness. Insurance companies' payment by private patients and all other third party carriers pay on the basis of AWP.

However, in all categories, the hospital bills the patient as if a private party was paying. In the case of Medicare, the hospitals expense the amount not paid under the schedule as a loss.

If a wholesaler sells a product for less than the AWP, the manufacturer rebates to the wholesaler, but only if the sale was to a recognized institution at a special contract price less than AWP.

At times, some manufacturers find that they have an overabundance of a particular product. They then resort to what is referred to in the industry as dumping. The manufacturers bypass the normal wholesale outlets and send their representatives directly to the hospitals, purchasing groups, health maintenance organizations, and occasionally even to retailers dealing in large volumes.

These representatives offer the pharmaceutical at a contract price substantially less than the AWP.

In my opinion, much of the diversion activity that occurs takes place when the wholesale outlets are bypassed and sales are made directly from the manufacturer to the institution at contract prices which, as I have previously demonstrated, are substantially below AWP.

I want to get into pharmaceutical samples.

Sales people are under tremendous pressure to meet manufacturers' sales objectives and upper echelon corporate management is less concerned with how the objectives are met, than with the bottom line figures.

Marketing and sales management bring pressure on their field forces to get the job done. They provide these detail people with samples, sales material, and sales and pricing strategies. The manner of meeting sales quotas is then limited only by the ingenuity of the individual sales person.

Pharmaceutical trade practices vary with the manufacturers, the variety of their products, anticipated demand for the products and

competitive influences. Diversion and related problems, misbranding, and adulteration of drug samples are a result of these trade practices.

Sample abuses generally occur with newly introduced products and diversion occurs when products have reached their demand maturity and have become available from manufacturing competitors. When a product reaches demand maturity, many manufacturers manipulate pricing structures to extend the product's demand life cycle.

The prevailing attitude among wholesalers, retail chains, and individual retailers is that such pricing manipulation by the manufacturers unfairly discriminates against them and makes competition difficult.

Manufacturers and the representatives frequently give excessive amounts of samples to physicians. Some physicians sell them to diverters or trade them to pharmacies for other goods. The vast majority of physicians I have known, use and dispense samples legitimately, and I presume this would prevail nationally.

In fact, many physicians do not accept or give out samples, period.

Physician samples are used extensively by many manufacturers and representatives to acquire additional business from retail pharmacies, hospital pharmacies, and so forth, and to meet competition by sweetening the kitty with merchandise. Although the manufacturers and representatives deny such activity prevails, the situation has been well documented by many leading trade publications.

Lederle Laboratories, for example, uses a code on their computer called Transaction 85 to designate that certain regular stock packages are to be sent to their representatives at the representatives' request to be utilized in negotiating deals with potential purchasers.

Physician samples are also given to purchasers to entice them to buy larger quantities of other products such as over-the-counter merchandise being promoted by the manufacturer. These samples entice purchasers to promote merchandise for representatives, working out arrangements with local physicians to prescribe the products more frequently, and in the case of over-the-counter products, make stronger recommendations for the product to the customer.

Better shelf position on the over-the-counter drug sections of pharmacies often result. Samples are sometimes used by representatives to acquire merchandise for personal usage, such as toiletry items, medications for personal use, or for family and friends and household goods.

Generally, the representative will allow the pharmacist a price on the samples well below the pharmacist's actual cost. There have been instances where the representative traded up for other pharmaceuticals in original containers and resold them to other pharmacists for cash.

The cost of most branded products is very high. One tablet or capsule may cost the pharmacist as much as \$1 each, or as little as 5 cents each, depending on the product. Newer products on the market generally fall in the much higher price category, and are generally the one sampled quite heavily by the manufacturers.

Consequently, there is considerable temptation by the representative to turn these samples into use for personal gain, such as selling them for cash or trading them for other goods.

The above situation is compounded by the fact that most manufacturers will at times provide representatives as much as \$3,000 per month in samples for promotion of their products.

In conclusion, I believe that manufacturers who send out large quantities of samples to the representatives hurt themselves, since the practice leads to a reduction in legitimate sales that would otherwise occur. The practices which I have described have been common to the industry for years, although supposedly not condoned by the manufacturers. I believe sampling should be halted completely. A discount coupon or some other discount credit method could be utilized in lieu of samples.

A prescriber could pass the credit onto the patient for redemption at the pharmacy on the first prescription. Multitier pricing is the parent of diversion. To reduce diversion, some pharmaceutical manufacturers such as Merrill-Dow have voluntarily implemented a single-bid pricing structure. They stand to lose money unless the practice becomes common to the branded product industry as a whole.

The generic companies have no diversion problems because the pricing differential between AWP and the contract prices are so small. That is precisely why institutional accounts favor brand name merchandise over generics.

These institutions are not likely to abandon the branded products because they can buy at low contract prices and charge AWP to the patient and third party providers at a substantial profit not available to them through the use of generics, which have a lower AWP and substantially less difference between contract bid price and the AWP.

Institutional health care costs to the American public would be significantly less if there was a prohibition against billing based on AWP rather than the cost actually paid for the products. Competition between the branded products and the lower priced generics would thus be enhanced.

Patients for whom branded products are prescribed while confined to institutions are customarily given prescriptions for the continued use of the same medication upon their release to outpatient status. Thus, the use of branded products instead of less expensive generic products is fostered.

This practice is economically devastating to the vast number of fixed income people who are necessarily the primary consumers of the more advanced and costly medications.

[The prepared statement of Mr. Burklow follows:]

## STATEMENT OF EDDIE RONALD BURKLOW

PRESCRIPTION DRUG DIVERSION AND PRACTICES OF PHARMACEUTICAL COMPANIES  
AND SALES REPRESENTATIVES RELATED TO DRUG SAMPLESBEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS  
COMMITTEE ON ENERGY AND COMMERCE  
SEPTEMBER 19, 1985

My name is Ed Burklow and I have been in the pharmaceutical business for eighteen years. I have worked in sales and marketing capacities for Pfizer Laboratories and Lederle Laboratories, and I am presently Southeast Regional Sales Director for Barr Laboratories, a generic drug manufacturer. From 1976 until March 22, 1982, I was Special Accounts Manager for Lederle.

While working for Lederle, I bid on a pharmaceutical supply contract with Pharmacy Resources Corporation, an Atlanta, Georgia hospital pharmacy purchasing group. During several discussions with the President of Pharmacy Resources, Mr. William F. Cash, Jr., he said that his member hospitals had excess supplies of certain pharmaceuticals. I discussed this problem with a Lederle salesman, who I know had disposed of excess Lederle merchandise through clinics in his area. He suggested I talk to Larkin Wholesale, a Glasgow, Kentucky pharmaceutical wholesaler.

I spoke with an official of that company and asked him if Larkin was interested in the purchase of excess pharmaceutical inventory. He immediately agreed as long as the expiration dates of the products were good and the merchandise was not stolen. He was not otherwise concerned as to the source from which Pharmacy Resources would obtain the pharmaceuticals. This information was relayed to Bill Cash, and within a short period of time, Pharmacy Resources was selling the excess hospital inventory of several manufacturers to Larkin. I do not recall the exact nature of the products except that none were controlled substances and the transactions were on a small scale.

Pharmaceutical Diversion

The idea to become involved in drug diversion evolved because we could buy at well below wholesale prices through Pharmacy Resources' approximately 55 member hospitals, including both non-profit and for profit institutions, and sell the products through wholesalers at a good profit. The hospital purchasing group increased the quantity of certain products ordered from the manufacturers, ostensibly for the use of about five member hospitals, thereby creating excess inventories. We would either pay the invoices directly, or we would reimburse the hospital for our purchases. We sold the products to licensed wholesalers and paid by check. This proved to be a profitable, but small, side business activity. Bill and I operated our business as a partnership, under the name of Benchmark Medical Services. Mr. Cash obtained a Federal I.D. number, a De Kalb County Business License and, on several occasions, advertised regionally. In no way did we attempt to hide the business. I was still employed at Lederle and this side venture remained a small scale activity with little time or effort expended by me.

In late 1981 or early 1982, Bill Cash contacted me at Lederle and asked me to inquire of Lederle management as to the possibility of Pharmacy Resources Corporation purchasing merchandise for export. I referred his inquiry to the Regional Manager, Fat Rizzotto, who contacted the Lederle National Sales Manager, Larry Tilton. Together with John Kelly, Chief of Prices and Quotations, they decided to proceed with direct sales to Pharmacy Resources, even though Lederle had an international division which was responsible for export sales. The Lederle Domestic Division did not want to pass the sales lead to the international division and thereby lose sales credit for the ensuing transactions. Even though Pharmacy Resources obviously did not fit any trade class for opening such an account, particularly since Pharmacy Resources had no warehouse, Lederle expedited the opening of the account without any concern as to the eventual destination of their



product. On more than one occasion the Regional Manager told Cash that they were elated to have the account, and that on several occasions the account had helped them make their budget on the products sold. Benchmark Medical, of which I was a part, was not involved in these transactions.

On March 22, 1982, I resigned from Lederle to assume my present position with Barr Laboratories. In August 1982, Pharmacy Resources and Benchmark Medical moved their offices to Roswell, Georgia to obtain warehouse space. I also rented an office at this location for Barr Laboratories. After moving to these new quarters, Pharmacy Resources opened accounts with Pfizer and Wyeth Laboratories with no more difficulty than experienced earlier with Lederle. Again, no misrepresentations or false statements were made in order to make direct purchases from these manufacturers. The goods obtained were sold through Benchmark Medical to several licensed wholesalers including Durr Drug Company of Montgomery, Alabama, Lawrence Drug Company of Jacksonville, Florida, Med Sales Company of Miami, Florida, Larkin, Inc. of Glasgow, Kentucky, and Chapin Medical Company of Anaheim, California.

In August 1982, the member hospitals of Pharmacy Resources Corporation began a new program under which all purchase contracts were to be honored through one wholesaler, Owens and Minor of Wilson, North Carolina. In November 1982, we began purchasing larger quantities of pharmaceuticals via Owens and Minor through two of our hospitals. At all times we maintained proper records so that in the event of a recall or other action, proper notification could be given. In all cases we properly stored and packed the merchandise. Broken, mislabeled or otherwise less than perfect products were discarded.

In September 1982, Bill Cash and I traveled to Costa Rica in an effort to develop the export market. We met with a Mr. Fernando Melo, who was Vice President of D.M. Associates, S.A., the company that organizes and awards bids for the Social Security System (Health System) there. We hired two representatives to represent us there and formed a Costa Rican company, Implemed, S.A. Our representatives made several trips from Miami to Costa Rica. We submitted bids in several large orders. We contacted the domestic sales representatives of several other pharmaceutical vendors including Bristol, Upjohn and Cutter, and they all agreed to sell to us if we should win the Costa Rican bids. In mid-1983, the bid process stalled after we had spent several thousand dollars, so Bill and I decided to call the project off.

During the early part of 1983, another company opened a direct account with us. The company was Invenex. They primarily make generic injectible products. We bought these products and sold them to Bravo Export Management Company, Inc. in Miami Florida. Earnest Bravo, President of that company, had several countries for whom he was the primary supplier of certain pharmaceuticals. The business with Bravo continued until about mid-1984, at which time it ceased due to our inability to supply huge quantities. He told us that he had some hospitals in the Miami area through which he was buying products.

In mid-1983, because of a decline in the pharmacy management business and certain reimbursement limitations, we decided to either get out of the pharmacy management business or sell Pharmacy Resources Corporation. Benchmark would cease to exist. Bill Cash had come in contact with Rymer Rivers, President of another small management firm in middle Georgia who had purchased two contracts from Pharmacy Resources and was severely in default of payment for the purchase. On one occasion, Cash had discussed with Rivers the possibility of buying excess pharmaceuticals through his five accounts. Over the phone, Cash told Rivers that Pharmacy Resources was being sold and that he was getting out of the business altogether. Within one day, Rivers called back and told Cash he wanted to do business and that he and his associate, Billy Scott, wanted to visit him. Subsequent to that meeting, Pharmacy Resources did purchase pharmaceuticals through the hospitals operated by Rivers.

The system worked as follows:

- 1) We had a list of products (mainly injectible and unit dose products) for which we knew there was a market.

- 2) We would place orders through the prime vendor (Owens and Minor) and the products would be shipped to the respective hospitals and held for Rivers and Scott.
- 3) Rivers and Scott would deliver the products to our warehouse where they would be inventoried, checked, boxed and shipped.
- 4) We would sell the products to the companies previously named.
- 5) The invoices for the Owens and Minor products would be paid by Benchmark.
- 6) The profit on this arrangement would be shared 50/50.

In February 1984, Cash sold the assets of Pharmacy Resources Corporation to Innovative Pharmacy Service, Inc. in Austin, Texas and accepted a position as Executive Vice President with them. Innovative Pharmacy Services was not involved in diversion, only hospital pharmacy management.

Benchmark continued to do business from February 1984, until October 1984, in a limited capacity. We purchased directly from Pfizer, Wyeth and Invenex during this time and through two former Pharmacy Resources hospitals via Owens and Minor.

Benchmark Medical Services was formed strictly as a sideline venture. Neither of us drew a salary or otherwise lived off any proceeds. We kept meticulous records and filed detailed tax returns through our C.P.A., Olin Harrell. Neither of us had ever before knowingly broken a law. In our cases, neither of us knew that "diversion" was against the law or considered our activities to be criminal. Conversely, we had read several legal opinions to the contrary. The publicity about diversion had not started while we were doing business. In fact, we were not able to find any material on diversion in the literature prior to October 1984.

On October 9, 1984, Bill Scott revealed to me that he was actually Carl F. Christiansen, a Special Agent with the FBI, and that he was investigating drug diversion in an undercover operation. I was informed that the purchases of Pharmacy Resources at lower prices directly from Lederle, Pfizer, Wyeth and Invenex were not considered illegal, but that the Gozen or so purchases by Pharmacy Resources and Benchmark of hospital inventory obtained by representations to the manufacturers that the products were intended for hospital use constituted fraud.

Pharmaceutical diversion has grown enormously in the past years for several reasons. The principal cause is discriminatory or multi-tier pricing. Most manufacturers have different prices for the same product for different market categories. These prices vary tremendously depending upon competition, marketing strategy, product age, company financial posture, and product demand.

Most companies give the best prices at the hospital and government levels. In descending order come the clinics, wholesalers, chain drug outlets, and finally, independent pharmacies. Chains and independent pharmacies will usually buy at the same level unless, through bulk purchases, they may benefit from quantity pricing levels. The difference in the lower tier level cost and the higher tier level cost can vary as much as a multiple of fifty. Tier pricing multiples that vary from three to fifty are going to promote diversion, whether it be pharmaceuticals or automobile tires.

The revision of state anti-substitution laws and the growing acceptance of generic pharmaceuticals have caused many manufacturers to raise prices to the retailers and lower them to the institutional market. Such multiple tier pricing schemes by the manufacturers are as varied as the schemes by diverters to circumvent these pricing practices. Institutions, whether designated "non-profit" or otherwise, dispense pharmaceuticals to their patients at a profit. The profitability of a product dispensed by these hospitals, nursing homes, and clinics is directly related to the product's "Average Wholesale Price," or AWP. The AWP of a product is an artificial price established by the manufacturer on a given product and it is the price standard utilized by the wholesaler in price bargaining with the chains, pharmacies and institutions, which fully expect to obtain the drugs at a price less than the AWP.

The AWP is set by the manufacturer as its wholesale price to any licensed purchaser. The AWP is considered by institutions as the standard mark up device. It is my understanding that on every product, institutions such as hospitals charge the patient a

price based upon AWP, multiplied by a low of three to a high of six, although 3 and 1/2 to four is a common multiple.

Almost every hospital has a minimum charge of between \$.75 and \$1.00 per tablet or capsule dispensed. If a whole bottle of tablets or capsules costs them \$2.00, they charge the patient \$1.00 per tablet. Thus, the revenue produced is \$198.00 per bottle of pills at this price. On injectible products, the minimum charge is \$5.00 to \$8.00 per injection. Many ampules cost the hospital only \$.11 and the hospital charges a minimum of \$5.00 to \$7.00 to administer it.

The circumstances are different with expensive pharmaceutical items. The cost of a pharmaceutical is directly related to the length of time it has been on the market, the competition experienced by the product and whether or not there is a generic substitute. It is these products which are targeted for diversion.

Referring to Exhibit 1, which is a product analysis by tier pricing, the third item listed is Omnipen-N, Inj., 1 g., which came ten to a package and carry an AWP of \$148.69, or \$14.87 per injectible. The typical mark-up by the institution is a multiple of 4, thus each injectible is billed to the patient at \$14.87 multiplied by 4, plus \$5.00 to administer it, or \$64.48. Under hospital purchasing programs, this injectible can be purchased at a contract price of \$35.70 for the same package of ten or \$3.57 per injectible. However, the hospital does not afford the patients the savings realized by the contract purchase price. Patients are charged the AWP multiplied by four, regardless of the contract purchase price paid by the hospital. Medicare expenses are paid based upon the diagnosis of the illness. Insurance companies, payment by private patients and all other third-party carriers pay on the basis of AWP. However, in all categories, the hospitals bill the patient as if a private party was paying. In the case of Medicare, the hospitals expense the amount not paid under the schedule as a loss.

If a wholesaler sells a product for less than the AWP, the manufacturer rebates to the wholesaler, but ONLY if the sale was to a recognized institution at a special contract price less than AWP.

At times, manufacturers find that they have an over-abundance of a particular product. They then resort to what is referred to in the industry as "dumping." The manufacturers by-pass the normal wholesale outlets and send their representatives directly to hospitals, purchasing groups, health maintenance organizations and occasionally even to retailers dealing in large volumes. These representatives offer the pharmaceutical at a contract price substantially less than the AWP. In my opinion, much of the diversion activity that occurs takes place when wholesale outlets are by-passed and sales are made directly from the manufacturer to the institution at contract prices which, as I have previously demonstrated, are substantially below AWP.

#### Pharmaceutical Samples

Sales people are under tremendous pressure to meet manufacturer's sales objectives, and upper echelon corporate management is less concerned with how the objectives are met than with the bottom line figures. Marketing and sales management bring pressure on their field forces to get the job done. They provide these detail people with samples, sales material and sales and pricing strategies. The manner of meeting sales quotas is then limited only by the ingenuity of individual sales persons.

Pharmaceutical trade practices vary with the manufacturers, the variety of their products, anticipated demand for the products and competitive influences. Diversion and a related problem, misbranding and adulteration of drug samples, are a result of these trade practices. Sampling abuses generally occur with newly introduced products and diversion occurs when products have reached their "demand maturity" and have become available from manufacturing competitors. When a product reaches demand maturity, many manufacturers manipulate pricing structures to extend the product's demand life cycle. The prevailing attitude among wholesalers, retail chain stores, and individual retailers is that such pricing manipulation by the manufacturers unfairly discriminates against them and makes competition difficult.

Pharmaceutical samples are intended for physicians' use only. The physician gives them to patients they believe should respond to that particular drug. If the patient's response to the drug is positive, the physician will generally prescribe that particular drug. If the patient's response is negative, the physician will prescribe another drug or otherwise alter treatment. Samples are given patients when the physician knows the patient may have difficulty in obtaining the medication from the pharmacy within a reasonable time period.

A pharmaceutical should be stored out of sunlight and away from excessive heat and cold and ideally between temperatures of fifty-five to eighty degrees. A salesman receiving samples from his company will in most instances store them under less than ideal conditions, such as in his or her garage. They will then be placed in the trunk of an automobile and distributed. Sometimes these products are stored like this for months. The manufacturers themselves condone the storage and handling conditions that prevail throughout the industry. They are indifferent to the compromise of the chemical integrity of the products.

Physician or pharmaceutical samples come in miniature bottle form, unit dose sleeve package form, and in what the industry calls a "stock-package" which are bottles or unit-dose packages with quantities of 100 or more tablets or capsules per package. Stock-package samples are the standard package sold to retailers, wholesalers, hospitals, etc. Many times the manufacturer will identify these packages with "sample" printed or stamped on the package.

The true physicians' sample is packaged so as to appeal to the physician and the patient and so as to identify the product. Quantities may vary from as low as one tablet or capsule per package to as high as forty-eight per sample pack. Many times the manufacturer will imprint on the package (or tablets and capsules) the words "physician sample," "sample," or "complimentary."

Manufacturers and their representatives frequently give excessive amounts of samples to physicians. Some physicians sell them to diverters or trade them to a pharmacist for other goods. The vast majority of physicians I have known use and dispense samples legitimately, and I presume this would prevail nationally. In fact, many physicians do not accept or give out samples.

Physicians' samples are used extensively by many manufacturers and representatives to acquire additional business from retail pharmacies, hospital pharmacies, etc. and to meet competition by "sweetening the kitty" with "trunk merchandise." Although the manufacturers and representatives deny such activity prevails, the situation has been well documented by leading trade publications. Lederle Laboratories, for example, uses a code on their computer called "transaction 85" to designate that certain regular stock packages are to be sent to their representative, at the representative's request, to be utilized in negotiating deals with potential purchasers. Physicians' samples are also given to purchasers to entice them to buy larger quantities of other products such as over the counter merchandise being promoted by the manufacturer.

These samples entice purchasers to promote merchandise for representatives by working out arrangements with local physicians to prescribe the products more frequently and, in the case of over the counter products, to make stronger recommendations of the product to the customer. Better shelf position on the over the counter drug sections of pharmacies often results. Samples are sometimes used by representatives to acquire merchandise for personal use such as toiletry items, medications for personal use or for family or friends and household goods. Generally, the representative will allow the pharmacist a price on the samples well below the pharmacist's actual cost. There have been instances where the representative "traded out" for other pharmaceuticals, in original containers, and resold them to another pharmacist for cash.

The cost of most "branded products" is very high. One tablet or capsule may cost the pharmacist as much as \$1.00 each, or as little as \$.05 each, depending on the product. Newer products on the market generally fall in the much higher price category and are generally the ones sampled quite heavily by the manufacturers. Consequently, there is considerable temptation by the representatives to turn these samples into use for personal

gain, such as selling them for cash or trading-out for other goods.

The above situation is compounded by the fact that most manufacturers will at times provide representatives as much as \$3,000 per month in samples for promotion of their products.

Physician samples or "trunk merchandise" is often sold to so-called "shuckers." These people are involved in buying this merchandise from salesmen and from physicians' offices. Sometimes the individual salesman will take the capsules or tablets out of the sample containers and put them in other containers or "baggies," but usually the "shuckers" do it. The shuckers then use this merchandise within the confines of their own drugstore operation or sell them to other drugstores. The price margins generally vary with the demand for the product.

I have heard of the use of acetone to remove the words "sample" or "complimentary" from the capsules. While I was working in the Atlanta investigation, electric erasers were revealed as a means of word removal from capsules.

#### Conclusion

I believe that manufacturers who send out large quantities of samples to their representatives hurt themselves since the practice leads to a reduction in legitimate sales that would otherwise occur.

The practices which I have described have been common to the industry for years, although supposedly not condoned by the manufacturers. I believe sampling should be halted completely. A discount coupon or some other discount credit method could be utilized in lieu of samples. The prescriber could pass the credit on to the patient for redemption at the pharmacy on the first prescription. This would: (1) eliminate sample diversion; (2) insure product integrity; (3) provide a more honest and accountable marketing system; (4) reduce marketing costs; and (5) improve the industry's image with the pharmacy profession and the public.

Multi tier pricing is the parent of diversion. To reduce diversion, some pharmaceutical manufacturers, such as Merrill-Dow, have voluntarily implemented a single-bid pricing structure. They stand to lose money unless the practice becomes common to the branded product industry as a whole.

The generic companies have no diversion problems because the pricing differentials between AWP and the contract price are so small. That is precisely why institutional accounts favor brand name merchandise over generics. These institutions are not likely to abandon the branded products because they can buy at low contract prices and charge AWP to the patient and third party providers at a substantial profit not available to them through the use of generics, which have a lower AWP and substantially less difference between contract bid price and the AWP.

Institutional health care costs to the American public would be significantly less if there was a prohibition against billing based on AWP rather than the cost actually paid for the products. Competition between the branded products and the lower-priced generics would thus be enhanced.

Patients from whom branded products are prescribed while confined to institutions are customarily given prescriptions for the continued use of the same medication upon their release to out-patient status. Thus, the use of branded products instead of the less expensive generic product is fostered. This practice is economically devastating to the vast number of fixed income people who are necessarily the primary consumers of the more advanced and costly medications.

## PHARMACEUTICAL DIVERSION

## EXHIBIT 1

## PRODUCT ANALYSIS BY TIER PRICING

<u>Product</u>	<u>AWP (\$)</u>	<u>Contract (\$)</u>
Tylenol tabs., 325 mg., 1000	32.54	2.84
Proventil inhaler, each	9.18	2.95
Omnipen-N, inj., 1g., 10s	148.69	35.70
Velosof, 250 mg. caps., 100s	38.71	14.80/10
Lotrimin 1% cream, 15 g. each	5.27	.99
Garamycin, 80 mg./2 ml. inj.	84.50	10.20
Alupent tabs., 10 mg., 100s	12.22	2.99
Depo-medrol, 40 mg. inj.	4.95	2.30
Transderm Nitro, 2.5 mg.	28.70	.30
Nilstat Susp., bowel	13.84	1.78
K-Lor, 15 mg., 100	28.58	3.50
K-Tab, 10 mg., 100	10.44	.62
Kaon-ce tabs, 100	9.49	3.00

Mr. SLATTERY. Mr. Burklow, thank you very much for your testimony. I have several questions for you, and then the gentleman from Virginia will also have some questions for you.

You said, Mr. Burklow, that Pharmacy Resources Corp. opened an account with Lederle for foreign sales; is that correct?

Mr. BURKLOW. That is correct.

Mr. SLATTERY. Did your company ever sell any of Lederle's product abroad?

Mr. BURKLOW. No.

Mr. SLATTERY. Did Lederle ever check whether Pharmacy Resources was, in fact, selling Lederle's products abroad?

Mr. BURKLOW. No.

Mr. SLATTERY. Did they seem to care where you were selling it?

Mr. BURKLOW. No, they didn't really care.

Mr. SLATTERY. Did the goods purchased for overseas sales have English language packaging and labeling?

Mr. BURKLOW. Absolutely. Yes.

Mr. SLATTERY. Is that typical of the drug industry, to be shipping overseas drugs that don't have the language of the country of destination?

Mr. BURKLOW. That has been my experience, from what part of this I have seen.

Mr. SLATTERY. So it is typical that these companies are shipping drugs overseas with English lettering, even if the country of destination's language is French, Portugese, Spanish, or whatever it might be?

Mr. BURKLOW. That is right.

Could you repeat that question, sir?

Mr. DAVIS. I believe the witness may have misunderstood the question.

Mr. SLATTERY. I would be happy to restate the question.

I am just concerned, is it typical for drug manufacturers to ship overseas or to sell to a company that is involved in drug exporting, drugs that are packaged and labeled in English?

Mr. BURKLOW. That's pretty typical. As far as the facet of these overseas things that I have seen, shipping an English label to a Spanish country, for example, or whatever.

Mr. SLATTERY. Is that of concern to you, Mr. Burklow? That the ultimate consumer overseas may not be able to read the directions on the bottle?

Mr. BURKLOW. Well, I think it's obvious what is going on. I think it's rather obvious as to what is going on.

Mr. SLATTERY. So you think that the manufacturers involved in the sale of drugs to companies like yours are involved knowing that a big part of those drugs will never leave this country?

Mr. BURKLOW. I think so. I think we can assume that.

Mr. SLATTERY. Are you familiar with an instance in which a large chain drugstore apparently bought up significant quantities of dumped merchandise and held the goods for a period of time and returned the goods to Lederle for credit?

Mr. BURKLOW. I would assume that, yes, sir.

Mr. SLATTERY. Could you describe the instance that you are aware of?

Mr. BURKLOW. Well, on several occasions while I was still at Lederle and in my job as special accounts manager, I actually received and sold to what you'd consider large accounts like this, and Revco sent back on several occasions huge returns, primarily returns of—you could consider the most frequently diverted items that were in Lederle's product line, and to the best of my recollection, it was anywhere from \$25,000 to \$50,000 returns on like four or five items, and this came in, and I did question the Lederle management people about it, my regional manager, a couple of times, and the issue was dropped, and I never heard. I don't know what happened afterward.

Mr. SLATTERY. In most cases the manufacturers sell pharmaceuticals with the right that unsold expired merchandise can be returned. But when companies have excess supplies of certain products, they may dump sales on a nonreturnable basis; isn't that correct?

Mr. BURKLOW. Yes, sir, I have seen that happen and have been a part of that on several occasions.

Mr. SLATTERY. What is the expiration date on some of the sales that you have seen like this, some of the nonreturnable sales?

Mr. BURKLOW. Well, as long as 12 months, and I have seen that happen, and I have seen companies where at the end of that time they may give special prices to maybe go out to certain retailers or certain large accounts who buy up a significant amount and try to get rid of it in that way. But generally it takes about a year before a company can get pretty much a guideline as to how much product inventory they have and the flow, and if this gets near a year, they will generally try some type of dumping technique, and get rid of this merchandise.

Mr. SLATTERY. The Chair at this time will recognize the gentleman from Virginia, Mr. Bliley.

Mr. BLILEY. Mr. Burklow, you have about 18 years of experience in the industry; what was the prevalent attitude of manufacturers relative to returns of expired or excess merchandise?

Mr. BURKLOW. I would say that they didn't want returns.

Mr. BLILEY. Would sales representatives, then, sometimes replace expired merchandise with samples rather than send the expired goods back to the company?

Mr. BURKLOW. Yes, sir, that was a fairly common practice of some of the people I've worked with, yes.

Mr. BLILEY. Well, what would happen to the expired merchandise?

Mr. BURKLOW. Generally, it would be returned to the company but would be left with the pharmacist, you know, to dispose of as he saw fit.

Mr. BLILEY. Would it be returned to the company or would it be left with the pharmacist?

Mr. BURKLOW. Generally left with the pharmacist, sir.

Mr. BLILEY. I see. Do most companies have strict accounting programs for expired merchandise that would prevent pharmacists from selling expired goods if they were so inclined?

Mr. BURKLOW. Not that I ever saw, sir, although of late, I do have word that many companies are really tightening up their ship on this.



Mr. BLILEY. What value would sales representatives normally receive from a company?

Mr. BURKLOW. Sir, that would vary by the manufacturers, but in some cases I have seen or heard of sales people getting as much as \$2,000 or \$3,000 per call cycle, or business cycle. And that is generally how long it takes the sales person to get around his territory. You know, he's on an itinerary-type arrangement. Say on a 6-week cycle.

Mr. BLILEY. Is that about average, a 6-week cycle?

Mr. BURKLOW. I would think so.

Mr. BLILEY. Would you say that the companies maintain strict accountability over the sale representatives in their use of the samples?

Mr. BURKLOW. Up until 3 years ago I didn't think so. And I don't know of any effective accountability system that exists out there right at this time. I'm sure some companies may have some.

Mr. BLILEY. Well, to the best of your knowledge, what was the usual practice among sales representatives? What did they usually do with these things? Did they give them all to doctors, or what?

Mr. BURKLOW. Sir, the physician samples are a powerful selling tool to enable the sales representatives to get in the doctor's office. They give sample merchandise to pharmacists to obtain larger orders or, in effect, reduce the price of an order. They use them, as I mentioned, to avoid returns. They sometimes get doctors or pharmacists to recommend a product to get a favorable shelf position on like an OTC-type product. And I've even heard of sales representatives bartering samples for other personal use items.

Mr. BLILEY. Did that latter occur very often? In your opinion, was that a common practice?

Mr. BURKLOW. Yes, sir.

Mr. BLILEY. In other words, if he needed something, a hair dryer or a shaver or—

Mr. BURKLOW. The world is the limit, sir. Each salesman got his own things and used his ingenuity on what to do.

Mr. BLILEY. I see. And isn't true that the products that are sampled are usually newer and more expensive patented items?

Mr. BURKLOW. That's correct.

Mr. BLILEY. Have you heard that companies sometimes send stock merchandise rather than sample packages for the use of sales representatives in negotiating with prospective customers?

Mr. BURKLOW. Yes, sir. When I was with Lederle, this process was known as a transaction Code 25, and I am since told it has changed to a transaction Code 85.

Mr. BLILEY. I thank you, and I certainly appreciate your testimony and your help with this subcommittee. Thank you, Mr. Chairman.

Mr. WYDEN [presiding]. The gentleman from Ohio, any questions from you, sir?

Mr. LUKEN. Not at this time.

Mr. WYDEN. Thank you very much, Mr. Burklow, and you are excused.

[The following letter was received:]

Eddie R. Burklow  
c/o Guy E. Davis, Jr., Attorney  
5430 Glenridge Drive, N.E.  
Atlanta, Georgia 30342

October 16, 1985

The Honorable Thomas J. Bliley, Jr.  
Congress of the United States  
House of Representatives  
213 Cannon HOB  
Washington, D.C. 20515

Re: Subcommittee on Oversight and Investigations,  
September 19, 1985 testimony of Eddie R. Burklow

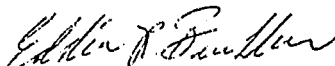
Dear Mr. Bliley:

The following response is made to your letter of October 7, 1985, requesting clarification of points of my testimony:

1. No. To my knowledge Owens and Minor did not participate in any profit arrangement whatsoever.
2. No. I have no direct knowledge that Owens and Minor were aware their products were being "resold".

Please advise if I can be of further assistance.

Sincerely,



EDDIE R. BURKLOW

ERB/md

Mr. WYDEN. Our next witness, Mr. Stephen Eckstein, President of R.E.A.C.T., Inc. of Hewitt, NJ, if he would come forward.

Mr. Eckstein, good morning. Let me brief you on the rules of the subcommittee. It is the practice of the subcommittee to swear all witnesses. Do you have any objection to being sworn?

Mr. ECKSTEIN. None at all.

Mr. WYDEN. Please stand and raise your right hand.

[Witness sworn.]

Mr. WYDEN. Mr. Eckstein, you also have the right to be represented by counsel and to have a copy of the committee rules with you at all times throughout your attendance here. We will make a copy of your prepared remarks a part of our hearing record in their entirety, and if you would like to just summarize your principal concerns, that would leave plenty of time for members who have questions.

**TESTIMONY OF STEPHEN ECKSTEIN, PRESIDENT, R.E.A.C.T., INC.,  
HEWITT, NJ**

Mr. ECKSTEIN. To begin with, my professional career as a loss prevention consultant, fraud auditor, and private investigator includes some 25 years of experience with white collar crimes for U.S. corporations. In September 1980, I formed my own company, R.E.A.C.T., Inc., which now operates as a licensed private detective agency in New Jersey.

During the past 5 years, R.E.A.C.T. has investigated 19 cases of product diversion. Of these, 13 cases involve prescription health care and/or pharmaceutical products, while the remaining 6 cases had to do with industries such as textiles, automotive products, health and beauty aid items such as cosmetics and fragrances. In only one of these cases did the diverted product—in that case, a textile item—source from within the United States.

It's more significant, however, that with one or two exceptions, our investigations revealed that the diverted goods sourced from a facility owned and/or operated by the manufacturer and that these diversions occurred with the willing participation of an employee of that facility, who often violated established company procedures or committed outright fraud as a means of channeling large quantities of his company's product into the hands of a diverter.

Our investigations have also led us to conclude that very often the internal systems and procedures which might deter this type of diversion and/or alert the company to a diverted shipment were poorly planned, poorly implemented, and sometimes ignored entirely by the company. Thereby permitting a dishonest employee to assume all the authority necessary to perpetrate a diversion fraud.

It should be noted that huge amounts of goods can be diverted by anyone armed with little more than a Telex machine and a good working knowledge of a given product or market. Furthermore, the leniency we have seen as exhibited by most banks in issuing letters of credit permits a diverter to operate without risking any of his own capital.

Therefore, it is not surprising to find the ranks of diverters swelled daily by ex-salesmen of pharmaceutical companies or other disgruntled past or present employees of the very companies whose

products they now divert. Though many of these diverters are smalltimers, they can nevertheless cause considerable damage in the marketplace.

One major diversion operation we've run across several times over the past few years is an Eastern bloc entity known as D.A.L. International Trading Company. Their address and the key personnel involved are included in my written statement. Their primary method of operation is to target on off-shore managers of U.S. companies whose products they wish to get their hands on. Primarily in the United Kingdom and in Western Europe. They will purchase goods through a broker. Deals are usually on an F.O.B. shipping point or ex-works basis, the purpose being to prevent the seller from exercising any authority over the shipment once it has left his premises. Payment for the goods is generated via the broker on his letter of credit, rather than that of the purchaser.

Deals are characterized usually by invoice dilution frauds, wire and Telex frauds, confused, multilevel shipment routing and recontainerization by a confederate freight forwarder in Rinjhaven in The Netherlands. The goods purchased through the D.A.L. organization are not intended for distribution in Poland, and except for a sampling of goods used to "salt" local Polish shops, never reaches Poland at all. Instead, these goods are shipped to the true buyer who, through the use of the D.A.L. scheme, is allowed to remain anonymous.

A typical D.A.L. invoice will amount to between \$500,000 and \$1 million United States, so there's a great deal of money being turned through this operation.

So sophisticated is the D.A.L. scheme that we found one of our clients had been selling to D.A.L.—or at least thought it was D.A.L. he was selling to—for at least the past 5 years, never realizing that the goods he sold were being diverted.

D.A.L. is essentially a shell company used by diverters as the apparent customer, and as a Telex drop through which the diverters can communicate with their victims while maintaining anonymity.

According to officials at the Polish Embassy in London, D.A.L. is set up as a buying arm of the Polish Government to supply Western goods to the Polish people. Therefore, we must presume that its activities are condoned by the Polish Government. Our investigations have revealed other clues as well which tend to support that contention. The broker used by D.A.L. in all of the cases we have investigated to negotiate purchases on their behalf is a gentleman by the name of Brian Morrison who operates a company called Nagal, Ltd., located in Paris, France.

Essentially, the goods are sold to Nagal, who then serves as both the exporter and the principal in the letter of credit used to pay for the goods. Hence, the Nagal operation becomes a buffer to prevent the seller from knowing (a) the true destination of the goods, and (b) the true identity of the payee.

On goods sourcing from the United Kingdom, Nagal will specify the pickup from the manufacturer's premises and delivery to the shipping point—usually the Ipswich docks—is to be handled by PSA freight forwarders. PSA stands for the Polish Shipping Authority, and in fact is housed at the same building which houses the Polish Embassy in London at 15 Devonshire Street.

PSA in turn will subcontract this haulage to any one of a variety of local characters; one of these is LEP Transport who is located at Ipswich. It is at LEP that the first alteration of the shipping documents occurs.

Discarding the manufacturer's paperwork, such as container notes, picking tickets, packing slips, certificates of origin and so on which are prepared by the manufacturer, LEP will then prepare new documentation and waybills showing himself as the exporter and the consignee not as D.A.L. in Warsaw, Poland, but as a freight forwarder called Karl Rapp, located in Rinjhaven in The Netherlands.

I have with me some typical documents showing that alteration, and the committee is welcome to them. This first document is the certificate of dispatch prepared by PSA showing the Nagal Co. as the exporter—

Mr. WYDEN. Mr. Eckstein, I would just direct that that document be submitted for the record following your testimony.

Mr. ECKSTEIN. The goods will then be berthed by LEP on a Geest lines ship, usually the *Britta 1* or *Hans Kroger*, which are the two ships used for this purpose by Geest, and shipped to Rapp in The Netherlands.

During one of our cases involving the D.A.L. pipeline, we visited the Polish Embassy in London and spoke with a Mr. Eric Wood concerning documents related to the D.A.L. shipments. During the course of our conversation, Wood was called from the room and we had a chance to leaf through the D.A.L. file which remained on his desk. The file contained little of substance, which in and of itself was conspicuous; however, a green copy of a freight invoice from PSA had apparently become lodged between two Telexes and was thus overlooked by whomever cleaned out the file in preparation for our visit. The invoice was for freight charges for our client's shipment from London to Carl Rapp in Rinjhaven, the amount charged to the account of OPEX, GmbH., located at Dr. Eigenolf Strasse in Kalkheim, West Germany. The address turned out to be a private home in a rather affluent suburb of Frankfurt. The home is owned by a Mr. Leslie Milward, who is registered as the manager of OPEX.

It would appear that OPEX in this case was the main diverter of the goods. However, when we attempted to verify this through entry records at U.S. Customs, we were refused cooperation.

In any event, it is Karl Rapp who performs the second alteration of documents which reroutes the goods to the destination specified by the diverter; in this case, OPEX. It is also Rapp's function to break down the original shipping container and repack the goods, presumably to separate the shipments according to the instructions of OPEX's customers, who we presume are located in the United States. This, of course, obviates tracking the shipment by container number through the container leasing companies.

In at least two of our D.A.L. cases, Rapp forwarded a small portion of each shipment to Poland, presumably to be used as "salt" to convince the visiting representatives of the manufacturer that the entire shipment had, in fact, arrived in Poland as anticipated.

The sophistication of this particular move is not readily apparent. Perhaps a word of explanation is necessary. You see, if you

wish to enter Poland for business purposes, you are required to obtain an invitation to do so from the company you are dealing with. Therefore, D.A.L. has a built-in mechanism for determining precisely the time you will arrive in Poland and therefore, precisely the time at which to "salt" the local Polish shops with the small portion of goods they have received. So when you arrive in Poland you are, in fact, convinced that your shipment has arrived.

While investigating the D.A.L. operation on another occasion, we paid an unannounced visit to the Polish Embassy in London and upon entering one of the offices there, we came upon a Telex operator in the midst of sending a Telex to our client. The call and send signatures entered by the operator had been falsified to make the message appear to have emanated from the offices of D.A.L. in Warsaw.

This is a copy of that Telex, and attached to it is a valid Telex so that you can see the difference in the call and send signatures, and I'd like to have this submitted into the record.

Mr. WYDEN. Without objection, it also will be inserted into the record.

Mr. ECKSTEIN. On yet another D.A.L. case, we found that our client's employees had in fact conspired with the Polish Embassy officials to make it appear that a diverted shipment had actually arrived intact in Poland. In this case, our client's invoices had been imprinted with the Polish Consular Stamp, thus signifying that the Polish Government accepted responsibility as consignee for the goods. However, according to our contacts in the British Department of State, Foreign Office and the Eastern Bloc Trade Commission, the stamp which was indeed applied by an Embassy official was a phony.

I have here an example of that stamp, along with it an example of a stamp which might more likely have appeared on the invoice so you can see the difference between the two. Also, I have a copy of the signature, the actual signature, of the Polish trade attaché, and you will note by looking at the documents that the two signatures are in no way similar. And these documents should also be included in the record.

One final note which might give some insight to the impact that the D.A.L. pipeline is having on the U.S. economy, and particularly the companies that are victimized by this diversion operation, during the unannounced visit to the Polish Embassy which I mentioned before, we also observed a handwritten note in English lying atop a file on a Telex operator's desk which appeared to list the shipments for the month of November 1983 which were to be sent through the same maze as described above. The list contained the names of no less than 13 major U.S. companies. One of those companies, in fact, was G.D. Searle, though I have no knowledge that the name Searle had anything to do with the Ovulen problem.

With respect to the Caribbean diverters, I want to make clear that virtually every major pharmaceutical manufacturer is represented in Puerto Rico. And indeed, for some manufacturers, a sizeable percentage of their domestic market is supplied from goods manufactured in Puerto Rico. It should therefore come as no surprise that Puerto Rico is a primary source of Caribbean pharmaceutical diversion. Goods are often routed from Puerto Rico via

phony Latin American distributor market accounts to Panama, and then reshipped into the United States.

However, we have also found instances where shipments were invoiced to dummy or nonexistent companies and/or government organizations in Puerto Rico but actually were shipped directly into the United States. This is quite easy in the Caribbean since diverter accounts are usually on a COD or cash-in-advance basis. Hence, receivables booked for such orders can be cleared with cash payments to prevent identification of the payee. So it is conceivable that the companies whose name appears on the invoice never placed the order and, in fact, knows nothing about it.

The subcommittee has already stated that Florida is a hotbed of diverters. However, it is my view that what we may be seeing in Florida are the receivers of diverted LADM—Latin American Distributor Market—goods, rather than the diverters themselves. Florida then may be the mainland entry point for diverted pharmaceuticals only because of its proximity to Puerto Rico and the LADM.

Diversions from the Caribbean are characterized by invoice dilution frauds, inadequate shipping documentation, or shipping documentation which has been altered or simply destroyed by the branch sales office, falsification of customer names and addresses; indeed, treachery and deceit are so much a part of doing business in the Latin American distributor markets that at times it appears that in that part of the world, integrity in business is considered a weakness rather than a virtue.

It has been our experience that the international diverters most often obtain goods directly from the manufacturer through authorized offshore sales branches and/or distribution points where corporate scrutiny and supervision is likely to be more relaxed. Symptomatic of purchases intended for diversion is the need to obtain goods at a price which will permit a profit margin large enough to pay the reshipment costs, provide a profit to the diverter and still enable the goods to be sold in the United States at a price which is more attractive than that offered by the manufacturer's own domestic sales force.

In many cases, this end-line pricing may undercut the manufacturer by only a few cents; however, this savings, though small in terms of unit price, becomes substantial when one considers that a single diverted shipment may consist of hundreds of thousands or even millions of units.

In short, the diverter prefers to source goods from the manufacturer because doing so insures first, a stable source of supply, second, the best opportunity for negotiating price, and third, a source large enough to supply the entire diversion market.

The most common methods we have found by which diverters obtain goods are as follows. First, collusive fraud with manufacturers' offshore sales representatives. This includes invoice dilution, falsification of customer records and shipping documents.

Second, promotional deals offered by the manufacturer which are then siphoned into the redistribution market, as you have already heard from other witnesses.

Triangular deals which involve broker/agent relationships and third party countries such as the D.A.L. scheme.

Repurchases from special discount or tax exempt customers, as in the case of diversion through hospitals.

Two-for-one buy-back schemes; mixed inventory consignment sell-offs—

Mr. WYDEN. Mr. Eckstein, excuse me. We just have a vote. If you'd like to finish and you feel you can finish very briefly, we'll proceed with yours and then come back for questions. And if not, we can just submit the rest of your remarks for the record.

Mr. ECKSTEIN. OK. I only have a few more comments to make so it will only take a second. In fact, this is my final comment.

The situations I've been discussing here are substantially a summary of the information contained in my written statement, and it is my sincere wish that the information contained herein will provide a better standing of the diversion issue as a whole and lead to the development of sound antidiversion legislation in the future.

[Testimony resumes on p. 276.]

[The prepared statement and attachments of Mr. Eckstein follow:]



U.S. House Of Representatives  
Subcommittee On Oversight And Investigations  
Washington, DC 20515

STATEMENT OF

Stephen Eckstein

A. Background And Experience

My professional career as a loss prevention consultant, fraud auditor and private investigator includes some twenty five years of experience with "white collar" crimes.

In September 1980, I formed my own company, R.E.A.C.T., Inc., a licensed private detective agency.

During the past five years R.E.A.C.T. has investigated nineteen cases of product diversion. Of these, thirteen cases involved prescription health care and/or pharmaceutical products, while the remaining six cases had to do with industries as diverse as textiles, automotive products and HEA items such as cosmetics and fragrances. In only one case did the diverted product (a textile item) source from within the U.S.A..

It is more significant, however, that with one or two exceptions, our investigations revealed that the diverted goods sourced from a facility owned and/or operated by the manufacturer and that these diversions occurred with the willing participation of an employee of that facility, who often violated established company procedure or committed outright fraud as a means of channeling large quantities of his company's product into the hands of a diverter. Our investigations have also led us to conclude that very often the internal systems and procedures which might deter this type of diversion and/or alert the company to a diverted shipment, were poorly planned, poorly implemented or ignored entirely by corporate management, thereby permitting a dishonest employee to assume all the authority necessary to perpetrate a diversion fraud.

## X B. Definitions

It is important to understand that there are essentially two forms of diversion. The first is called "redistribution" and pertains to goods which are merely "juggled" between buyers within a particular national market place. It is this form of diversion which the committee has primarily concentrated upon thus far. Goods diverted through redistribution do not pass through customs check points, nor are they subject to international shipping regulations, import/export licensing requirements, entry/exit tariffs, etc.

While there are, as the committee knows, instances of illegal redistribution (ie.- hospitals selling off excess pharmaceuticals at a profit), there is a vast opportunity for legal redistribution arising from occasional promotional "deals" offered by manufacturers as well as from volume discounts or pricing differentials which are effected constantly by the manufacturer. For example:

Account Type	Minimum Order	Price/ea. \$
A. Distributor	10,000 ea.	\$0.50
B. Mass Retailer	5,000 ea.	0.75
c. Drug Store	12 ea.	1.00

The consumer may buy from the Mass Retailer for perhaps \$1.50 or from the Drug Store for \$2.00.

In the above example it is presumed that the distributor will sell to drug stores who, in turn, will sell to the consumer. Similarly, it is presumed that the mass retailer will sell directly to the consumer. Nevertheless, it is clear that redistribution can occur when distributors undercut the manufacturers price to sell to mass retailers or when retailers undercut the distributors price to sell to drug stores. This would, of course affect the manufacturers domestic sales in terms of lowering the average realized price per item. It would also precipitate a credibility gap between the manufacturer and his customers and would demoralize his sales force, thereby reducing its effectiveness.

Diversion, on the other hand, occurs when goods intended for one national market are siphoned away from that market and dumped into another country... usually at a price substantially below that at which the goods would normally be available in the receiving country. The methods by which the pricing of diverted goods is diluted to effect this circumstance and the subterfuge used to hide the true destination of the goods, have constituted the basic components of diversion frauds uncovered in the majority of our cases. The specific workings of these frauds will be described in detail later in this statement.

#### C. The Impact Of Diversion

1. On the consumer:- To begin with, while diverted goods enter the retail distribution system at a lower-than-normal price, it may be somewhat naive to presume that any savings realized by the distributor or retailer will be passed on to the consumer. Hence, diversion can not be presumed the consumers friend, even in the best of circumstances.

Indeed, the opposite is often true since the diversion is costly to the company and may ultimately force the manufacturer to raise prices in order to offset the loss once the marketplace has absorbed the diverted product. Thus the "bargain", if any, is short lived and the consumer once again must pay the piper a higher price than might have existed had there been no diversion.

Furthermore, as the subcommittee has already learned, there is a potential for substandard product to enter the diversion pipeline and this presents a safety hazard to the consumer. In fact, since rejects or out of date goods can be bought cheaply by diverters, this becomes one method by which an unscrupulous diverter can dilute the cost of his purchase.

- y 2. On the National Economy:- Unlike redistribution, the effects of diversion are to produce a glut of product in the U.S. domestic market. In turn, domestic sales will drop forcing the manufacturer to reduce inventory levels by cutting back domestic production. This, in turn, could lead to a loss of jobs for the U.S. work force. Similarly, domestic salesmen employed by the manufacturer would be directly affected by lost sales both to those accounts who have access to the lower priced diverted goods as well as accounts which refuse to buy from the manufacturer in anticipation of being able to get diverted goods. One must also consider that any significant drop in production by a major manufacturer in any industry must necessarily affect the entire supply line (ie.- raw material suppliers, subcontractors, etc.)

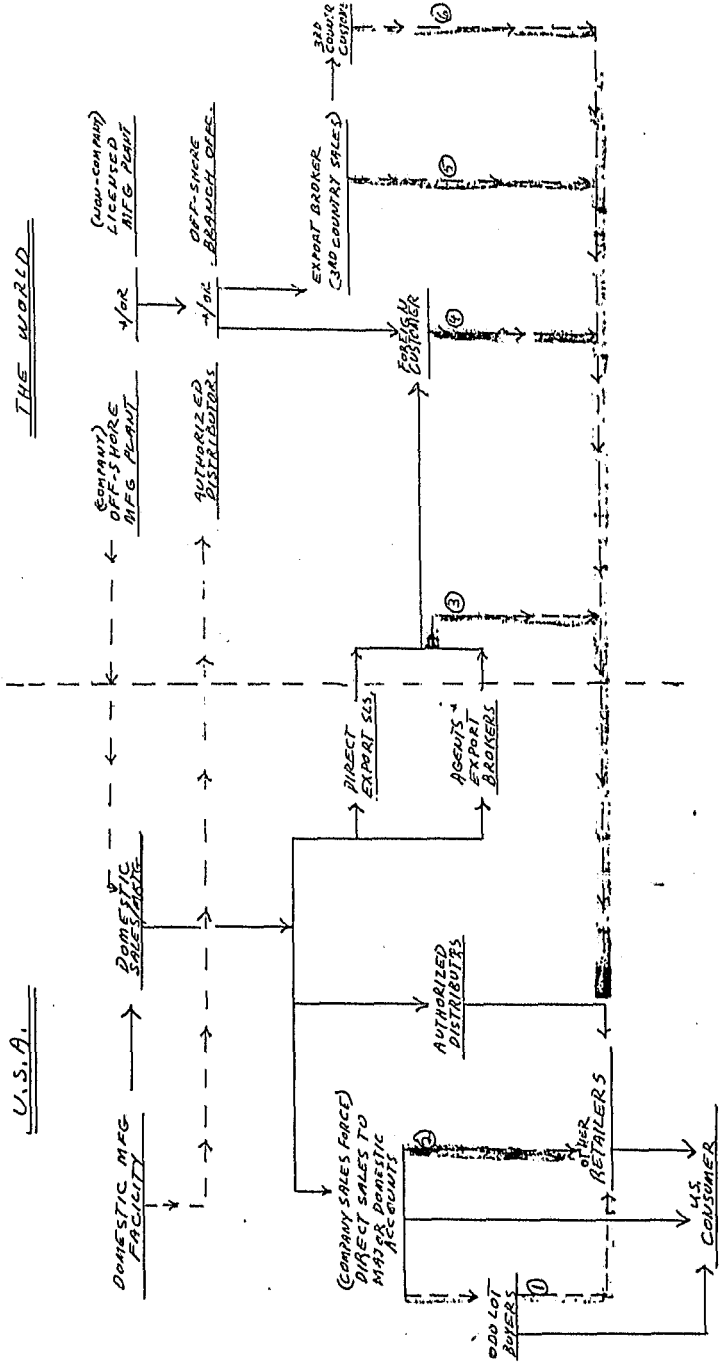
- X 3. On corporate profits and image -
- a. Product saturation and gross profit in off-shore markets drops sharply as products slated for those markets are siphoned away by diverters.
  - b. The manufacturers domestic sales plunge as low priced diverted goods begin to flood the home market.
  - c. Armies of domestic salesmen, dependent upon the manufacturer for their livelihood, become disgruntled and demoralized as their incomes are affected by reduced sales potential.
  - d. Even those domestic customers with no access to diverted goods will wrongly presume the manufacturer is denying them what they perceive as preferential discounts to their competitors. Thus, in anger, they too will abandon the manufacturer.

X In theory, the ultimate danger faced by the manufacturer is the simultaneous erosion of both off-shore and domestic markets. Such erosion would force the company into increasing dependency upon the diverter as he becomes the only sales outlet for its products. Accordingly, as the diverters strangle hold increases, he can demand lower and lower costs from the manufacturer while selling to the consumer at ever increasing prices.

X D. Global product distribution systems.

Though I do not claim to be an expert on product distribution systems, I have taken the liberty of preparing the attached chart which depicts a typical global distribution system based upon those which I have examined in the course of my investigations into diversion. The chart is fairly self explanatory and depicts the six basic danger points from which diversion or redistribution is likely to source.

GLOBAL PRODUCT DISTRIBUTION



~~CONFIDENTIAL~~

## E. The Diverters

It should be noted that huge amounts of goods can be diverted by any one armed with little more than a telex machine and a good working knowledge of a given product and/or market. Furthermore, the leniency exhibited by most banks in issuing letters-of-credit permits a diverter to operate without risking any of his own capital. Therefore, it is not surprising that the ranks of diverters are being swelled daily by ex-salesmen and/or other disgruntled past or present employees of the very companies whose products they now divert. Though many of these diverters are "small timers", they can, nevertheless, cause considerable damage in the marketplace.

The following are the names, and other descriptive data relative to major diverters identified during investigations conducted by REACT, Inc. (Note:- acts of diversion perpetrated by the following entities include, but may not be limited to, pharmaceuticals alone).

1. D.A.L. International Trading Company  
12 Swietokrzyska Street  
Warsaw, Poland 00-044

Key Personnel: Ms. Teresa Wojcicka  
Mr. Leszek Kozka

M.O.: Targets primarily on off-shore managers of U.S. manufacturers (primarily in the U.K. or western Europe) whose products they wish to obtain. They will purchase goods through a broker. Deals are usually on a F.O.B. shipping point or ex-works basis. Payment for goods is generated via the

broker on his letter of credit. Deals are characterized by invoice dilution fraud, telex fraud, confused multi-level shipment routing and re-containerization by freight forwarders at Rinjhaven, Neth. The goods purchased through D.A.L. are not intended for distribution in Poland and, except for a sampling of said goods used to "salt" Polish shops, never reaches Poland. Instead, these goods are shipped to the true buyer who, through use of the D.A.L. scheme, remains anonymous.

A typical D.A.L. invoice will amount to between \$500,000 and \$1 million U.S. dollars.

So sophisticated is the D.A.L. scheme that we found one of our clients had been selling to D.A.L. for at least the past five years, ... Never realizing that they were diverting his goods.

Operation and Structure - ( The "Pipeline" ):

1. D.A.L. is essentially a "shell" used by the diverters as the apparent customer and as a telex drop through which the diverters can communicate with their victims while maintaining anonymity. According to officials at the Polish embassy in London, D.A.L. is set up as "A buying arm of the Polish Government". Therefore, we must presume that its activities are condoned by the Polish government. Our investigations have revealed other clues as well which tend to support that contention. The broker used by D.A.L. to negotiate purchases on their behalf is:



Mr. Brian Morrison  
 c/o Nagal, Ltd.  
 91 Rue Fauberge St. Honore  
 Paris, France

Essentially the goods are sold to Nagal who then serves as both the exporter and the principal in the letter of credit used to pay for the goods. Hence, the Nagal operation becomes a "buffer" to prevent the seller from knowing (A) the true destination of the goods and (B) the true identity of the payee.

On goods sourcing from the U.K., Nagal will specify that pick up from the manufacturers warehouse and delivery to the shipping point (usually the Ipswich docks) is to be handled by PSA freight forwarders. (Note.- PSA, which stands for Polish Shipping Authority, is actually based at the Polish embassy on 15 Devonshire Street in London). PSA, in turn, will subcontract this haulage to any one of a variety of local carriers. One of these is LEP Transport at Ipswich.

It is at LEP that the first alteration of shipping documents occurs. Discarding the manufacturers paperwork which shows D.A.L. as the consignee, LEP will prepare new way bills and H.M. customs "T" forms showing the consignee as "Karl Rapp, Bv. a freight forwarder located in Rinjhaven. The goods will then be berthed on a Geest lines ship (usually the Britta 1 or the Hans Kroger) and shipped to Rapp.

During one of our cases involving the D.A.L. pipeline we visited the Polish embassy in London and spoke with a Mr. Eric Wood concerning documents related to the D.A.L. shipments. During the course of our conversation, Wood was called from the room and we had a chance to leaf through the D.A.L. file on his desk. The file contained little of substance, (which in-and-of-itself was conspicuous). However, a green copy of a freight invoice from PSA had apparently become lodged between two telexes and thus was overlooked by whomever cleaned out the file in preparation for our visit. The invoice was for freight charges (amounting to some 600 pounds sterling) for our clients shipment from London to Karl Rapp in Rinjhaven. This amount was charged to the account of OPEX, GmbH. at Dr. Eigenolf Strasse in Kelkheim, W. Germany. This address turned out to be a private home in a rather affluent suburb of Frankfort. The home is owned by Mr. Leslie Milward, manager of OPEX.

It would appear then that OPEX was the main diverter of the goods in this case. However, when we attempted to verify this through entry records at U.S. customs we were refused cooperation.

In any event, it is Karl Rapp who performs the second alteration of documents which reroutes the goods to the destination specified by the diverter (ie.- OPEX).

It is also Rapp's function to break down the original shipping container and repack the goods, presumably to separate the shipments according to the instructions of OPEX's customers (probably located in the U.S.A.). This, of course, obviates tracking the shipment by container number.

In at least two of our D.A.L. cases, Rapp forwarded a small portion of each shipment to Poland presumably to be used as "salt" to convince visiting representatives of the manufacturer that the entire shipment had arrived in Poland as anticipated.

While investigating the D.A.L. operation on another occasion, we paid an unannounced visit to the Polish embassy in London. Upon entering one of the offices there, we came upon a telex operator in the midst of sending a telex to our client. The call and send signatures entered by the operator had been falsified to make the message appear to have emanated from the offices of D.A.L. in Warsaw, Poland.

On yet another D.A.L. case we found that our clients employees had conspired with Polish embassy officials to make it appear that a diverted shipment had actually arrived intact in Poland. In this case our clients invoices had been imprinted with a Polish "Consular Stamp" thus signifying that the Polish government accepted responsibility as consignee for the goods. However, according to our

contacts in the British Department of State, The Foreign Office and the Eastern Bloc Trade Commission, the stamp (which was indeed applied by an embassy official) was a phony.'

One final note which might give insight to the impact that the D.A.L. pipeline is having on the U.S. economy: ... During the unannounced visit to the Polish embassy mentioned above, we also observed a hand written note (in English) lying atop a file on the telex operators desk which appeared to list shipments for the month of November, 1983 which were to be sent through the same maze as described above. The list contained the names of no less than thirteen major U.S. companies.

## 2. Caribbean Diversifiers

Virtually every major pharmaceutical manufacturer is represented in Puerto Rico and indeed, for some manufacturers, a sizeable percentage of their domestic market is supplied from Puerto Rico. It should, therefore, come as no surprise that P.R. is a primary source of Caribbean pharmaceutical diversion. Goods are often routed from P.R. via phony LADM accounts to Panama and then re-shipped to the U.S.A. However, we have also found instances where shipments were invoiced to "dummy" or non-existent companies and/or government organizations in Puerto Rico but actually shipped directly into the U.S.. This is quite easy in the Caribbean since the diverter accounts are usually on a C.O.D. or cash-in-advance basis. Hence,

receivables booked for such orders can be cleared with cash payments to prevent identification of the payee. Thus, it is conceivable that the company whose name appears on the invoice never placed the order and knows nothing about it.

The Subcommittee has already stated that Florida is a hot-bed of diverters. However, it is my view that what we are seeing in Florida are the receivers of diverted LADM goods rather than the diverters themselves. Florida then, may be the mainland entry point for diverted pharmaceuticals only because of its proximity to Puerto Rico and the LADM.

Diversions from the Caribbean are characterized by invoice dilution frauds, inadequate shipping documentation, and falsification of customer names and addresses. Indeed, treachery and deceit are so much a part of doing business in the LADM that at times it appears that in that part of the world, integrity in business is considered a weakness rather than a virtue.

Major diverters in the Caribbean are as follows:

\* DIVERTERS - LATIN AMERICA

- |   |  |
|---|--|
| 1. Harry Bilgray -<br>DBA: Servicios Comerciales                | P.O. Box 3173<br>Zona Libre De Colon<br>Colon, Panama  |
| 2. Monogram, S.A. -   | P.O. Box 6454<br>Zona Libre De Colon<br>Colon, Panama  |
| 3. Isabel Martinez<br>DBA: Servicios Marche S.A.                | Apartado 60 4569<br>Estafeta El Dorado<br>Panama   |
| 4. Liberal Exchange Enterprise                                  | Apartado 2087<br>Zona Libre De Colon<br>Edificio 43, Locale 5<br>Colon, Panama                   |
| 5. Julio E. Ulloa<br>DBA: Market Managers, Ltd.                 | Edificio #45<br>Locales #2 y #2A<br>Calle 17.5 y P.Gordas<br>Zona Libre De Colon<br>Colon Panama |
| 6. Gloriella Carbone<br>DBA: Glorcom<br>DBA: Listom Enterprises | Bldg. #62, Whse #1<br>Francefield<br>Zona Libre De Colon<br>Colon, Panama                        |
| 7. S. Harris<br>DBA: Caribe Wholesalers                         | Custodie Almacenage<br>Buildg. 44, Locale 2<br>Zona Libre De Colon<br>Colon, Panama              |

8. Ricaurte E. Savaí R.  
DBA: Drogueria Sara  
Ave. Justo Arosemena  
(Cor. Calle 45)  
Edificio Balboa  
Office #7  
Panama 5, Panama
9. Martín Thiuna  
DBA: Savon Drug  
DBA: Drogueria Puerto Rico Isla  
Carr. 686, Km 0.5  
Bo. Campo Alegre  
P.O. Box 265  
Manati, P. R.
10. Laura Distributors  
Ave. San Marcos (cor.  
Vlqz El Comandante)  
Rio Piedras, P.R.
11. Drug Center  
DBA: Farmacia Moscoso  
DBA: Moscoso Hno's.  
Carr. 1, Ramal 175  
Km. 0.2  
Caguas, P.R.
12. Drogueria Braulio  
DBA: Drog. Cabalero Del Caribe  
1608 Ponce De Leon  
Santurce, P.R.
13. COD Drug  
1611 Fdez. Juncos  
Santurce, P.R.
14. Arguelles Distributors  
205 Calle Cruz  
Old San Juan, P.R.
15. Irma Bermudez  
DBA: Distribudora Antillana  
Ave Boulevard, R.A.8  
Levittown, P.R.

## F. How Diverters Get Merchandise

It has been our experience that international diverters most often obtain goods directly from the manufacturer through authorized off-shore sales branches and/or distribution points where corporate scrutiny and supervision is likely to be more relaxed. Symptomatic of purchases intended for diversion is the need to obtain goods at a price which will permit a profit margin large enough to pay the reshipment costs, provide a profit to the diverter and still enable the goods to be sold into the U.S. at a price which is more attractive than that offered by the manufacturers own domestic sales force. In many cases, this end-line price may undercut the manufacturer by only a few cents. However, this savings, though small in terms of unit price, becomes substantial when one considers that a single diverted shipment may consist of hundreds of thousands or even millions of units. In short, the diverter prefers to source goods from the manufacturer because doing so insures (1) a stable supply source, (2) the best opportunity for negotiating price and (3) a source large enough to supply the entire diversion market.

The most common methods by which diverters obtain goods are as follows:

1. Collusive fraud with manufacturers off-shore sales reps. (invoice dilution, falsification of customer records and shipping documents).
2. Promotional deals offered by manufacturer.
3. Triangular deals
  - a. Broker/agent relationships and 3rd party deals.
  - b. Compensation/switch barter deals.
4. Repurchases from special discount or tax exempt customers.
5. The two-for-one buyback scheme.
6. Mixed inventories and consignment sell-offs.
7. Buying substandard product to dilute pricing.



X G. Corporate Practices Which Are Exploited By Diverters

1. The law of "Supply and Demand" vs. pricing and packaging considerations.
2. Sales pressures can invite diversion.
3. Shipping vulnerabilities. (Consignee-to-order)
4. Invoicing weaknesses.
5. M.I.S. failures.
6. Diversion as a short-term benefit to the victim.

X H. Other Factors Which Aid The Growth Of Diversion

1. Diversion is not illegal.
2. Robinson-Patman concerns.
3. Jurisdictional constraints often prevent investigation.
4. Lack of cooperation between private and governmental agencies.
5. Lack of cooperation between U.S. and foreign governments.
6. Territorial marketing agreements which deter diversion may in-and-of-themselves be a violation of free trade agreements.
7. A lack of corporate education about diversion.

X I. What Can Be Done To Stop Diversion.

1. Establish broad-based anti-diversion laws
2. Establish a global methodology for verifying the bona fides of international buyers.
3. Establish a federal licensing provision for private investigators which:
  - a. Provides access to U.S. Customs data.
  - b. Establishes a basis for federal investigators to work in cooperation with private agents on crimes of international scope.

- c. Eliminates interstate jurisdictional constraints on corporate investigations.
4. The singlemost effective tool in identifying diversion emanating from the manufacturers own facility is the "operational" audit. Such audits are the basis of a professional investigators approach to the problems of corporate fraud and diversion. An operational audit should be mandated on a yearly basis just as financial audits are now. Furthermore, professional investigators should be specifically licensed to conduct such audits.
5. Establish a greater level of cooperation with foreign customs services.

The foregoing information has been provided in response to the Subcommittees request for a written statement of my experiences with international diversion. It is my sincere wish that the information contained herein will provide a better understanding of the diversion issue as a whole and lead to the development of sound anti-diversion legislation in the future.

Sincerely,

Steve Eckstein  
President  
R.E.A.C.T., Inc.

Carrier:  
**NAGEL LIMITED**  
**65, OXFORD ROAD SOUTH**  
**LONDON W4 3DD**

Consigned to  
**DAL**  
**12, SWIETOKRZYSKA STREET**  
**00-444 WARSZAWA - POLAND**

Date of Departure: **31.10.1984**      Port of Loading: **IPSWICH**

Unit No.:  
**106005-0**

We confirm goods shown below have been exported from United Kingdom.  
**AS PER THE INSTRUCTIONS OF**  
**DAL - WARSZAWA - DESTINATION POLAND**

**CERTIFICATE OF DESPATCH**

CAN



Our Reference: **EC/26-0051**  
 Date Issued: **31.10.1984**

**PSA TRANSPORT LIMITED**  
 INTERNATIONAL SHIPPING & FORWARDING AGENTS

16 DEVONSHIRE STREET LONDON W1N1FSS  
 Telephone 01-6373271 (10 lines)  
 Telex 886204 PSATRANS LONDON  
 Cables PSATRANS LONDON EC2

Marks, Nos. & Container No.	No. & Kind of Packages / Description of Goods	Gross Wt (Kgs) Said to be
<b>DAL WARSZAWA</b>	<b>686 cartons - said to contain</b>	
<b>DAL - ORDER NO.</b>		<b>14,139,55 kilos</b>
<b>80-122-4-9164-84</b>		<b>(14,140 kilos)</b>
<b>POZNAŃ/GDANSK/WARSZAWA/KATOWICE</b>		

Systemtrans Ltd Perm RT - 02 (171)

REFERENCE	ITEM	UNITS
4892	[REDACTED]	17ML 75.000
4892	[REDACTED]	30ML 16.000
4892	[REDACTED]	60ML 10.750
4897	[REDACTED]	30ML 8.000
4891	[REDACTED]	60ML 4.000

**IRREVOCABLE DOCUMENTARY CREDIT NO. 684-1058/SN**      GOVERNING SHIPMENT OF **[REDACTED] PRODUCTS**

WE FURTHER CONFIRM THAT THE UNDERMENTIONED DOCUMENTS WERE DESPATCHED AS SHOWN ACCOMPANYING THE GOODS.

- |   |                          |
|---|--------------------------|
| <input type="checkbox"/> Commercial Invoice/Specification | <input type="checkbox"/> |
| <input type="checkbox"/> Specification/Packing List       | <input type="checkbox"/> |

DESPATCHED PER AIRMAIL TO: **DAL - WARSZAWA POLAND**

- |  |
|--|
| <input checked="" type="checkbox"/> Copy Invoice/Specification |
| <input type="checkbox"/>                                       |
| <input type="checkbox"/>                                       |

for PSA TRANSPORT LIMITED

CO. LIMITED, (MANUFACTURERS) NAME		For Forwarder's Use Customs Reference Number
BR11 8M2 Consignee's Name, full name, street, town and address DAL 12 ŚMIEŁOKHYZYŃSKA STREET, CO-04, WARSZAWA, POLAND.		Forwarder's Name MORFIZ: MACEL LIMIVENI 65 OXFORD ROAD SOUTH LONDON W4 3DD

Freight Forwarder P.S.A. TRANSPORT LIMITED 16 DEVONSHIRE STREET LONDON E.C.1.	If required, this space may be used for other address, e.g. Buyer, Place of Assignment/Delivery, additional Notify Party
Receiving/Collection Details Date/Time/Container Issue etc.	Country of Origin of Goods UNITED KINGDOM
Dispatched By Place of Receipt	Country of Final Destination POLAND
Vessel/Aircraft etc. Port of Loading	If required, this space may be used for other address or other information.
Port of Discharge Place of Delivery	Please insert approved air route plus air

Marks and Numbers, No. and kind of Packages, Description of Goods*  DAL ORDER NO. BO-122/4-9164/84 POZNAŃ GDANSK WARSZAWA KATOWICE 3771-3853, 4454-4533, 6001-6354, 6420-6588.  IRREVOCABLE DOCUMENTARY CREDIT NO. 684-1058/84 ACCOUNTS & BREAKDOWN IN DUPLICATE.  YERIGET TO DELIVER.	Tariff/Trade Code No.  HAZ 14044X650  NON HAZ 94X900	Gross Weight (kg) 55.108m <sup>3</sup>  0.496m <sup>3</sup>
	Quantity 2 for U.K. Customs HAZ 12555X850	Net Weight £121329.1
	Quantity 3 for U.K. Customs NON HAZ 82X450	FOB Value for U.K. Customs if it NO CHARGE VALUE £3762.90
	* Indicate the correct Tariff/Trade Code No. for each commodity and attach a copy of SITPRO Dangerous Goods Note.	

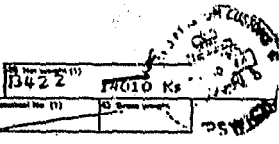
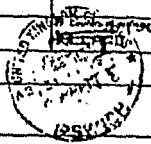
DANGEROUS GOODS  
 Indicate the correct Tariff/Trade Code No. for each commodity and attach a copy of SITPRO Dangerous Goods Note.

Type of Shipment Consignee of Despatch Air, Sea or other Vessel Bill of Lading UK Customs Form Consular Form T Form where appropriate Other FOB Service charges	FREIGHT DOCUMENTATION Indicates service required and to whom charges should be debited, by marking in a circle A, B, C, D or E. In a circle A, B, C, D or E.	Import Duties Storage charges/CO UK port/airport Dumps/CO or port charges in U.K. Freight to: WARSAW Dumps/CO or port charges in destination Dumps/CO Place of delivery	Business Price Special Instructions Name of Contact and Telephone Number CO. LIMITED D.T.M. ROSS WITH BOURNEMOUTH - 31ST OCTOBER 19
The goods are NOT European Community Goods.	Clean Freight Payable to: DESTINATION	No. of Bills of Lading Required 2 Original 2 Copy	I/We hereby declare that the above particulars are correct and true.

EXPORTATION <b>LEP TRANSPORT LTD</b> <b>ELTON PARK INDUSTRIAL EST</b> <b>HADLEIGH ROAD</b> <b>IPSWICH</b>		1 Freight reference <b>019/0041611</b>		2 Importer's reference _____	
11 Consignor <b>KARL RAPP</b>  <b>ROTTERDAM, HOLLAND</b>		REGISTRATION OF DECLARATION Office of Departure <b>653 IPSWICH</b>  No and Date <b>03973; 31.10.84</b>			
12 Principal <b>Geest North Sea Line BV</b> <b>Geest House, Hadleigh Road</b> <b>Ipswich, Suffolk</b>		13 Country of origin <b>UK/22</b>		14 Previous Customs procedure _____	
15 Identity of owner of transport <b>HANS KROEGER</b>		16 Number of marks _____		17 Weight or measure _____	
18 Marks, numbers, labels and kind of packages, description of goods <b>CONTAINER MVGL 106005/0</b> <b>686 CARTONS</b>  <b>Seal nos 000000 000000</b>		19 Dimension (1) _____		20 Gross weight <b>14010 Kg</b>	
21 Marks, numbers, labels and kind of packages, description of goods _____		22 Dimension (1) _____		23 Gross weight _____	
24 Dimension (1) _____		25 Dimension (1) _____		26 Net weight (1) _____	
27 Country of origin <b>ROTTERDAM NL</b>		28 Office of destination (name and address) <b>ROTTERDAM /HOLLAND</b>			
CONTROL BY OFFICE OF DEPARTURE Results of examination _____ Date and place _____ Remarks _____		29 Declaration by the principal The principal, authorized by _____ <b>STEVEN PAUL BEALES</b> hereby undertakes to produce the goods described in this declaration and to comply with the provisions laid down in the regulations			

Please see Section 16, 751 before completing this form

COPY FOR THE PRINCIPAL



Shipper <b>LEP TRANSPORT LTD IPSWICH</b>		B/L no.	
Consignee (if 'Order' state Notify Party) <b>KARL RAPP ROTTERDAM, HOLLAND.</b>		Exporter's ref.	
		F/Agent's ref. <b>0041611</b>	
		<b>Geest North Sea Line B</b> GEEST NORTH SEA LINE B.V. Monumentweg 117 - 2001 JD 's-Gravenzande - Holland Telex 31110 - Telephone (01748) 3841 (8 lines)	
Pre Carriage by			
Vessel <b>HANS KROEGER</b>	Port of loading <b>IPSWICH</b>		
Port of discharge <b>ROTTERDAM</b>	Date of sailing <b>31/10/84</b>	Freight payable at <b>IPSWICH</b>	Number of original B/L <b>TWO</b>
Leading marks and numbers: <small>(Declared by shipper without any responsibility for the carrier)</small>	Number and type of packages <small>(containers)</small>	Description of goods	Gross weight
<b>1 X 40 ft. container</b>  <b>WVDU 106005/0</b> <del>106005/0</del> <b>106005/0</b> contain <b>686 CARTONS</b>		<small>(Declaration of shippers, the carrier not taking any responsibility for the weight, measure, contents, quality, quantity, condition, value)</small>  <b>14010</b>	
<b>Goods to be carried from LONDON</b>		<b>to ROTTERDAM</b>	
<small>Shipped in apparent good order and condition at the stowage Port of loading (see Particulars) by SHIPPER (see Particulars) on board the good vessel (see Particulars) to the Port of Discharge (see Particulars) or to any other port or ports as may be ordered hereunder (see Particulars) which are to be delivered in the said good order and condition at the stowage Port of DISCHARGE (see Particulars) or to his or their Assignee, Shipper or Consignee (see Particulars) to pay freight plus other charges incurred in accordance with the provisions contained in the Bill of Lading.</small> <small>Weight, measure, marks, number, quality, quantity, condition, contents and value unknown.</small> <small>It is mutually agreed that in accepting this Bill of Lading the Shipper and/or Consignee of the goods expressly accepts and agrees to all its stipulations, exceptions, terms and conditions on both sides, whether written, printed, stamped or incorporated, as fully as if they were all signed by such Shipper and/or Owner of the goods. In Witness whereof the Master or Agent of the ship has signed the number of original Bills of Lading stated below all of this tenor and date, one of which being accomplished, the others to stand void.</small>		Disbursement Incl. shipper's charges forward (if any) Coll. fee £ <b>0,00</b> Total £	
		Number of Packages (in words)  Place and date of issue <b>30/10/84</b>	

COPY

FREIGHT COLLECT

VALID TELEX

2506

24873 LONHIT G  
403 ACT G

8TH MAY 1985 REF. [REDACTED]

ATTENTION : MR STEVE EKSTEIN - GUEST

SORRY I FORGOT TO MENTION IT ON THE 'PHONE, BUT OUR OFFICE CLOSES AT 1 P.M. ON FRIDAYS. IT WOULD THEREFORE, BE BEST IF YOU COULD TRY TO COME DOWN TO [REDACTED] ON A FAIRLY EARLY TRAIN (OR EVEN ON THURSDAY NIGHT) SO THAT YOU HAVE A REASONABLE AMOUNT OF TIME IN THE OFFICE.

IF THERE IS ANY PROBLEM PLEASE RING ME EITHER AT THE OFFICE [REDACTED] ) OR AT HOME ([REDACTED]).

KIND REGARDS

MIKE [REDACTED]

++

403 ACT G  
24873 LONHIT G

DAL.  
FRAUDULENT  
TELEX

403 ACT G  
814831A DAL PL

TELEX NR 2441

85-05-14

ATTN: MR. JOHN [REDACTED]

WE HAVE RECEIVED A TELEX FROM PSA TRANSPORT LTD - LONDON ASKING FOR OUR AUTHORISATION THAT THEY MAY SUPPLY YOU WITH INFORMATION YOU HAVE REQUESTED RELATING TO SHIPMENTS OF GOODS WE PURCHASED 1984.

YOU WILL RECALL WE SPENT SOME TIME DISCUSSING THIS MATTER IN DETAIL WITH YOU AT THE TIME OF YOUR PREVIOUS VISIT, AND WE UNDERSTOOD YOU ACCEPTED THE EVIDENCE WE PROVIDED FOR YOU RELATING TO OUR PURCHASE.

WE HAVE AGREED WITH YOUR PARTNER IN OUR CURRENT TRANSACTION, NAGAL LTD., TO PURCHASE GOODS ON A CIF GDYNIA BASIS AND, AT HIS REQUEST, WE ARE TALKING WITH INTERNAL DISTRIBUTORS ABOUT POSSIBLE 3RD QUARTER PURCHASES OF YOUR OTHER PRODUCTS.

WE BELIEVE THAT LONG TERM BUSINESS COOPERATION CAN ONLY BE BASED ON CONFIDENCE. IF CONFIDENCE DOES NOT EXIST, THERE IS NO BASIS FOR A LASTING RELATIONSHIP.

WE WISH TO KNOW IF YOU ARE INTERESTED IN DEVELOPING THE COOPERATION WITH OUR COMPANY OR NOT. IF YOU WISH TO DO SO, IT CAN ONLY BE DONE ON THE BASIS OF MUTUAL RESPECT. BEFORE WE TAKE ANY FURTHER STEPS IN THIS MATTER, WE WOULD LIKE TO RECEIVE YOUR COMMENTS.

REGARDS  
DALOS 122

403 ACT G  
814831A DAL PL



Mr. WYDEN. Mr. Eckstein, we thank you. The Chair will return right after he votes, and we appreciate your testimony. Thank you.

[Brief recess.]

Mr. WYDEN. The subcommittee will come to order. I am sorry, Mr. Eckstein, that the delay was so long. The voting machines have broken down so we may get summoned to do this again.

Mr. Eckstein, if we might, you have got considerable experience dealing with diversion problems in the Caribbean Basin, is that correct?

Mr. ECKSTEIN. Yes. I have investigated several cases for U.S. manufacturers in that region since 1980.

Mr. WYDEN. And it would be fair to say that many U.S. pharmaceutical houses have manufacturing or sales branch operations in Puerto Rico?

Mr. ECKSTEIN. Yes, that's correct.

Mr. WYDEN. Now, I think you have an internal memorandum that we have gotten dated June 19, 1981 from a management employee in a Puerto Rico facility of a U.S. firm, to the U.S. management. Are you familiar with this document?

Mr. ECKSTEIN. Oh, yes.

Mr. WYDEN. We will enter into the record as Exhibit A.

[The document referred to follows:]

Exhibit A

Memorandum

**CONFIDENTIAL**

Puerto Rico

To : [REDACTED] RECEIVED  
 From : [REDACTED] JUN 22 1981  
 Date : June 19, 1981  
 Subject: Surprise Visits of Internal Auditors to [REDACTED] Puerto Rico

I would like to take this opportunity to bring to your attention certain serious developments that transpired during the recent internal audit that was conducted here in Puerto Rico and to express my total displeasure and dissatisfaction with the manner in which it was handled.

From the outset, on Monday, June 1st, two internal auditors for the [REDACTED] Division arrived at our offices for the purpose of conducting a surprise audit of our records. We were not extended the courtesy of previous notice that the audit was to be conducted, which proved to be quite embarrassing upon being notified by my Controller of this visit while I was specifically attending a [REDACTED] Manager's Meeting in Florida. I am grateful to Mr. John [REDACTED], who called me to explain to me the importance and needs for surprise audits and for convincing me of the need for such practice.

It was quite obvious that the auditors, Mr. Al [REDACTED], a [REDACTED] Internal Audit Supervisor, and Mr. Steven Eckstein, an outside consultant from R.E.A.C.T. Audit Advisory, were looking for indications of diversion practices within our [REDACTED] product line. Throughout the four-day investigation these auditors received full cooperation from my staff and were provided with whatever information they requested.

However, on Friday, June 12, 1981, we had another surprise visit by the same auditors who then began searching for promotional invoices involving charitable institutions who specifically received large quantities of [REDACTED]. They found several invoices that indicated that certain promotional orders for said [REDACTED] were dispatched to fictitious charitable organizations [REDACTED]. [REDACTED] said orders were in fact delivered to several large wholesalers under the instructions given to the Warehouse Supervisor [REDACTED] directly by Mr. [REDACTED]. Though this was cause for some speculation, it is my feeling that this matter was blown totally out of proportion and that the methods of investigation were quite extreme.

After conducting an investigation of our own, I learned that this action was undertaken by the Puerto Rico [redacted] Division for the following reasons:

- It was their intention to camouflage these special offers being made to specific wholesalers in order to prevent other wholesalers from learning of these deals.
- It was a possible manner of bypassing trade restrictions.
- This was done in order to lower the price of the [redacted] by giving these customers large amounts of [redacted] under disguise of promotional offers to non-existent charitable organizations [redacted].
- Also, I might point out that inasmuch as the [redacted] Division had already committed themselves to extend these offers to the above-mentioned wholesalers, they were compelled to camouflage the orders in this fashion upon receiving [redacted]'s memo of March 26, 1981 [redacted]. This memo specifically restricted the sale of the [redacted] at a net price of \$ [redacted].

Although I do not approve of the action taken by our [redacted] personnel in dissimulating certain promotional orders for the sole purpose of keeping a previously established sales commitment, I feel the afore-mentioned pressure tactics [redacted] was uncalled for and unmerited.

I want to make clear the fact that I had specifically advised Mr. [redacted] of the importance of complying with the restrict price of the [redacted] and [redacted]. If he violated this price, was against my personal instructions and also because he was in his final days at [redacted] before his departure to Ayerst Labs. of Puerto Rico, and he knew I could not take any measures against him.

It has always been my experience and understanding that any comments the auditors have to make concerning their findings should be directed to the Management who will then investigate the matter further with their employees. Unfortunately, this was not the case during the audit. Our employees were given a very poor example of the "American way of doing things". The negative repercussions that may arise in the morale of our personnel are yet to be seen.

During my tenure with [redacted], I have shown a consistent record of improvement and our operation has always been exemplary. It is my hope that we have succeeded in clarifying any possible questions concerning our operations, the honesty of our employees, and that the incidents involved in this audit will not become a blemish on the reputation of our subsidiary which we have worked so hard throughout the years to attain.

mh

cct

K. [redacted]  
 C. [redacted]  
 W. [redacted]  
 J. [redacted]  
 R. [redacted]  
 JPT [redacted]  
 J. [redacted]

Mr. WYDEN. This memo is, in fact, a memo that complains of a surprise audit that you conducted at the behest of the U.S. management; is that correct?

Mr. ECKSTEIN. Yes.

Mr. WYDEN. Could you describe the principal features of this memorandum?

Mr. ECKSTEIN. Well essentially, the memo shows that diversion through alleged charity organizations, phony charity organizations, was a routine practice. So much so that the Puerto Rican manager was actually outraged at the fact that the practice was being questioned by his corporate superiors in the United States.

Perhaps I could read some of the—

Mr. WYDEN. That would be good. I just wanted to make sure I understand the Puerto Rico manager just thought this was the normal course of things. He was outraged because someone had doubted that that was the way things ought to be done.

Mr. ECKSTEIN. Absolutely. He was outraged that anyone would question the diversion practice because to him it was the normal way of doing business, particularly through phony organizations and the fraudulent methods he had used.

Just to go over some of the paragraphs in this letter, he starts off by saying, "I would like to take this opportunity to bring to your attention certain serious developments that transpired during a recent internal audit conducted here in Puerto Rico and to express my total displeasure and dissatisfaction with the manner in which it was handled."

He says, "Two internal auditors arrived in our offices for the purposes of conducting a surprise audit of our records. . ." And he goes on to say, "We were not extended the courtesy of previous notice that the surprise audit was to be conducted, which proved to be quite embarrassing."

"It was quite obvious that the auditors were looking for indication of diversion practices. These auditors received full cooperation from my staff and were provided with whatever information they requested."

"However," he says, "on Friday, June 12, we had another surprise visit by the same auditors who then began searching for promotional invoices involving charitable institutions who specifically received large quantities of . . ." and the name of the goods has been deleted to protect my client. "They found several invoices that indicated certain promotional orders for said product were dispatched to fictitious charitable organizations. Said orders were, in fact, delivered to large wholesalers under the instructions given to the warehouse supervisor directly by . . ." and he names the employee in charge.

"Though this was the cause for some speculation, it is my feeling that this matter was blown totally out of proportion and that the methods of investigation were quite extreme."

He goes on to say, "This action was, in fact, undertaken by the Puerto Rico Division for the following reasons," and he cites these reasons.

"One, it was their intention" . . .—by "their," he is actually saying "our"—". . . intention to camouflage these special offers being made to specific wholesalers in order to prevent other whole-

salers from learning of these deals." Which on the face of it is nonsense.

He goes on to say, "It was a possible manner of bypassing trade restrictions," thereby, he is overlooking the fact that he exposed the entire company to the penalties of doing so.

He further says, "This was done in order to lower the price of the goods by giving these customers large amounts of product under the disguise of promotional offers to nonexistent charitable organizations." So in the main, he admits that it was done.

Then he goes on to say, "Also, I might point out that inasmuch as the division had already committed themselves to extend these offers to the above-mentioned wholesalers, they felt compelled to camouflage the orders in this fashion upon receiving a corporate memo which specifically forbids such sales."

In other words, the loyalty here was not to the company but to a diverter to whom they had made a commitment, and that commitment was, in fact, made after receiving a memo which specifically forbid such diversions.

He further says, "It is my hope that we have succeeded in clarifying any possible questions concerning our operations, the honesty of our employees, and that the incidents involved in this audit will not become a blemish on the reputation which we have worked so hard throughout the years to attain."

So I think it's quite obvious from that memo as to exactly what the turn of mind in that office, and as my investigations have revealed, throughout the Caribbean, in fact, really is when it comes to doing business and doing diversion business in particular.

Mr. WYDEN. Well, we appreciate your going into such detail with respect to this memo. Certainly, it's kind of an oxymoron to say that you should get notice with respect to a surprise visit. But you have pointed up a number of important practices that are important to the subcommittee with respect to the way things go on in Puerto Rico, and we appreciate that.

Let me turn now to another region of the world and find out if you're familiar with Zona Libre, the so-called Free Zone, in Panama.

Mr. ECKSTEIN. Yes. I visited it twice, most recently in 1982.

Mr. WYDEN. How would you describe the physical operation there?

Mr. ECKSTEIN. It is essentially a walled-off city within a city adjacent to Colon, Panama at the eastern tip of the Panama Canal. Entry to the zone is usually restricted by armed guards and you would normally require a valid business reason to access the zone.

I would say it's quite a large place, probably about 2 square miles in total. The armed guards really are not there to prevent access; they are more there to prevent local Panama residents from entering the zone, purchasing duty-free items and then exiting the zone without paying the duty to Panama.

Mr. WYDEN. Tell us, if you will, about some of the so-called services that are available in Zona Libre.

Mr. ECKSTEIN. Well, one of the services was exhibited in storefront after storefront where I observed signs advertising prowess in smuggling; some of them, in fact, stated an expertise in smuggling goods directly into the United States. One, in fact, claimed that

smuggling was a proud family tradition for more than 40 years. So that's certainly one of the services offered in the Zona Libre.

Mr. WYDEN. I gather you can obtain diversion services as well in Zona Libre.

Mr. ECKSTEIN. Yes. There are a number of major diverters based in the Zona Libre. I have given the committee a list of those names.

One particular example is an operation known as Market Managers, S.A. They not only divert merchandise but they also offer re-packaging services for other diverters, as well as freight forwarding and storage services.

Mr. WYDEN. How did the Panamanian Government treat all this? What was their attitude with respect to these practices, these so-called services that you talk about?

Mr. ECKSTEIN. Unfortunately, I don't know. Everyone suggested it was frankly useless to ask. The Panamanians at that time were not friendly to Americans, generally.

Mr. WYDEN. Describe the role of the Zona Libre, if you would, just in drug diversion generally. What role did that play?

Mr. ECKSTEIN. Well, the Zona Libre is a major trans-shipment point for diversion from Puerto Rico back to the U.S. market. Sales allegedly from U.S. firms in Puerto Rico to Caribbean and Latin American distributors are diverted through Panama back to the United States.

Mr. WYDEN. I want to keep moving around the globe, if we might be able to, Mr. Eckstein. We've been to Zona Libre, we've been to the Caribbean. Let me ask you about another document in your materials, exhibit B. This deals with the statement of an employee of a Japanese subsidiary of a United States firm which manufactures medical devices and pharmaceuticals. Is that a correct identification of what you have, exhibit B?

Mr. ECKSTEIN. Yes, sir, it is.

Mr. WYDEN. Could you please describe the diversion scheme that is outlined in exhibit B?

Mr. ECKSTEIN. Yes. The Japanese branch manager in this case was hoping to boost sales. He used several methods to defraud his firm. First, he employed a consultant, who is a diverter, and paid him in free product. The consultant then set up a phony Japanese company to receive the product at greatly diluted prices.

The manager wrote tens of thousands of invoices which were created for small sales with accounts receivable which were never intended to be collected because the invoices were to phony companies. There were thousands more invoices written to other phony companies for additional, free-of-charge and promotional goods, which were then credited at a higher price than the invoice pushed the goods out at.

The effect that this had was to drop a certain portion of the goods to the bottom of the barrel as free goods. In other words, if he wrote an invoice for \$2 per item and sent 600 items, then credited the invoice for 300 items at \$4 per item, he had 300 items left over. He would then invoice an additional 300 items to the diverter at the regular price, so the diverter ended up with 600 items at half price. I hope you're all following that.

Now, all of these sales which appeared on the books as accounts receivable never to be collected indicated that the company was doing a land office business and in fact, led to an increased inventory allocation to the Japanese branch by the home office, and that increased inventory allocation would, of course, have gone into the diversion cycle as well.

In fact, so successful was the scheme, that the company awarded him their "manager of the year" certificate for having such an extraordinary record of sales.

An internal audit was conducted by the company shortly before our arrival on the scene. The audit, however, revealed only a collection problem and did not reveal the fact of the diversion or all the phony invoices.

Mr. WYDEN. So we've got thousands of phony invoices, a phony Japanese company, a branch manager with his manager of the year certificate, and I guess what we'd want to know is how the goods got back into the United States.

Mr. ECKSTEIN. Exactly. The consultant's company acted essentially as a consolidator. He then shipped the goods to a Santa Monica, CA diverter.

Mr. WYDEN. And what about the Hong Kong connection?

Mr. ECKSTEIN. Well, the Tokyo manager was very friendly with a distributor of their products in Hong Kong. The Hong Kong operation was apparently failing at the time, and the Tokyo manager suggested transferring the Hong Kong inventory to Tokyo, in return for which the Hong Kong manager would get some sort of a commission.

The shipment did, in fact, come from Hong Kong to Tokyo, but we were able to stop it before it went into the diversion mechanism.

Mr. WYDEN. Now what happened to the guy in Japan?

Mr. ECKSTEIN. Well, he was fired by the company. Unfortunately, it was recognized from the onset that trying to pursue him legally in the courts in Tokyo was just a useless endeavor.

Mr. WYDEN. What's he doing now? Is he back doing this for somebody else?

Mr. ECKSTEIN. Yes. As a matter of fact, he is. I understand that he went with Ayerst Labs.

Mr. WYDEN. I'm sorry, I just couldn't hear that last part?

Mr. ECKSTEIN. My understanding is that he went with Ayerst Labs.

Mr. WYDEN. So we see him fired because you caught on to this, but he just was hired by somebody else, and he is back at this practice.

Mr. ECKSTEIN. That's correct. As a matter of fact, I have seen over and over again employees who have been caught, prosecuted, terminated have simply turned around and gone to work for other companies in the pharmaceutical industry.

So the methods, the knowledge, the learning of diversion, the techniques that are used are simply handed on from one company to another through the movement of these guilty employees.

Mr. WYDEN. Well, let's talk for just a moment more about the statement by the former sales manager. I understand that some of this money was used to have an affair with the secretary?

Mr. ECKSTEIN. Yes.

Mr. WYDEN. I gather that you have uncovered some side benefits to the diversion.

Mr. ECKSTEIN. Yes. As a matter of fact, he was having an affair with his secretary for some 18 years. Frankly, I could never understand it.

Mr. WYDEN. He used \$43,000?

Mr. ECKSTEIN. That was just one situation where he purchased an apartment for his secretary which he used as a trysting place between the two of them. That apartment, we understand, cost him in the neighborhood of 10 million yen, which equates to about, at that time, \$43,478 U.S. The apartment was far beyond the means of the secretary, who at maximum earned no more than \$7,000 or \$8,000 U.S. a year.

Mr. WYDEN. I'm going to ask that exhibit B be made a part of the record in its entirety as well.

[The document referred to follows:]



STATEMENT:Exhibit B

I, [REDACTED], formerly employed as Sales Manager for [REDACTED] of Japan, do hereby certify that the following statements are true to the best of my knowledge. I make these statements voluntarily and of my own free will, without duress of threats or promises made to me. I stipulate only that my statements contained herein may be used by [REDACTED] for the purpose of internal company knowledge, and not as a basis for civil or criminal action against myself or others named herein.

During my tenure as Sales Manager for [REDACTED] of Japan, I became aware that my superior, Mr. M. [REDACTED], President of [REDACTED] Japan, was working in concert with Mr. Sam [REDACTED], a local [REDACTED] dealer, to divert [REDACTED] into the U.S.A.. Specifically, M. [REDACTED] instructed me to prepare the shipping documents for the original shipment of diverted goods, a copy of which is attached to this statement, and to teach Mr. O. [REDACTED] how to prepare such documents for future shipments.

Actually, the way things worked out, my assistant, Mr. T. [REDACTED] prepared the documents for these subsequent shipments upon instructions from M. [REDACTED] and O. [REDACTED].

In all, we know of thirteen (13) shipments totaling 21,668 [REDACTED] ( [REDACTED] ) which were diverted to Mr. W. [REDACTED] of [REDACTED] Company, Inc., located at [REDACTED] Blvd. in Santa Monica California.

On one occasion, I think it was during February or early March of 1983, my assistant and I overheard O. [REDACTED] place a phone call to Mr. K. [REDACTED] to arrange the details of the first shipment of diverted [REDACTED]. This, of course, can be verified by checking the [REDACTED] office phone bill for those months.

The plan devised by M. [REDACTED] and O. [REDACTED] to divert [REDACTED] was very simple. O. [REDACTED] set up a "dummy" company called F. [REDACTED] to whom [REDACTED] "invoiced" the [REDACTED]. The real purpose of F. [REDACTED] was to provide a "buffer" between [REDACTED] and [REDACTED] and thus to shield M. [REDACTED] from blame once the diversion was noticed in the U.S.A.

In reality, when I stop and think about it, F█████ also provided a mechanism by which the true profits from the sale of the diverted ██████ could be hidden from ██████ U.S.A.. For example, the ██████ were invoiced to F█████ at \$13.91 USD but actually were sold to S█████ at \$16.00 USD each. This would leave a hidden profit of \$2.09 per ██████ which could be pocketed by F█████.

Of course, as I now know the true price at which F█████ purchased ██████ was much lower because free goods were added to each order to dilute the pricing shown on the invoice. M█████ arranged these free goods by breaking the quantities up into smaller amounts and billing them to several fictitious companies (as free goods). In these smaller quantities they would not be questioned. Sometimes the free goods were obtained by writing a fictitious invoice and then reversing the invoice at a higher unit price than at which it was billed. This meant that less ██████ would be reversed while the total dollar amount of the original and reversal invoice remained the same.

In any event, considering that F█████ was a dummy company set up to divert ██████, and considering that M█████ was aware of this fact, it is quite possible that M█████ gained personally by pocketing a share of the F█████ profits. However, I do not know that this is true in fact.

Asside from the above ██████, I also know that O█████ planned to obtain ██████ from Hong Kong and sell them to S█████ as well. I know this because he asked me to instruct him in the method of negotiating the letters of credit and documenting the shipment. However, I do not know if this shipment was made. *in 17 documents*

I am currently attempting to obtain copies of shipping documents pertaining to this and the other F█████ shipments from ██████ the freight forwarder whom we used to ship the ██████ to S█████. I and my former assistant ██████ have a friendly relationship with ██████ and there is every reason to believe that they will make these documents available to us and ██████.

One further matter that has disturbed me concerning Mr. M. [REDACTED] is that he has been having an affair with his secretary for the past 18 years. During April of 1981 she purchased a new flat for ¥10,000,000 (\$43,478.00 USD at current rate of exchange) I and others in the office, question this since such a purchase was beyond her means. It is rumored that Mr. M. [REDACTED] paid for the flat.

I am pleased and grateful for the opportunity to come forward and speak of these matters, which so greatly disturbed me while I worked for [REDACTED].

Signed: [REDACTED]

Date: 22 Jan. 1984

Witness: [REDACTED]

Date: 22 Jan 1984

Witness: [Signature]

Date: 1/22/84

Mr. WYDEN. Let's keep moving around the world, Mr. Eckstein, to Poland. You discussed a Polish company, D.A.L. at some length. Is this firm sanctioned by the current regime in Poland?

Mr. ECKSTEIN. Well, according to the Polish Embassy in London, D.A.L. is a Polish state trade organization set up to provide Western goods to the Polish market. They do, in fact, have an office in Warsaw, and they are known by the state police in Warsaw. The state police, as a matter of fact, wished to be most helpful to us in our initial cases into diversion, but when the name D.A.L. was mentioned it was the same as turning off a light switch and all cooperation stopped immediately.

Mr. WYDEN. In how many instances were your clients' products diverted through D.A.L.?

Mr. ECKSTEIN. Well, at least six separate cases, though it's hard to break it into separate cases. In one situation, as I mentioned earlier, a client thought he was selling large quantities of pharmaceuticals and other products to D.A.L. for at least the past 5 years. So each shipment could almost be considered a separate case.

Mr. WYDEN. Are you aware of other Eastern European state trading companies involved in these kind of schemes?

Mr. ECKSTEIN. I've had no occasion to personally investigate other East European situations. However, it is widely believed throughout Europe that diversion does occur through similar firms in Czechoslovakia, Romania, Bulgaria and the U.S.S.R.

Mr. WYDEN. You obviously have had experience with other diversion schemes in Europe. Could you describe the case involving the Belgian principals?

Mr. ECKSTEIN. Yes. As a matter of fact, I brought with me the statement of one of the guilty individuals that was caught and prosecuted in the Belgian case.

Mr. WYDEN. Would you have any objection to allowing subcommittee staff review that?

Mr. ECKSTEIN. Not at all.

The statement tells a story of a former international operations manager who in fact set up the international division for this particular company, who subsequently became disgruntled, left the company and after that, began to approach the various country managers of his former company and educate them into the ways and means of diversion.

He spoke with the distributor markets manager in the Belgian office of his former company as well as the branch office manager of the Italian branch, and convinced the two men to set up a shell company in Vaduz Lichtenstine.

As you probably know, lawyers in Vaduz sell corporate identities. It's probably the mainstay of their employment. Using that corporate identity, they then opened up bank accounts in Zurich, Switzerland under the name of Pharmtraco, which was their shell company.

They then sold goods using their authority in the company to dilute pricing to the Pharmtraco shell which they owned. The Pharmtraco shell, in turn, sold the goods to a North Carolina diverter at a profit. The moneys were paid into the Pharmtraco account by the diverter, the profits were skimmed off and pocketed and the remainder went to the company to pay its invoice.

The scheme was so successful that this former international operations manager then proceeded to travel around the rest of the world contacting all the rest of the branch managers of his former company and at least half a dozen of them saw some advantage to participating in the same kind of scheme, and they were all subsequently caught as well.

Mr. WYDEN. One last line of questions. Back when you worked for clients in Puerto Rico, did you have cause to examine storage facilities for returned goods; the drugs which were out of date or were scheduled for destruction?

Mr. ECKSTEIN. Yes, I did. Most of the merchandise I saw in these facilities was awaiting examination by quality control and disposition.

Mr. WYDEN. How was the security at these facilities?

Mr. ECKSTEIN. Actually, very lax. In most cases, the goods were mixed with other types of merchandise; quarantined goods, used machinery parts, what have you, so that the need for access to the facility was not and could not be restricted solely to those who had need to access out of date or returned goods alone.

Furthermore, most of this goods is considered low priority by the companies involved, since the credits have already been taken by the customers in many cases and the loss has been presumed.

Mr. WYDEN. What kind of personnel are involved in all of this, Mr. Eckstein?

Mr. ECKSTEIN. They're usually low level warehousemen types. Certainly types whose salary could be greatly augmented by selling off such goods.

Mr. WYDEN. Has it actually happened? Has this been a salary booster for these people?

Mr. ECKSTEIN. Well, as far as my clients are concerned I know of no actual sales of such goods. However, I am aware that their graveyard operations have, in fact, been approached repeatedly with offers—people who drive up in vans and trucks and simply ask if anything is for sale. To the best of my knowledge, those offers have been refused.

Mr. WYDEN. But this certainly could be a source of outdated pharmaceuticals if one were to pursue it as a source.

Mr. ECKSTEIN. It certainly is likely. One problem, as I said earlier, is that there are many levels of access to the storage areas. No end to the number of people that go in and out. In fact, the company salesmen are entering and leaving the facilities I have seen very often, and they certainly would have a vested interest in getting their hands on such merchandise.

Mr. WYDEN. How frequently are drugs actually destroyed?

Mr. ECKSTEIN. From what I have seen, destruction is usually on a rather irregular basis; sometimes monthly, sometimes it may be as long as 6 months before destruction occurs. It tends to depend more on how much goods can be crammed into the facility before they finally have to turn around and bulldoze it.

Mr. WYDEN. But the fact is that outdated drugs and manufacturers' rejects and a whole host of potentially harmful subjects are not routinely destroyed by the manufacturer.

Mr. ECKSTEIN. That is correct, and they cannot be. The reason is that the quality control examination, which must be performed, is always severely backlogged. So the goods have to go into a holding area of some sort.

Mr. WYDEN. And then it's a hit and miss operation.

Mr. ECKSTEIN. Absolutely.

Mr. WYDEN. Minority counsel I understand has a few questions.

Mr. SMITH. Thank you, Mr. Chairman. Mr. Eckstein, I've just got a couple of quick questions. Going back to the Polish situation I want to clarify. These drugs that are diverted are shipped back into the United States; is that right?

Mr. ECKSTEIN. That's correct.

Mr. SMITH. Do you have any idea who purchases these drugs, by name?

Mr. ECKSTEIN. Not offhand. As I said in my opening statement, when we attempted to locate the incoming shipments through U.S. Customs, we were refused access to those records. I would imagine, however, that they went to much the same category of individuals as who have testified here earlier.

Mr. SMITH. Do you have any idea what the volume of the fraudulent diversion was by the Polish state trading company?

Mr. ECKSTEIN. On one order alone, we're talking in excess of \$1 million at manufacturer's cost.

Mr. SMITH. And do you have any sense of how long a period of time this practice has been taking place, and how many of these kinds of orders could have been processed?

Mr. ECKSTEIN. With respect to the D.A.L. pipeline, my understanding is that they have been in business for at least the past 8 years, possibly as long as 10.

Mr. SMITH. So we're talking in the tens of millions of dollars, possibly.

Mr. ECKSTEIN. More likely in the billions.

Mr. SMITH. And what kind of profits would you estimate the state-owned company has made on this kind of activity?

Mr. ECKSTEIN. I truthfully couldn't even hazard a guess. With respect to my clients' operations, the profitability is enormous; perhaps 60 to 70 percent.

Mr. SMITH. Thank you very much. Thank you, Mr. Chairman.

Mr. WYDEN. I thank the minority counsel. Mr. Eckstein, you have been an excellent witness who's been very helpful to us. The subcommittee's hearings are going to continue into this very serious matter. Today I think we got the startling news about just how widespread this practice is, and what your testimony has given us is literally concrete evidence that it spans the globe, number one. And also, additional evidence to back up what the other witnesses have said about the large number of providers, health care providers, and the large number of manufacturers that are involved in it.

I think it has got to be a cause of great concern to the American consumer; in fact, consumers worldwide. And we are going to continue, our subcommittee, to pursue solutions, legislative solutions, administrative solutions and others, and we just very much appreciate your cooperation with the subcommittee, and if you don't have any further comments you will be excused.

Mr. ECKSTEIN. Thank you.

Mr. WYDEN. The hearing of the subcommittee is adjourned.

[Whereupon, at 1:35 p.m., the hearing was adjourned, to reconvene at the call of the Chair.]

[The following letters were received:]

## BRISTOL-MYERS COMPANY

1155 15<sup>th</sup> STREET, N. W.  
WASHINGTON, D. C. 20005

WILLIAM G. GREIF  
VICE PRESIDENT

October 8, 1985

RECEIVED

OCT 10 1985

Subcommittee on Oversight  
and Investigations

The Honorable John D. Dingell  
Chairman  
Subcommittee on Oversight and Investigations  
of the Committee on Energy and Commerce  
2221 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Dingell:

Bristol-Myers Company has followed with interest your recent hearings on drug diversion, and supports your efforts to reduce diversion in both the domestic and international markets, since diversion could result in health and safety problems for the consumer. However, during your hearing on September 19, 1985, certain statements were made by one of the witnesses, Stanley Kowitt, regarding Mead Johnson and Co. and Bristol Laboratories, that I would like to clarify for the record.

In his testimony, Mr. Kowitt reviewed sales by major pharmaceutical companies at favorable prices to three Florida hospitals, which then apparently resold the drugs to the retail trade. Specifically, Mr. Kowitt alleges that Bristol Laboratories sold unusually large quantities of Polycillin, an antibiotic, to Coral Gables Hospital over a 3-month period, while three Mead Johnson products, Poly-Vi-Flor, Colace and Peri-Colace, were sold in excessive volume to Miami Dade Hospital. Both Bristol Laboratories and Mead Johnson have reviewed their records related to these products; those records reveal that the problems identified by Mr. Kowitt occurred almost 10 years ago, and were recognized and corrected at that time.

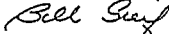
A review of Bristol Laboratories' sales records, for example, shows that for the period 1978-1984, sales of Polycillin to Coral Gables Hospital ranged between \$28-\$600 per year. Bristol Laboratories also temporarily changed the color of Polycillin capsules sold to hospitals to enable quick identification if the drug were diverted to the retail trade. Similarly, with respect to Mead Johnson, sales of the products in question to Miami Dade at favorable prices were halted in the mid-1970s, prior to any third party notification of excessive product purchases by that hospital.

The Hon. John D. Dingell

Since that time, the Company has taken steps to alert itself to unusually large purchases relative to an individual customer's needs, including the training of company personnel to look for extraordinary orders. We believe we are able to identify attempts to divert any significant quantity of our products, and to take appropriate action.

Once again, Bristol-Myers supports your efforts to reduce diversion of pharmaceutical products, and respectfully requests that this letter be placed in the hearing record.

Sincerely,



William G. Greif

cc: Members of the Subcommittee on Oversight  
and Investigations of the Committee on  
Energy and Commerce



CHAMBER OF COMMERCE  
OF THE  
UNITED STATES OF AMERICA

ALBERT D. BOURLAND  
VICE PRESIDENT  
CONGRESSIONAL RELATIONS

October 25, 1965

1015 H STREET, N. W.  
WASHINGTON, D. C. 20062  
202/463-5000

The Honorable John D. Dingell, Chairman  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

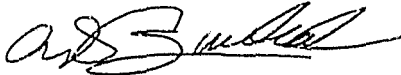
On behalf of the Chamber of Commerce of the United States, I commend the Subcommittee on Oversight and Investigations for its work on drug diversion--the sale of brand name drugs not obtained from the manufacturer or its authorized distributor.

Drug diversion raises important issues relating to the quality and affordability of health care. Quality issues involve the effectiveness of drugs resold outside the control of the manufacturer, as well as the degree to which counterfeit drugs enter the market. The affordability issue relates to the ability of nonprofit health care providers to purchase drugs at a discount for their own use.

Some of our members most concerned with drug diversion are reviewing the problem and are seeking imaginative and positive solutions to it. We urge that the Subcommittee on Oversight and Investigations continue to work toward a solution to this problem. Our members stand ready to work under your good leadership.

Thank you for including a copy of this letter in the hearings record.

Sincerely,



Albert D. Bourland

## PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING

THURSDAY, OCTOBER 31, 1985

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:20 a.m., in Room 2123, Rayburn House Office Building, Hon. John D. Dingell (chairman) presiding.

Mr. DINGELL. The committee will come to order.

This morning, the subcommittee holds its fourth public hearing into the dangers posed to the health of American consumers by the diversion of prescription drugs.

When this investigation began last year, the committee was primarily concerned with the threat posed by the widespread availability of subpotent, impotent, and even toxic counterfeits of American brand-named pharmaceuticals abroad. Having examined the distribution patterns of counterfeit goods in other markets, the committee had reason to fear the dangerous foreign knockoffs might soon reach our shores.

Regrettably, the discovery last November that over 1 million counterfeit Ovulen birth control pills had reached unsuspecting American consumers through the diversion market, proved the fears of the committee to be well founded. Some of these pills were being distributed as recently as last month.

In September, the Food and Drug Administration was also forced to move against another counterfeit drug imported into the United States, Ceclor, an antibiotic, which in its proper form is marketed inside the United States. Fortunately, this latest case appears to have posed no danger to the public health. A matter for which we may all be properly grateful.

In response to the request of the subcommittee, the U.S. Customs Service and FDA have recently inaugurated a joint program to interdict counterfeits and other suspect drugs entering this country claiming to be fully potent, American-produced pharmaceuticals manufactured under all the safeguards required by American law.

These agencies have agreed to hold back all imports claiming to be American goods returned in Customs custody until their ownership can be traced back to the original manufacturer, conditions of storage and shipment and other circumstances ascertained, and packaging and labeling fully checked. If there is any doubt regarding the conditions of manufacture, storage, shipment, packaging or

labeling, the FDA will require the importer to supply a potency analysis by a certified laboratory prior to release by the Customs Service.

This appears to be a good step, and the subcommittee applauds it. The subcommittee staff is carefully reviewing the performance of the FDA and the Customs Service to ascertain the effectiveness of this program, and also to ascertain whether sufficient resources are present in the FDA and the Customs Service to carry out those very important responsibilities.

We are, of course, concerned about the possible situation of the Customs Service plugging one loophole while it is busily shifting resources to do so from other areas of great public importance. Even if the program stops 100 percent of the dangerous drugs attempting declared entry, it will not stop the smuggling of these substances into this country, as our experience with proscribed and controlled substances demonstrates.

Last August, this subcommittee and the American public learned that foreign-sourced counterfeits are not the only serious danger to the public health. Mr. Larry Thompson, the U.S. attorney in Atlanta, announced the filing of 46 criminal informations against individuals and firms in six States for wire fraud, mail fraud, and dealing in adulterated drugs. These criminal informations and subsequent guilty pleas were the result of a 2-year investigation and sting operation conducted jointly by the Federal Bureau of Investigation and Georgia State authorities.

The committee feels it a matter of particular pride and pleasure in the accomplishments of Mr. Thompson and those who worked with him in these important matters. Mr. Thompson, you and your associates merit not only the commendations of the committee, but quite honestly the commendations of everyone for the work you did.

The pills which can be seen today, stored in baggies, and the other commodities stored in soft drink bottles and other containers with labeling removed by Acetone and other means, are just some of the examples of the appalling manner in which sensitive, potentially life-saving chemical compounds were handled prior to sale to American consumers.

To those who would have us believe that prescription drug diversion is just another way to give the consumer a price break, I say, look about you. These are not counterfeit tee shirts or counterfeit Gucci handbags. No consumer can possibly weigh the risk involved in the purchase of medicine which has not been properly stored, or which has been shipped outside channels of commerce where it is properly protected in conformity with law.

That is why strict quality control of the manufacture and sale of pharmaceuticals is mandated by law. The diversion market undermines that system of quality control and must be dealt with as a clear and present danger to the public health.

Last August, neither the U.S. attorney, nor the FBI were able to testify because of legal constraints. The committee understood that and the committee appreciated the problem which they had at that time. They are here today, however, to present us with a vivid picture of the threat posed by this illegal market in pharmaceutical products.

The Department of Justice, the U.S. attorney, the FBI, and the George State authorities are indeed to be congratulated on a job well done.

Furthermore, their cooperation with the subcommittee has been of an outstanding character. The American public owes, as I mentioned, a special debt to all of these outstanding public servants. Especially to Mr. Carl F. Christiansen, the FBI special agent, who undertook the undercover work in this matter. Because he will be a potential witness in future trials, the Chair and the committee have determined that it would not be appropriate for Mr. Christiansen to testify today, but I do not want his labors and outstanding efforts to go unrecognized at this time.

The Chair will recognize my colleagues for comments at this time.

The Chair recognizes the gentleman from Oregon, Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

Mr. Chairman, I want to commend you for your tenacity in pursuing this extremely important investigation. I think it is clear that we have turned up blatantly criminal and dangerous operations and it seems to me that it is high time to break the daisy chain that links crooks and ripoff artists to the unsuspecting purchaser of pharmaceuticals.

And what particularly disturbs me, is that the participants in these scams, blinded by greed and the lure of easy money, have exhibited a total and callous disregard for the health and safety of the American consumer.

What we are going to learn today and what we have seen earlier, is that we have on our hands not just an innocent diversion of a bottle of pills from one purchaser to another. In far too many cases, drugs were removed from their original packages, handled in a manner that totally disregards health and safety standards, relabeled, repackaged in unauthorized containers with phony lot numbers and phony expiration dates, and then sold at big profits.

And at the end of this daisy chain of course, as with most criminal activities, lies an unsuspecting, innocent victim. And I don't think you need to be a physician or pharmacist to realize that this is a prescription for hurting people in this country.

We have got to bring it to an end. And, Mr. Chairman, I want to commend you for your tenacity in pursuing this important investigation and helping to develop the remedies for it.

Thank you, Mr. Chairman.

Mr. DINGELL. The Chair recognizes now the gentleman from Virginia, Mr. Bliley.

Mr. BLILEY. I have no opening statement, Mr. Chairman.

Mr. DINGELL. The Chair recognizes the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Just a few remarks. I, too, want to commend you, sir, for your tenacity, and I want to associate myself with your remarks.

You said it all, basically. We are not talking about counterfeiting Gucci bags. We are talking about people's lives. And, as I said earlier, I can't think of too many worse crimes.

The statistics seem to indicate that drugs are typically used by the elderly. And, since the elderly buy about 50 percent of all

drugs, and since my district is about 50 percent elderly, I have even a greater concern about this subject.

I think it is important, Mr. Chairman, that we realize that these hearings not only afford us with information and, I suppose, in a sense are also alerting prescription drug customers to the serious problem of diversion, but I think it is also important to realize that we are putting fear in the minds of these customers.

I suppose, if I were back home and watching C-Span and watched this hearing take place, I probably would have second thoughts every time I walk into the drugstore to buy drugs, wondering if these are bad drugs or not. And certainly would not have the knowledge that it would take to be able to determine whether the drug might be outdated, or counterfeit, or whatever the case may be.

So, it is just critical that while we do alert these people, and while we gain knowledge that we also obtain constructive tangible results from these hearings. I'm not really sure what those would be, but if we find out that the laws are not adequate, do we change those laws and afford whatever backup support we can to the FBI, and the other law enforcement agencies. It is critical, because we are scaring an awful lot of drug customers, Mr. Chairman, in the process.

So, if we do that, fine. But, at the same time, we have got to make sure we something constructive comes out of these hearings.

Thank you.

Mr. WYDEN [presiding]. The Chair thanks the gentleman.

The gentleman from Minnesota.

Mr. SIKORSKI. As the subcommittee begins its fourth hearing on drug diversion, I commend the Chairman and our staff for a thorough investigation of a criminal practice that really undermines the American public's confidence in the safety and effectiveness in the billions of prescription drugs that are purchased annually in our country.

Also deserving of high praise are the FBI and its dedicated agents, the district and the assistant district attorney, and Rick Allen of the Georgia Drugs and Narcotics Agency, for taking on an investigation and carrying it through when others ignored it.

Drug diversion is a \$1 billion a year illegal business. A scam involving crooked hospitals and doctors, pharmacists and clinics, sales representatives and corporate executives. It is built on greed and deceit. It is fostered by lax Government regulation and it is hidden by an "I don't want to get involved" industry morality.

What emerges here today is a grimy image of a problem that is as shadowy and murky and off color, as the pictures that we are going to see on the monitors here before us in a few minutes.

It is a sordid tale with villains like Lenny Schlein and Frank Macosky. They sit around swilling beer and bragging and boasting about their scams. They shuck pills in filthy conditions, scrape off labels, lot numbers, and expiration dates. They soil pills with acetone, nail polish remover, rubbing alcohol, throw drugs into garbage bags and Dr Pepper bottles, and roasted peanut bottles, empty boxes, and baggies. They store pills such as haldol, corgard, inderal and dyazide, insulin, children's antibiotics, asthma medicine, in hot attics, damp basements, and dirty garages, and they skirt around

agencies like the FBI, the FDA, and the U.S. Customs Service. Finally, they violate a host of customs, food and drug, antitrust, conspiracy, mail fraud, and racketeering laws.

Now, behind all the odd talk that we are going to hear today, the technical terms and drug names, the bizarre language like "pharmoney," strange props, and unscrupulous personalities, is a white collar, subterranean industry which threatens to undermine the public's faith in the American prescription drug industry.

With all the counterfeited, contaminated, adulterated, improperly stored and misbranded and mislabeled drugs floating around unaccounted for in the prescription drug distribution system, we run the risk of a catastrophe wider, deeper, and more terrible than the Tylenol incident a few years ago.

Ironically, we will see in a few minutes how these criminals will steal, lie, cheat all the Americans who depend upon prescription drugs, including the very young, the very old, the sick. But they claim that they won't lie to each other.

Well, whatever the color of their neatly pressed collars, the size of their bank accounts, or the fancy print of their titles and their college degrees, what we have got here is a bunch of low lifes leading a very good life at the expense of American lives.

Mr. WYDEN. I thank the gentleman.

The gentleman from New York.

Mr. ECKERT. I don't have any formal opening statement. But, I do want to join my colleagues in commending the chairman, the gentleman from Michigan, for his leadership on this very important issue. And also the U.S. attorney's office and the Federal Bureau of Investigation.

White-collar crime is, generally speaking, not life threatening. But this is a white-collar crime that very much is, and it is very difficult to get long sentences for these kinds of offenses, because there is so little knowledge about it and so little perception of the danger posed here.

I think the gentleman from Michigan has taken a strong leadership in calling this to the attention of the country.

I have some other concerns that the gentleman from Florida expressed about not overalarming. But, consumers have to have confidence in the drugs that they take. Someone who makes a huge profit by substituting an inadequate heart pill, for example, can literally execute a person who went into a pharmacy with full confidence that he was going to continue on the medicine that would sustain his life.

So, this is a very important issue, little understood. And I am delighted that we are proceeding in this manner.

Mr. WYDEN. The gentleman from Ohio.

Mr. OXLEY. Thank you, Mr. Chairman.

I would like to welcome our witnesses today, and commend the Chair on these very timely hearings.

I think in many cases in the past, certain "sting" operations have received some negative publicity in the media. And I think that today's hearing will very much put to rest the lack of efficacy of this type of operation.

In some cases, when you are dealing with the kind of people that law enforcement is dealing with, clearly the best way to bring those people to justice is through a sting operation.

I am looking forward to the viewing of this sting operation to see how it works, particularly to see how it was set up originally, while simultaneously providing for and protecting people's rights.

Mr. WYDEN. The Chair thanks the gentleman.

The gentleman from Colorado, Mr. Schaefer.

Mr. SCHAEFER. I have no statement.

Mr. WYDEN. Mr. Bliley, a statement?

Mr. BLILEY. No, Mr. Chairman.

Mr. WYDEN. Let the record show that our witnesses are present at the table, Mr. Larry D. Thompson, U.S. attorney, northern district of Georgia; Atlanta, GA; Ms. Gale McKenzie, assistant U.S. attorney, northern district of Georgia; Atlanta, GA; Mr. Hal N. Helterhoff, section chief, white-collar crime section, Criminal Investigative Division, FBI, Washington, DC; and Mr. Robert C. Fay, Supervisory Special Agent, Atlanta Division, Federal Bureau of Investigation, Atlanta, GA.

Let me advise all of our witnesses that you have the right to counsel throughout your appearance today, and also to a copy of the rules of the subcommittee which I note are before you.

It is also the practice of the subcommittee to swear all of our witnesses. Do any of you have an objection to being sworn?

[No response.]

Mr. WYDEN. Please stand and raise your right hand.

[Witnesses sworn.]

Mr. WYDEN. Let us begin with Mr. Larry D. Thompson, U.S. attorney, northern district of Georgia.

We welcome you, Mr. Thompson. We will make a copy of your prepared remarks a part of the record in their entirety, and if you would like to, summarize your principal concerns, then allow plenty of time for questions.

**TESTIMONY OF LARRY D. THOMPSON, U.S. ATTORNEY, NORTHERN DISTRICT OF GEORGIA; AND HAL N. HELTERHOFF, CHIEF, WHITE-COLLAR CRIMES SECTION, CRIMINAL INVESTIGATIVE DIVISION, FEDERAL BUREAU OF INVESTIGATION**

Mr. THOMPSON. Good morning, Mr. Chairman.

Mr. Chairman and members of the subcommittee, it is a pleasure to appear before you today and report the results of an important investigation and prosecution undertaken by the FBI and my office, the U.S. attorney's office for the northern district of Georgia.

The investigation involved an Atlanta-based FBI undercover operation code named "Pharmoney." The FBI and the U.S. attorney's office were ably assisted in the investigation by the Georgia Drugs and Narcotics Agency and the Georgia Board of Pharmacy. The investigation and resulting prosecutions covered a variety of illegal practices which are sometimes referred to as drug diversion and drug adulteration and misbranding.

Members of the subcommittee, I believe this investigation and resulting prosecutions are important for two reasons: First, they have served in a significant way, we believe, to protect the American

public's absolute right to receive safe and high-quality prescription drugs. They also serve to put on notice to others, who might be tempted to try such illegal schemes, that the fraudulent procurement of drugs and the adulteration and misbranding of drugs will not be tolerated, and that such practices will be investigated and prosecuted to the fullest extent by the Department of Justice in cooperation with State law enforcement officials.

To date 48 individuals and three companies have been charged in criminal informations with violating Federal wire fraud, mail fraud, conspiracy, interstate transportation of drugs obtained by fraud, and drug adulteration and misbranding statutes. Most of these defendants have pled guilty. Over half have received periods of incarceration, some as many as 5 years in jail. Significant amounts of community service were made a condition of those sentences which were probated. Our investigation is continuing on approximately 40 subjects who have yet to be charged.

These white-collar criminal prosecutions received a very high priority in my office. And one senior assistant U.S. attorney, Ms. Gale McKenzie sitting to my left, was assigned almost full time to the investigation for a period of 9 months. This is consistent with the directive of my boss, Attorney General Meese, in his Economic Crime Council, of which I am a member, that all 98 U.S. attorneys give high priority to white-collar crime law enforcement initiatives.

We are also pleased that many of these defendants received sentences which involved periods of incarceration. It is the policy of the Department of Justice to seek, and not oppose, jail time for white-collar violators in appropriate cases and in a manner consistent with the efficient administration of justice and the responsible allocation of prosecutive resources.

In a speech this year before the Economic Crime Council in Boston, Attorney General Meese stated that incarceration was proper, appropriate, and necessary in many white-collar crime cases, in order to serve as a deterrent to the future commission of such crimes.

Pursuant to our obligations under the Victim-Witness Protection Act enacted by Congress in 1982, we filed victim-impact statements with the courts in the northern district of Georgia in all cases. I will now summarize for you what we told the courts regarding the deleterious impact of this illegal activity on its collective victims, the American drug-consuming public.

Pharmaceutical diversion involves a scheme wherein false and fraudulent representations are made directly and indirectly to drug manufacturers that pharmaceuticals are being purchased for use in hospitals, clinics, nursing homes, export, and charities in order to obtain low purchase prices.

The drugs so purchased are then diverted from such use to resale at substantial profit for ultimate dispensing to consumers with prescriptions. Some defendants in these cases were involved in actual misrepresentations. Others knowingly purchased drugs originally obtained under such false and fraudulent pretenses.

In addition to defrauding the pharmaceutical manufacturers and the drug-consuming public of money and property, such diversion jeopardizes the ability to trace drugs in the event of a product recall, since the drugs are not used by the entity for which they



were ordered. Efforts to avoid detection often result in diverted drugs being drop shipped across the country or abroad and stored in warehouses, garages, attics, basements, ships, and loading docks not subject to inspection where environmental controls and sanitary conditions can be virtually ignored.

Many defendants involved in diversion had no State wholesale license, which made their purchase and sale of drugs illegal on that basis alone. And, of course, their premises were not subject to inspection because the State boards and the FDA charged with that duty were unaware of their activity.

While some individual defendants may not have been fully aware of the specifics of such treatment by others in the distribution system, they did have reason to know that the distribution of diverted drugs is necessarily more complex and offers a less timely delivery to the ultimate consumer than a normal manufacturer-to-wholesaler-to-hospital or retailer system. Furthermore, this secondary distribution system is attractive to those wishing to dispose of stolen, foreign made, counterfeit, or adulterated and misbranded drugs.

Every American family is affected, not only by the cost of prescription drugs, but also by the medication's integrity, or lack thereof. The problem is enormous. Annual diversions of the drugs involved in this investigation from hospital, nursing home, clinic, export, and charitable use, amount to an estimate one-half billion dollars. Of course, these first 50 defendants were not responsible for this entire amount.

The low purchase prices obtained by diverters through their false pretenses are not passed on to the ultimate consumers. Instead, the drugs are resold through many levels within the secondary diversionary distribution system with the initial diverter usually doubling his money, and subsequent purchasers also making substantial profits, until the ultimate consumer is given a miniscule discount, if there is any discount at all. The losses of the manufacturers are passed on to the drug-consuming public through higher prices. However, I am certain it is obvious to the members of the subcommittee that prescription medications are not items that a consumer can decline to purchase should the price be too high.

In addition, having access to lower priced diverted drugs gives those involved in that illegal activity a competitive advantage over others in the same trading class, a circumstance which is proscribed by the Robinson-Patman Act.

Adulteration and misbranding involves the removal of drugs from their original packaging and labeling under less than good manufacturing practices, and the placing of loose pills in plastic baggies or other unauthorized containers without accurate and verifiable lot numbers, expiration dates, and other required data.

The FDA has rigid safeguards for the handling and packaging of drugs, including among other requirements, sterile hand, head, beard, body, and feet coverings in rooms with no windows having special air-filtering systems. Those who deal in adulterated and misbranded drugs disregard all safeguards consisted essential by Congress and by health experts in this country.

Drugs were shucked or removed from their original packaging and labeling for a number of reasons, we found, including: They

were expired, the identifying stock number on their label caused by their misrepresentation that they were for consumption by the nonpublic sector had to be removed, they were manufactured under Spanish labels without U.S. inspection and controls in Mexico, they were marked "Sample, not to be sold," and had been originally obtained from drug manufacturers under the false and fraudulent pretense that they would be dispensed for promotional purposes free of charge to patients of doctors and clinics.

The investigation found that the removal of the word "sample" imprinted on individual tablets and capsules, was accomplished either through scraping with razorblades, or through applications of the chemical acetone, fingernail polish remover, and rubbing alcohol. Such scraping of tablets reduced their unit dosage. We believe that millions of these adulterated pills were sold and continue to be sold across the United States for ultimate dispensing to consumers with prescriptions.

Such drugs were stored and resold in open boxes, used paper grocery sacks, cellophane bread wrappers, old soft drink bottles, plastic baggies, and other unauthorized containers. Many of these pills had been expired for over 5 years. Electric erasers and silver paint were used to conceal the sample notations on backs of birth control pills.

The presence of diverted, adulterated, and misbranded drugs in the prescription drug distribution system is a national problem. At least one drugstore in every city, town, and village involved in the FBI investigation, was found to be dispensing such medications. These adulterated and misbranded drugs included blood pressure and heart medications as well as thyroid pills, ulcer solutions, birth control pills and antibiotics. Almost any type of noncontrolled prescription medication. Some had been expired for over 5 years. The drugs that were not out of date when placed in plastic baggies, were often treated as if they had everlasting potency, since the expiration date was no longer printed on the package.

Many of these sales representatives and doctors did not realize how the samples were treated during the removal from their original packaging and labeling. Some of the many pharmacists who ultimately dispensed to consumers with prescriptions from baggies and other unauthorized containers, had no knowledge of the detailed history of the drugs. This is also true for others in the distribution chain. Yet, many of the defendants in the distribution chain did, in fact, have such actual knowledge.

However, because they were dealing in adulterated and misbranded drugs, all defendants—all defendants, lacked the assurance of sealed, stocked bottles, with original packaging and labeling, lot numbers, expiration dates and other required data. They had no assurance that they were not dealing in expired, stolen, Mexican made, contaminated or other drugs otherwise harmful to the consumer. In most cases, they were, in fact, dealing with such pharmaceuticals.

The victim impact in these crimes, lies in the fact that in addition to defrauding the pharmaceutical manufacturers and drug-consuming public of money and property, product integrity is compromised because such adulterated and misbranded drugs cannot

be recalled in an emergency, and their potency and purity cannot be assured.

Members of the committee, this investigation and resulting prosecutions have received widespread public attention. The U.S. attorney's office and FBI office in Atlanta have received many calls from citizens concerned about the safety of prescription drugs.

The courts in my district have also done their job in these cases by sending certain defendants to jail for their transgressions against society. These jail sentences serve the all-important function of deterrence.

In closing, I would like to read to you a brief excerpt from the sentencing hearing before the Honorable Richard C. Freeman of the U.S. District Court for the Northern District of Georgia on October 19, 1985, which we believe summarizes both the import and nature of the problem addressed by this investigation and prosecutions. In sentencing the defendant in the case to 3 years in prison, Judge Freeman stated, and I quote from him:

I forgot about the diversion count, but that does present some problems because the trail usually ends there. If there is a recall, you have nobody. You don't know who has the drugs. You know they went to a hospital, but the hospital let them go to somebody else, so you don't know where they are.

It is a very serious thing, and I don't think really that the public understands quite yet the seriousness of what has been going on. You or somebody else said in a memo that I read recently: Maybe this will shake up the pharmaceutical industry and they will do some things to prevent this thing from happening in the future.

From the standpoint of deterrence, we have not only to think of Mr. X. I don't believe Mr. X will ever be back here again. He wouldn't be back here again on a charge such as this, I agree with you there. But it does not do good to have the United States Attorney's Office working with the Federal Bureau of Investigation on a great, big nationwide program to go out and round up hundreds of people who are doing this sort of thing and the public gets all riled and says, this is wonderful, somebody is spending our tax dollars wisely, they are catching these thieves and these people who are taking advantage of us, and then have some judge come along and give everybody probation.

On a personal note, I would like to express my deep appreciation of special agent Carl F. Christiansen of the FBI, senior agent Rick Allen of the Georgia Drugs and Narcotics Agency, and the lady to my left, Assistant U.S. Attorney Gale McKenzie, for the very fine job they did in overseeing the day-to-day details of the investigation and prosecutions.

I would also like to commend the subcommittee for its past and present work in bringing to the attention of the American public the serious problems associated with drug diversion.

Mr. Chairman, this concludes my prepared statement, and I would now like to introduce to you, with your permission, to the subcommittee Mr. Hal N. Helterhoff. Mr. Helterhoff is the chief of the white-collar crime section of the FBI's Criminal Investigation Division. Mr. Helterhoff will describe for you in more detail the results of Operation Pharamoney.

After Mr. Helterhoff's presentation, I would be pleased to answer any questions the subcommittee may have of me.

Mr. DINGELL. Mr. Thompson, that is entirely appropriate.

Mr. Helterhoff.

#### TESTIMONY OF HAL N. HELTERHOFF

Mr. HELTERHOFF. Thank you, Mr. Chairman.

First of all I would like to thank you, Mr. Chairman, and the members of your committee for your very complimentary opening

statements, and thank you, Mr. Chairman, particularly for mentioning the work of the undercover agent. The undercover agent was able to operate under a process with our undercover apparatus put into place by the Director of the FBI, William H. Webster. He was able to aggressively work on this successful case, and I will pass on your fine remarks to the undercover agent.

I am pleased to be here to present the views and experience of the Federal Bureau of Investigation regarding the diversion of pharmaceuticals. I will address the fraudulent activity and theft that has given rise to a secondary market for legitimate medicines.

Evidence in several FBI investigations has indicated that this market is nationwide and that its products are often adulterated, misbranded, or outdated. Generally, pharmaceuticals diverted into these markets are acquired when individuals make false representations to manufacturers and obtain products without cost at discount or at charitable prices. In many instances, manufacturers' sales representatives have ignored apparent fraudulent activity. These diverted medicines are then introduced into the retail market.

In August 1983, the owner of a small hospital pharmacy management firm complained to the FBI that he had been repeatedly approached by various individuals who requested that he order surplus pharmaceuticals for the seven-hospital pharmacy that he operates.

One individual promised the owner \$30,000 a month if he would place larger orders than needed by the nonprofit hospitals and sell the excess to him. What originally cost the owner 30 cents a tablet could bring him as much as 42 to 48 cents. That is a 40- to 60-percent markup. Our cooperating witness could make a significant amount of money with little or no effort by fraudulently using the not-for-profit or charitable status of the institutions.

After a brief preliminary inquiry, it became apparent that this type of activity was not only criminal but posed a danger to the health of the public who depend upon these medicines. Due to the nature of the criminal activity, in January 1984 the FBI's Atlanta office presented to the FBI's Criminal Undercover Operations Review Committee a proposal requesting authorization to conduct an undercover operation to address pharmaceutical diversion.

This investigation was given the code name Pharmoney. Its purpose was to determine the scope of pharmaceutical diversion and to obtain evidence to convict those engaged in this criminal activity.

Pharmoney focused on those who used their positions or businesses to purchase or receive pharmaceuticals at low or no cost and divert these products into the high profit retail market. Once it got underway, the operation also focused on those who repackaged outdated sample and stolen products under less than sanitary conditions. These contaminated pharmaceuticals were then sold to corner drugstores for ultimate delivery to the unsuspecting public.

An undercover agent working with a registered pharmacist from the Georgia Drugs and Narcotics Agency began building a reputation as an affiliate of the company which initiated the complaint. In a relatively short period of time, the undercover operative became known as a trader in diverted pharmaceuticals. Once established, the operation began receiving unsolicited telephone calls

from previously unknown individuals who expressed a strong desire to engage in the sale, trade, or exchange of diverted pharmaceuticals.

The diversion schemes took various forms. Among them we found: some pharmacists and purchasing agents submitting fraudulent orders in the name of legitimate institutions and reselling these goods; a fictitious clinic ordering pharmaceuticals; a clinic with only 8 beds claiming to have 200 and ordering enough products to meet their inflated need; and a manufacturer's sales representative ordering more samples than were needed to distribute to medical and dental schools and selling the excess for profit.

Generally, the diverters were pharmacists, physicians, and past or present employees of pharmaceutical manufacturers, hospitals, or clinics. They included large national drug wholesalers, manufacturers' sales representatives, individuals who set up storage facilities solely for the diversion, and even a former industry executive who found diversion more lucrative than his previous employment.

The undercover operation indicated that the demand for such diverted products far exceeded availability. Subjects constantly complained that they wanted larger quantities.

The statements of various subjects revealed numerous mechanisms which they used to obtain the diverted drugs and precautions they took to avoid detection. Some developed computer-generated profiles which, through a series of ordering procedures, allegedly maximized ordering capability yet made orders appear realistic in both quantity and type of product.

Others gained the assistance of the manufacturer's sales representative, who could benefit from increased sales income and share in the diverter's profits by merely going along with the ordering technique. At times, if questions were voiced regarding the amount of a certain pharmaceutical ordered, doctors and others vouched that the particular types of diseases requiring those medicines were prevalent in the area.

We realized that the scope of the undercover operation was not limited to fictitious and inflated ordering schemes. Adulterated, mislabeled, and expired drugs were being widely distributed within the secondary market and ultimately sold to the consuming public.

The FBI's investigation identified 13 medical doctors who wrote manufacturers requesting pharmaceuticals for their professional use and disbursement. These doctors asked for different samples each month and sold them to the diverters. The diverters removed the product from the original packages under less than sanitary conditions and eradicated the word "sample" any way they could. The medicines were put in Baggies or other containers and peddled through the back door of neighborhood pharmacies such as what you see here.

Outdated products which had been returned to the manufacturers' representatives for destruction were removed from the original packages and placed in any available container until they could be sold to the unsuspecting public.

In another instance, a California pharmacist said that he regularly drove into Mexico, picked up cartons of products and crossed the border into the United States with the products packed in the trunk of his car. These pharmaceuticals were similar to U.S.-manu-

factured products but were produced at plants which were not operated under strict Federal administrative standards. This pharmacist admitted repackaging and distributing these drugs of questionable purity on a cash basis only.

Pharmony also uncovered the theft of more than a quarter of a million dollars' worth of pharmaceuticals from a manufacturer's loading dock. This led to the charging of two sales representatives and a warehouse employee. But what is significant is the ease with which these goods flowed in through the secondary or diversionary market. The typical earmarks of stolen property have the same characteristics as diverted pharmaceuticals. They are significantly lower than market price, no documentation, and the use of cash in completing the transactions.

Statements from those who have pled guilty and who have assisted the FBI indicate that the practice of diversion is widespread and has existed for many years. In fact, a former buyer for one national wholesaler stated that when employed for that wholesaler, he was given the responsibility to seek out diverters and purchase as much of the diverted product as was available. He estimated purchasing over \$27 million in diverted pharmaceuticals during a single year.

The defendants include pharmacists from Alabama, Georgia, California, New Jersey, and Tennessee, physicians from Florida and Georgia, and drug sales representatives or wholesalers from California, Florida, Georgia, New York, and New Jersey. Some individuals have been sentenced to as much as 5 years in prison while others, less culpable defendants, were given lengthy community service and fines.

During the approximately 18 months of investigation, the FBI was able to gather sufficient evidence to execute 13 searches in 6 States. As of October 9, 1985, 46 subjects and 3 corporations have entered into various plea agreements. Of this number, approximately 30 defendants have pled guilty.

An estimated \$600,000 in diverted and adulterated pharmaceuticals were purchased and seized as part of this investigation, including hundreds of thousands of tablets and capsules packaged in containers varying from plastic sandwich bags to used bread wrappers. Some of these items are located on the table in the front and to my right.

Most of these packages lacked any identifying data such as drug name, strength, or expiration date, and in many instances when such data was on the container, it was erroneous. These drugs commonly sat in attics, many warehouses, storage sheds, and unloading docks for extended periods of time with no sanitary or environmental controls.

I would like to express my sincere gratitude for the efforts and support of U.S. Attorney Larry D. Thompson and, of course, Gale McKenzie of his office, and N.W. Chism, director of the Georgia Drugs and Narcotics Agency, in bringing this investigation to a successful conclusion.

Drug diversion is not a recent phenomenon. On September 19, 1985, the subcommittee heard of one group of individuals who were indicted in 1982 as the result of an FBI investigation into allegations that they had approached various drug manufacturers to buy medicines at charitable prices. Using bogus charities, they wrote

and telephoned manufacturers and requested a wide variety of products at a 40- to 60-percent discount. These fraudulent representations resulted in approximately 10 million dollars' worth of drugs being donated or sold to aid the sick of poorer countries.

In reality, these pharmaceuticals were resold to U.S. wholesalers for distribution through retail drug and national outlets. Ten people were convicted, and two others are presently fugitives.

Mr. Chairman, to give the subcommittee an example of this problem, I have provided both video and oral tapes for review. In addition, before me you see various tablets, capsules, and liquids which are exactly as we found them in attics, basements, garages, and pharmacy shelves. These for the most part are in unmarked bottles, bags, and jars.

Some tablets have the word "sample" removed with an electric eraser, others a razor blade, and still others used acetone, a toxic solvent.

Mr. Chairman, that concludes my prepared statement, and with your permission, I will further describe some of the materials on the table and will present an edited video tape from the Pharmacy investigation. After that, as with Mr. Thompson, we would be happy to answer any questions.

Mr. DINGELL. Mr. Helterhoff and Mr. Thompson, we certainly commend you for very fine work and for very helpful testimony, very completely and thoughtfully prepared testimony.

That is entirely appropriate and you may proceed.

Mr. HELTERHOFF. Thank you.

Supervisory Special Agent Bob Fay, to my right, will assist me in this part of the presentation. Next you will see excerpts of a videotape recording of a meeting held in San Diego, CA, on May 6, 1985. The undercover agent, off camera, met with Leonard Schlein, who will be seated to the right as you view the monitor, and Frank Macosky, who is seated to the left.

Schlein ran a retail pharmacy in the San Diego suburbs. He has pled guilty to one count of mail fraud and one count of distributing misbranded and adulterated pharmaceuticals in interstate commerce. Schlein is scheduled for sentencing in December 1985 and could be sentenced to 8 years in prison and fined \$11,000.

Macosky is a nonlicensed diverting wholesaler who has agreed to plead guilty to one count of mail fraud and one count of conspiracy. The maximum sentence which could be imposed on Macosky is 10 years in prison and an \$11,000 fine.

The purpose of this meeting which you will see on the video and from the excerpts that we will see was for Schlein to introduce the undercover agent to Macosky, who was purchasing diverted pharmaceuticals from hospitals allegedly managed by the undercover agent.

The three were to discuss the mechanics of future diversions and the availability of baggies, outdated pharmaceutical samples, and expired merchandise.

In the first excerpt, Schlein discusses how much Macosky has taught him and how much and how prevalent the distribution of baggies is in pharmacy.

[Testimony resumes on p. 333.]

[Transcripts of the videotape and an index of evidence displayed follows:]



EXCERPT #1:

In the first excerpt, SCHLEIN discusses how much MACOSKY has taught him and how prevalent the distribution of baggies is in pharmacy.

EXCERPT #2:

MACOSKY next talks of a sales rep offering to sell pharmaceutical samples.

EXCERPT #3:

MACOSKY and SCHLEIN discuss the fact that they could do a lot more business if they felt comfortable dealing with many individuals.

EXCERPT #4:

MACOSKY explains to our Undercover Agent that the Agent cannot supply enough diverted pharmaceuticals to satisfy MACOSKY's customers. MACOSKY claims he sold \$111,000 worth of pharmaceuticals the previous week.

EXCERPT #5:

MACOSKY explains that the Undercover Agent should line up a doctor who would say that he was prescribing large quantities of medications in the event a manufacturer realizes that unusual quantities are being ordered. MACOSKY goes on to explain the mechanics of diverting and the percentage of merchandise to invoice.

EXCERPT #6:

MACOSKY says he has been diverting for three years.

EXCERPT #7:

SCHLEIN discusses his scheme to smuggle pharmaceuticals into the United States from Mexico.

EXCERPT #8:

MACOSKY discusses the long hours he works and the fact that he works Los Angeles in addition to San Diego.

EXCERPT #9:

MACOSKY and SCHLEIN encourage the Undercover Agent to send them expired pharmaceuticals and explain that these transactions will be consummated with cash and with no documentation.

EXCERPT #10:

MACOSKY offers the Undercover Agent various pharmaceuticals in baggies.

EXCERPT #11:

MACOSKY and SCHLEIN stated that they have another "scam" of obtaining samples from doctors. Both encourage the Undercover Agent to send any samples he can obtain to SCHLEIN in San Diego, and they will arrange to have the samples put in baggies.

EXCERPT #12:

SCHLEIN discusses his previous activities in New York.

EXCERPT #13:

MACOSKY offers to sell a product without the lot number and expiration date which he removed.

EXCERPT #14:

MACOSKY claims to have pharmaceuticals for sale which came from the "nonpublic sector."

The three individuals in the video tape are the Undercover Agent (UCA), LEONARD SCHLEIN (LS), and FRANK MACOSKY (FM).

EXCERPT #1:

LS: You know I feel really comfortable with him. He showed me a lot of things. Lot of times I'm, in this stuff, I'm pretty, I, I think I know a lot. I come from New York but yet I realize there's a lot of things I don't know, and FRANK's definitely taught me a lot of the, the subtlety things. See that's what the real things to look at and things that I think about but I don't, he's very cautious. I trust and I do all my bus, basically all my business with him. Any type of stuff.

UCA: The side business

LS: Yeah, you know, anything extra. You know, I mean, buying loose whenever it's really big in pharmacy.

UCA: Yeah.

LS: You know, it's real prevalent, and I used to try to sell to a lot of different stores and stuff. Now I just, do just with FRANK, nothing else. Because the, I don't need people knowing that I, that I can get loose stuff, that maybe I can. The more people that know I do things, the less I like it. I realize in the beginning I wanted to be friends with everyone and I tried to call everyone I got this, and this, and this.

EXCERPT #2:

FM: But I'll also, I'll also say this that I had another friend of mine like LENNY and he wanted to introduce me to a sales rep, and so I called the sales rep up six or eight months ago, and he said well, I've changed my mind, and he hung up on me. He was from ROBINS. So I, I keep seeing this other pharmacist whose a friend of mine, like LENNY, and he did a deal with the same ROBINS rep, this was three or four weeks ago, and he said, FRANK did you ever call the guy. I said well I tried and he hung up. He says well now he's got a lot of stuff and he wants you to see him. I won't call him.

EXCERPT #3:

FM: I, I don't want to

LS: It's gotten to the point,

FM: extend myself.

LS: right, where it's not, I mean, if you really wanted to go crazy and go to this and that you could make a lot more

FM: See I don't

LS: but it's not worth it.

FM: that's right, see, I won't go to every, this store, this store, I used to have all of San Diego. I used to work Los Angeles, I worked for a drug company, I know all the people.

UCA: Right.

EXCERPT #4:

- LS: That's a lot, you know, that's more money than I thought monthly thing.
- FM: You can't buy enough for me.
- UCA: But see I have to, I mean, I guess I feel
- FM: Ah, to be very honest with you, you can't buy enough, okay.
- UCA: Okay.
- FM: Ah,
- UCA: So, un, unequivocally that won't be any problem getting rid of that much merchandise a month.
- FM: I sold a hundred and eleven thousand dollars last week. Invoiced. Invoiced, I invoiced it. Because when you start getting big, then we'll get into that because, you know, you started off, a couple of thousand here, a couple of thousand there, and you got your money in cash, it's fine.

EXCERPT #5:

FM: You own the company?

UCA: Yeah.

FM: So that

UCA: The management company. I don't own the hospitals.

FM: Okay. The management company owns the pharmacies.

UCA: That's right.

FM: That's all you're concerned. So, no, you don't have any superior with whom

UCA: No, no.

FM: So that no one's ever going to say you're stealing.

UCA: No.

FM: Alright. Then the only thing you ever have to worry about is a drug company saying you're ordering too much for the number of beds you got. Say, gee, I don't know, you know, why don't you go talk to this doctor or that doctor. Do you have a friendly doctor?

UCA: Oh yeah, these small towns, I mean, hell,

FM: Okay.

UCA: it's like

FM: All, all you ever have to do is call up the doctor and say, hey look, just tell 'em you're using a hell of a lot of blah, blah, blah product.

UCA: Yeah.

(Slight break).

FM: Mark it up ten to fifteen percent. Umm, we're talking about larger numbers. You can invoice, see what you should do is invoice maybe fifty percent of it, invoice twenty-five percent of it even.

UCA: Okay.

FM: And whatever you mark up keep it constant, make it realistic. Alright. So if something is costing you a dollar and you normally make, charging him a dollar fifteen, do it.

UCA: Okay.

FM: Okay. If you're sending him out ten thousand dollars worth of merchandise, invoice twenty-five hundred dollars of it. Okay. Invoice, it depends on how big you get, if you're sending twenty thousand dollars a week, you're gonna wind up invoicing ten to fifteen thousand a week.

UCA: Yeah.

FM: Okay. Then you may only mark that up five percent, and then in the cash take all your profit.

UCA: I see what you're saying.

FM: Okay. You wanna cover your transportation

UCA: Right.

FM: and you wanna make a realistic few points because in the wholesale business that's all they do is deal on points.

UCA: Yeah.

FM: And keep it constant.

UCA: Okay.

EXCERPT #6:

FM: Alright. So, I mean, I have been doing this for three years. Okay, um, I'm very good at what I do. Alright. And I don't want troubles from any sides.

UCA: Yeah.



EXCERPT #7:

LS: Okay, so look at it this way too, BILL. We have two separate things here too. One is all this hospital stuff, one other is the Mexican stuff.

UCA: Right.

LS: You know, I, are you making some things on this

UCA: Yeah. Yeah.

LS: is that working out?

UCA: You know, it's not a lot, but yeah, it's, it's worth it.

LS: Okay. So, that is two separate things.

UCA: Right.

LS: Okay. Is that

FM: I don't deal with Mexican stuff.

LS: He doesn't deal with any of that.

FM: Right.

LS: That we'll deal, that is part of our cash. There is a lot of cash in there

UCA: Right.

LS: that we will be able to make.

UCA: Right.

LS: Through that.

UCA: That's all cash just about.

LS: Basically, that's just all cash.

UCA: Yeah.

LS: You know, and that to me is the cash, so there's the pocket change I look to make to spend around.

UCA: Yeah.

LS: And here we got this little thing it looks like setup where we're covered on all bases and the worse thing that we, we're looking at here is a possible fine maybe.

UCA: Yeah.

LS: If, if everything ever hit the fan

UCA: Well, how do you pay for the stuff in Mexico? Cash?

LS: And now I'm even paying it in merchandise, I'm trading

FM: (Laughs). He's, he's going over the border, this guy.  
(Laughs).

LS: I'm going over the border. I brought over like fifteen hundred dollars worth of

- FM: See that's no problem. See, once it goes, once it,  
(unintelligible)  
if somebody ever comes to him and says where did you  
put it. I sold it in Mexico. They can't go over the  
border and check it.
- UCA: Yeah, that's true.
- LS: You know.
- FM: It's a different country.

EXCERPT #8:

FM: See I do this for a living. I have no other source of income. It's wild

UCA: It is.

FM: It's fun.

LS: This man works real hard. More than I have. He says he has hours much more than I have. I mean, I'm nine to five. He's like

FM: I start at six in the morning.

LS: Ya know.

FM: Now when I go to Los Angeles, I get up at quarter to three and I'm on the road a quarter after three to be up there by seven for my first stop. I don't like working in Los Angeles. But I'm back home by midnight that night. And it's a long day.

UCA: So, is your job basically buying goods or selling them or both?

FM: Both. Brokers. I'm brokering.

LS: Middle, middle, you play the middle. That's all, you know, you

EXCERPT #9:

UCA: Like this guy gives me stuff, and he's, you know, usually he gives it to me and then, like this stuff was dated, uh, February

LS: Uh huh.

UCA: of this year. You know, so it's like two months or something.

LS: Uh huh.

FM: Who cares.

UCA: And yeah, and, you know, and, and, uh, he, he just gives me the stuff, and you know,

FM: You get that, hey, you get that stuff, box it,

LS: just send it out.

FM: Just ship it out.

LS: Don't even ask.

FM: That's good.

LS: It's like I told ya, you don't even have to waste a phone call, just send it out.

FM: Get rid of it. First off, you get rid of it.

LS: Right. You don't want have to call.

FM: Right. Right. Just ship it out here and say, hey, LENNY, this is stuff from a rep.

UCA: Okay.

FM: you know, swack it up three ways, and here we go. Let's have a party.

LS: And we'll just send you back the money.

FM: And then, and then we'll know, it's all hundred percent cash

UCA: Right. Okay.

FM: There's something like this

LS: We got plenty other things

FM: see something like this, we ain't gonna write no checks.

UCA: Right. Okay. That, that was my main question

FM: Right. We got plenty,

UCA: Okay.

LS: we got plenty of other things going, yeah, we right now

FM: got a lot of things, alright.

LS: where we can make a lot of cash on the side.

UCA: Okay.

LS: And this is you know what I'm saying a lot of things.

FM: Yeah like, like this.

UCA: Yeah.

FM: Exactly. This is a hundred percent cash.

EXCERPT #10:

UCA: Well, that's what I'm saying, the only stuff you know, just laying it on the line, the only stuff I do outside of you all are the two pharmacists, and they're small time retailers that I'm selling the baggie stuff to. And that, that was my point, any, anything else you can get, besides the Mex, you know, the Mexican stuff,

LS: Uh huh.

UCA: odds and ends that you can't use

LS: If it comes along, I'll let you know.

UCA: send it to me.

LS: Yeah.

UCA: Just like that stuff that you had that, uh, I forgot what, I think you sent me Haldol

LS: Haldol

UCA: two milligram?

LS: Right.

UCA: Yeah.

FM: Yeah, do they want any more?



- UCA: Yeah. They can use any of that stuff. I mean they're
- FM: (Unintelligible).
- LS: Right. See he's got like fifty-two thousand.
- UCA: Oh well
- FM: fifty-two thousand.
- LS: Right. I remember I said to you that and you said, you know,
- FM: Man I, I mean, like, you know, I eat it.
- LS: You know, a couple of thousand, I send you
- UCA: What is, what do you have fifty-two thousand of?
- FM: Haldol two milligram.
- LS: Right. That, he don't, this one guy don't need fifty-two thousand.
- UCA: No, no, no, but I can probably sell 'em, uh,
- FM: You know, whatever you can take, we'll just, you know, I don't care if it's every month he wants me to send 'em, up, I ca
- UCA: Are they, what are they in? Bottles of hundred or bottles of a thousand?

FM: I had them in bottles of a thousand, but because of the labeling on the bottle

LS: They're in baggies.

FM: I have to take it out and pour it into baggies.

UCA: Okay.

LS: They're in baggies.

FM: So any multiple of a thousand, I can bag it. Alright.

UCA: What's the price on those things?

FM: I don't know what the price is.

LS: Forty off AWP.

UCA: Yeah, that's

LS: (Unintelligible) they're like

UCA: I can, I can, I can sell ten thousand of 'em.

FM: That would be great.

EXCERPT #11:

FM: And this is another scam I'm running. I have a few doctors that they give me their samples

UCA: Uh huh.

FM: then I have a place they process it and I split it with him.

UCA: Yeah.

FM: Whatever I get.

UCA: Yeah.

FM: You know, so that's another little scam I run. I run it with just two doctors. It's fun

UCA: That probably adds up.

FM: And it's

UCA: That's right.

FM: What's best is when, the last time I saw the doctor, I handed him three hundred and fifty dollars cash.

LS: Right. I did the same thing.

FM: And he know I made three hundred and fifty. I told him we splitting it.

- LS: I do the same thing in my clinic. I fill the garbage bag with the samples. I gave him the bag, he came back a week later he say here's a hundred and fifty for the garbage bag.
- UCA: Yeah.
- FM: For what he couldn't use.
- LS: I was walking around anyway collecting.
- UCA: That's right.
- FM: It's, it's a blast.
- UCA: Now see, if I, see I don't have the time. Those doctors up there, I, there's probably, there's probably twenty doctors up there that actually, in the past, have brought garbage bags full of samples and asking us to put them in the hospital incinerator because they don't
- (Slight break).
- LS: What you do is throw them right into a garbage, into a box, don't even, just
- FM: And don't say
- LS: the wrapping, everything.
- FM: yeah, and, and send it down the cheapest way
- LS: Third Class. Book rate.

FM: Yeah.

LS: Third Class. Whenever it gets here.

UCA: Okay.

FM: Yeah. Or UNITED PARCEL. Don't send it air.

LS: Don't send it (unintelligible) dollars.

FM: (Unintelligible).

LS: You know, Third Class Mail whatever.

FM: Send it cheap, cheap.

UCA: And you can take, I mean, I don't have time to pop, you guys take care of getting 'em all popped,

FM: Don't worry about it.

UCA: cause I don't

FM: (Unintelligible).

UCA: Okay.

LS: Just look like it is, what, all it'll be is money you get sent back.

FM: You don't

LS: Hey look, when I get that box, I don't sit down and write down what I gave (unintelligible).

UCA: I'm not worried about it, I'm not worried about  
LS: Right.  
UCA: keeping track of it.  
LS: Just dump it into a big box.  
UCA: I mean twenty dollars is better than  
LS: Get a big box, start filling it up, when the box  
gets filled, tape it, and send it.  
FM: Yeah.  
LS: I'll give it to him and about a week, two weeks later  
I'll send you money.  
UCA: Okay. I can't  
FM: It's a scam. Ah, that's the greatest

EXCERPT #12:

LS: Shhue. I said, it's incredible how this started.  
Two years ago when I started doing this, I was going  
to New York selling, remember, five hundred this,  
five hundred this, and it's, you know, I don't even  
deal in that any more, it's not worth my hassle.  
UCA: Yeah.  
LS: It's just not, you know, I used to make, you know,  
I'd make a hundred and fifty dollars. The first deal  
I did I remember I bought it from somebody like  
twenty thousand Corgard, and I think I made maybe  
three hundred dollars profit. I made about ten long  
distance phone calls. I have to wait three weeks  
for my money.

EXCERPT #13:

UCA: Okay. Wait. Tell me that again. Inderal-LA.

FM: Eighty.

UCA: Yeah.

FM: And a hundred and twenty milligram.

UCA: And a hundred and twenty.

FM: They are in stock packages, except the lot number and the expiration date, are, I took 'em off.

UCA: Okay.

FM: And the reason I did it is because the source I bought it from, there was an additional number underneath. I just purchased these four months ago, direct from the manufacturer. So, it's got three years, four years expiration date on it.

LS: Right.

EXCERPT #14:

FM: Does he, do you buy Dyazide?

LS: No, no.

FM: Like before? No, because on the Dyazide, sometimes I get it. I have to take like that except same bottle, but wrong label. I have to take the label off, but I have no trouble selling it for a hundred twenty-five dollars.

UCA: What do you mean the wrong label?

FM: I have the wrong label on the bottle. If you don't ask me too much, I don't have to

UCA: Okay.

FM: See I won't lie to you.

UCA: Okay.

FM: I won't lie. He'll justify it to that sometimes I don't want to tell you.

UCA: Okay.

FM: It, it's out of, it's out of a nonpublic sector.



(A) TECHNIQUES USED IN ADULTERATION

- (1) MACRODANTIN 50 mg - medicine for urinary tract infections  
Word sample erased with electric eraser
- (2) TOLECTIN - used in treatment of arthritic problems  
Word sample removed with razor blade
- (3) MACRODANTIN - used for urinary tract infections  
Word sample removed with acetone

(B) ADULTERATION USED FOR BIRTH CONTROL PILLS AND FOREIGN BIRTH CONTROL PILLS

- (4) OVRAL - Birth control pills imported from Mexico -  
No expiration date - not manufactured in FDA facility
- (5) Various means of removing "sample" wording from birth control pills -  
Punching - Green container - bottom  
Covering - Square container - top left  
Painting - Circle container - top right

(C) EXAMPLES OF EXPIRED DRUGS

- (6) PATHIBAMATE 200 - Medicine used in the treatment of ulcers  
Expiration date May, 1980 - recovered by FBI spring 1985
- (7) DEMULEN - Birth control pills  
Expiration dates - September, 1978 - January, 1980  
and January, 1981 - recovered by FBI spring 1985

(D) EXAMPLES OF IMPROPER STORAGE AND DISBURSING OF DRUGS

- (8) M.V.I.-12 - Multiple vitamin infusion expired and not stored as directed (36 - 46 degrees) located at attic of a subjects house - temperature in excess of 100 degrees (put picture)
- (9) PEDIAMYCIN 200 - PEDIAZOLE - Childrens' antibiotics  
No expiration date, no lot number no directions  
HAS VERY SHORT SHELF LIFE
- (10) THEO-DUR-300MG Asthma medicine stored and disbursed from a "Dryroasted Peanut Jar"  
Recovered by FBI in a pharmacy

- (11) CARDILATE - 5MG - Heart medicine  
No expiration date, no lot number, no directions  
Recovered by FBI in a pharmacy
- (12) VICON C - Vitamin capsule used for deficiencies of  
vitamin C and B complex  
DALMANE - 30MG - used for insomniacs  
  
Two drugs stored in same bottle  
Recovered by FBI in a pharmacy
- (13) QUIBRON - QUIBRON PLUS - Asthma medicine  
No expiration date, no lot number  
Stored and disbursed from soda containers  
Recovered by FBI in a pharmacy

Mr. DINGELL. Well, gentlemen and ladies, we want to express the committee's thanks for your very helpful testimony. Before the questions commence, Ms. McKenzie, we are going to get that monitor removed from in front of you. We apologize for that discourtesy to you, and we want you to know that certainly no discourtesy was intended toward you, for which the committee does apologize, nonetheless.

Mr. Thompson and Mr. Helterhoff, do you or Mr. Fay or Ms. McKenzie have any further comments at this time, before I recognize members for questions?

Mr. THOMPSON. Not at this time, Mr. Chairman.

Mr. DINGELL. I do observe that you attended the University of Michigan, and the high quality of your work certainly reflects well on that great institution. I might observe some pride because as you know, I come from that State and sent children to that school.

The Chair recognizes now my good friend from Oregon, Mr. Wyden, for 5 minutes.

Mr. WYDEN. Thank you very much, Mr. Chairman. I share the chairman's view. You all have done a first-rate job and we are very appreciative.

Mr. Thompson, a comment that you made on page 7 concerned me greatly, and it seems to me it would concern every consumer, where you talk about the fact that the diversion problem is a national problem; it is not one that is just turning up in an isolated community here and there across the United States.

And you go on to say that at least one drug store in every city, town, and village involved in the FBI investigation was found to be dispensing such medications. Are we talking about 10 towns or 20 towns or 200 towns? How many communities are we talking about?

Mr. THOMPSON. Searches were conducted and search warrants were executed in literally dozens of cities across the country as a result of this undercover operation, Congressman. Cities from Florida on the east coast to San Diego on the west coast, and as I said in

my prepared testimony, in each of those cities and towns in which the undercover operation took us—and it did not have to involve, as you know, a drug store; could have involved a manufacturer's representative or a doctor—but in each of those cities, we found at least one retail drug establishment, and at least one retail drug store which was dispensing adulterated and misbranded drugs to the American drug consuming public.

Mr. WYDEN. So could one logically infer from your investigation, Mr. Thompson, that this is going on in most towns in America? You found it in every town that you looked for it in?

Mr. THOMPSON. Of course, I would not be able to say it was going on in every city and town, but I think it is a fair statement to say that the problem is enormous and it is national in scope, and we probably do not have a true fix as to exactly how large it is.

Mr. WYDEN. Well, you have certainly painted it as one that stems from coast to coast and should concern every American consumer.

I would like to turn now to another area dealing with the telephone conversation between FBI Agent Christiansen, who posed as Bill Scott, and Leonard Schlein, the San Diego pharmacist. This is exhibit A, I think, in the materials that you have. [Transcripts designated exhibit A through exhibit E begin on p. 355.] Mr. Schlein pled guilty to criminal charges stemming from his active participation in the diversion market. When did this conversation take place?

Mr. HELTERHOFF. This is the conversation between—

Mr. DINGELL. Without objection, that will be appropriately marked and inserted in the record at the appropriate place.

Mr. HELTERHOFF. It's March 1985. Thank you, Mr. Chairman.

Mr. WYDEN. Mr. Schlein refers to Kenny King and the Atlanta connection. Who is Mr. King and what was the connection that Mr. Schlein is speaking of here?

Mr. HELTERHOFF. Kenny King was a broker of diverted and adulterated merchandise in the Memphis area, and the Atlanta connection is another individual, Jim Wilson, who is in charge of all the pharmacies for an Atlanta drug chain.

Schlein sold the drug Diabinese to King, who in turn sold to Wilson who used them in his chain stores in the Atlanta area.

Mr. WYDEN. Mr. Scott says that he wants to get a feel for the merchandise that Mr. Schlein has, and then give Mr. Schlein an idea of what to get. Mr. Scott then says he is particularly interested in "the Diabinese." What is Diabinese?

Mr. HELTERHOFF. It's a drug used for diabetes, the treatment of diabetes.

Mr. WYDEN. Mr. Schlein then says that the Diabinese comes from down under, from south of the border. What is he referring to there?

Mr. HELTERHOFF. That's the Mexico connection that we saw on the tape, and we have the one sample.

Mr. WYDEN. Are Mexican production facilities approved by the Food and Drug Administration?

Mr. HELTERHOFF. No, they are not.

Mr. WYDEN. Mr. Schlein then quotes a price of \$10.50 a bottle of 100. What is the average wholesale price?

Mr. HELTERHOFF. The average that we've run across is \$35.

Mr. WYDEN. On page 4 he says that he can either "break the bottles or send them sealed," adding that "when they come glass, it's real heavy to ship them." Now, isn't it a violation of FDA regulations to take pharmaceuticals out of a bottle and then ship them loose?

Mr. HELTERHOFF. Yes, it is. There are regulations and of course, there's criminal statutes, the same way, over and above the regulation.

Mr. WYDEN. Now, Mr. Schlein also agreed to take pharmaceuticals out of the bottle and ship them to Atlanta, didn't he?

Mr. HELTERHOFF. Yes.

Mr. WYDEN. He also indicated the type of records he likes to keep; specifically, no records at all. And he says that "there's no real—no invoices, things like that." He's talking just about cash transactions.

Mr. HELTERHOFF. That's correct, yes. All the transactions of baggies like that we found were in cash.

Mr. WYDEN. And persons in this type of business you found tend to deal in cash?

Mr. HELTERHOFF. Yes; both. In the baggies, it's pretty much all cash. In some of the larger diversion, once in a while they'd get a little antsy and want some checks to cover all the inventory and that type of thing. Of course, Mr. Thompson is looking at some IRS violations with regard to this.

Mr. WYDEN. Our subcommittee was also struck by the fact that Mr. Schlein does not exactly seem to be new to this kind of business. He goes on to say, and I quote here, "I tell ya, I do this my whole life, all the time. I grew up in New York doing this all the time." It appears he doesn't have any other gainful employment, does he?

Mr. HELTERHOFF. Correct.

Mr. WYDEN. He also says that, quote, "He has marked stuff," adding, "And I got Tolectin-DS up the gazutski." What kind of merchandise is he talking about there?

Mr. HELTERHOFF. That's sample merchandise.

Mr. WYDEN. Where did he get the samples?

Mr. HELTERHOFF. Well, he probably, in all probability, got them from a clinic at which he worked, or he could have gotten them there because he mentioned they're all over the place. He also could have acquired them from sales representatives or doctors, and most of the samples come from sales representatives.

Mr. WYDEN. Did Schlein attempt to sell the samples and unapproved Mexican-produced pharmaceuticals to his retail customers and to others such as through clinics?

Mr. HELTERHOFF. Yes.

Mr. WYDEN. I think my time has expired. I very much appreciate your diligence in this matter and I think it's going to help us to break that daisy chain that I talked about in my opening statement. Thank you all. Thank you, Mr. Chairman.

Mr. DINGELL. The time of the gentleman has expired. The Chair recognizes our good friend from Virginia, Mr. Bliley.

Mr. BLILEY. No questions at this time.

Mr. DINGELL. The Chair recognizes the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. How many doctors sell samples?

Mr. THOMPSON. How many were involved in this investigation?

Mr. BILIRAKIS. What percentage of doctors sell samples? Do you have any statistics? Do most of them sell samples, or is it a small percent that sell samples?

Mr. HELTERHOFF. We have identified close to—we can charge 12 doctors in this scheme, which in our opinion is quite high.

Mr. BILIRAKIS. All right, but you have talked to those doctors. What do they tell you? Do they tell you, all my colleagues do it, and that sort of thing?

Mr. HELTERHOFF. Well, it seemed to be a little bit regional on that aspect, from the standpoint of Georgia and Florida. In fact, one doctor there even quit becoming a medical doctor and went into the business of diverting drugs. He was the most—

Mr. BILIRAKIS. He was still getting samples?

Mr. HELTERHOFF. Yes; not as an M.D. because he got them through the diversion process. But the other doctors basically said well, you know, I did it to make a buck, but they didn't necessarily say it was nationwide with doctors. Although we had one instance where one of the doctors actually wrote letters to other doctors in your area saying, don't you want to participate in this and get all the samples and you can make some more money.

Mr. BILIRAKIS. By my area, do you mean Florida or do you mean my specific area of Florida?

Mr. HELTERHOFF. In the State of Florida.

Mr. BILIRAKIS. The State of Florida. You have no opinion, though, as to how widespread this practice might be.

Mr. HELTERHOFF. No; we do not at this point. Obviously, from this one undercover operation it certainly is widespread in that area. And as we continue our investigations in other areas, by whatever means, overt investigations or through cooperation, we may come up with more.

Mr. BILIRAKIS. Well, what's the volume of samples that are offered to doctors or given to doctors? Are we talking about just a few small packages, or are we talking about six-packs of drugs, or hundreds or thousands of drugs? Do we know that?

Mr. HELTERHOFF. Yes, it's the smaller amounts. They keep it up and they keep writing and saying where are my samples, and that type of thing. They don't come in large amounts. But cumulatively, obviously it increases quite a bit, but they're usually small amounts.

Mr. THOMPSON. And in this investigation, Congressman, we found that an unnecessarily large number of such samples were obtained by false and fraudulent pretenses, either from the drug manufacturers themselves or from the manufacturers' reps, or a combination of different kinds of factors.

Mr. BILIRAKIS. Do they sell these drugs, for the most part, to the pharmacies as some of the testimony here has indicated? Do they go to the back door of the pharmacy, or do they sell most of it to wholesalers who in turn might divert? Do we know?

Mr. HELTERHOFF. Both. They're a little bit more protected with the wholesaler, but they have sold in both places.

Mr. BILIRAKIS. Have we been able to basically isolate or come to sort of a conclusion as to the type of drugs that are involved here? I guess since we're talking about Florida and Georgia we probably are talking a large amount of drugs that would be used by the elderly; isn't that correct?

Mr. HELTERHOFF. Yes, that's correct.

Mr. BILIRAKIS. That should concern us even more, then, because they are less protected and are vulnerable.

Mr. HELTERHOFF. Absolutely.

Mr. THOMPSON. But to be quite honest with respect to that question, I think you really are talking about a wide variety of drugs from heart medication to blood pressure medication to antibiotics, which have special conditions of storage and handling, to birth control pills.

So this FBI undercover investigation did reveal a wide variety of drugs that were subject to illegal diversion.

Mr. BILIRAKIS. I see. Well, my last question, Mr. Chairman—and I think it is the bottom line, what can we do about drug diversion—as I said in my opening statement.

I'm what you might say, a former attorney, since I don't get time to practice anymore. But attorneys have always heard complaints from the law enforcement people that the laws are inadequate in some areas. So now I am a Member of Congress, what would you have us do, as Members of Congress, as legislators, in terms of taking care of this problem?

This is a question that would require an awful lot of time and maybe you can't give us an answer now and perhaps it is unfair to demand it now. But I certainly would—Mr. Chairman, I think it's just significant that we find out from these good people, what we can do. What can we do other than to compliment them and commend them, which is what we've all done and we mean it.

Mr. WYDEN. The gentleman poses a good question, and the Chair would be very interested in your view on it.

Mr. BILIRAKIS. It would be helpful if you have a brief summary answer to that and would possibly follow it up with something more substantive in writing to this committee. What can Congress do to help you and all law enforcement—this is terrible. This is sheer murder; white-collar murder, if you will, as my colleague from New York indicated.

Mr. HELTERHOFF. I think several points and a brief summary. First of all, this problem—and as you mentioned, it certainly is a very serious problem—is not totally a law enforcement problem, as I know you are aware. But I'll end up with getting specific but with a few things first.

I think what you have already done with your awareness program by your committee here is commendable. So, for the public to become aware and for this type of problem to be known. Some examples. I have mentioned we have high school kids removing the sample from pills. You wonder where the parents are. I mean, don't the parents know where they're working?

We've had situations where—and not just to talk about the high school individuals, but—where like the State inspectors would be

coming along for some of these pharmaceutical places, and the pharmaceutical owners would tell the children—and of course, they're paying for this—to move everything out of the pharmacy to their house. Well, I would think that would be a little bit suspicious. If they really wanted to get involved and really attack the problem.

And with that, the complaints of this activity would start coming into the proper authorities. And I think the forum of this committee is a good building block for this type of thing for the future. I think some of the State regulatory agencies might start some different auditing procedures, and in some of the smaller towns we noted that the local pharmacists would know the inspectors were in town and he would move it all out, just like I said, and then he'd move it back when they left.

Well, if you have unscheduled audits and at different hours, that might be a way.

Mr. BILIRAKIS. Is the State of Florida doing anything in this vein that you know of?

Mr. HELTERHOFF. Yes; we have been disseminating all of our information to the local authorities for this type of thing and also to the pharmacy boards for the pharmacy licenses, to the medical boards concerning the medical licenses. If we can hit it on all these different fronts, and including the FBI, including the U.S. attorney when it gets to the criminal stage.

Now what more can you do, I will yield to Mr. Thompson in 1 minute. In my opinion, from an investigative standpoint, we have pretty much adequate statutes to address this problem from the fraud by wire, from the statutes we have. If you've had a specific problem, Mr. Thompson, maybe you could address that here.

Mr. THOMPSON. Well, I think one of the first things you can do is really do what you're doing now; hearing testimony and gathering information from those of us who have been involved in the law enforcement efforts in this area with respect to any kind of future legislative items you want to undertake to correct the problem.

We can only tell you what we've uncovered—or what we've revealed in this undercover operation, although speaking as I guess a citizen and not as a public official, the undercover operation did indicate that there were a couple sensitive or what we may consider soft points in the distribution system; that is, the samples.

I might note that the Georgia Board of Pharmacy is considering regulations and procedures with respect to how samples are disseminated and controlled in Georgia.

Mr. WYDEN. Mr. Thompson, excuse me, to follow up on it, do you think that we need greater regulation of the wholesale market? Is that one area where the Congress could look legislatively to try to clean up this problem?

Mr. THOMPSON. Congressman, I really could not comment on the need for greater regulation or the need for different kinds of regulation. I do think it's important that you take the evidence that has been presented from these kinds of law enforcement efforts, look at what some of the—as Mr. Helterhoff said, look at what some of the State regulatory authorities are doing, and look at some of the pressure points that were uncovered in the FBI's investigation

here; that is, the samples, the control that the initial consuming organizations place on the drugs once they come into their use.

For example, the charitable organizations, clinics, hospitals, what kind of controls do those organizations have on the personnel who are ordering the drugs that they receive. Those are just—I guess I'd like to use the term—pressure points that were identified in the FBI's investigation. But I don't feel that we're competent at this point to comment on specific legislative proposals.

Mr. WYDEN. We appreciate that. I think what the concern of the subcommittee is, is that there's too much economic incentive out there to engage in these practices. And the goal of the subcommittee is to really control the supply and the availability of these kind of products.

We recognize your comments about the wholesale market, and we will leave the record open with respect to further comments that you would like to make on statutes and specific proposals because we want to take some of the economic incentives that your good investigation has turned up to deal with it and cut back on the availability.

I thank the gentleman.

The gentleman from Minnesota.

Mr. SIKORSKI. I thank the chairman.

Mr. Helterhoff, let's follow up on this discussion of the gentlemen from Florida and Oregon. You mentioned it is important that consumers are aware of what is going on. I think that is important, but from my involvement in this for about 1 year, it is very difficult, if not impossible, for consumers to protect themselves.

You have got a whole bunch of stuff there, that is going to be repackaged. By the time consumers get it, they have usually a man in a white outfit handing them a little orange bottle with a child-proof lid that they can't get off, and they have it there. They don't see that some of it is in baggies or in a roasted peanut bottle, or some of the asthma medicines in the old Dr Pepper bottle in the back room.

And beyond that, the people who do this stuff—especially in the counterfeit area—are very, very good at that. We saw in here 1 year ago some 3M products that were found at the drugstore right across from the 3M headquarters in St. Paul, and the 3M employees had trouble distinguishing the counterfeit trade dress.

These are Ceclor antibiotics, this is a counterfeit, and this is the real thing, and although the shape of the real thing is a little bit different, if I hadn't been told, I couldn't have told the difference. I don't know how consumers really can protect themselves in that kind of situation. It is important for them to be aware, so they are asking the questions of the pharmacist and the regulators and the Congress men and women, but other than that, I don't know how they can protect themselves.

Mr. THOMPSON. Congressman, in answer to your question and in following up your question and the Congressman from Florida's question, I do think—and maybe not to pat the FBI unnecessarily on the back, but we are real proud of this law enforcement effort that was undertaken by the FBI and Ms. McKenzie, but the publicity that has been given to it, the fact that we believe this is the largest such investigation and prosecution of this nature, we do be-



lieve it has had an important deterrent effect to the future commission of such crimes.

These individuals in many cases are professionals, college-educated businessmen and businesswomen. They are seeing their colleagues go to jail for this, and we do believe that this will have an important deterrent effect. We cannot estimate—

Mr. SIKORSKI. I am convinced of that. My point is that I think it is unrealistic to expect consumers to protect themselves in most instances. Sometimes there are going to be glaring examples where the pills just don't look right or the medicine doesn't look right.

I was down in Atlanta speaking to a drug group last year about this issue, and I think half the audience was diverters and half the audience were undercover agents.

Oh, that's not true, but I do know there were some of each in the audience.

Another question on this issue. You mentioned the statutes appear, at least some of them, with the exception of the sample area, to be sufficient. I am wondering if the resources are sufficient for enforcement. This is an excellent operation, and dedicated people a couple of years in the making, and it really has had a ripple effect across the country, but as I understand, the FBI doesn't have the resources to approve more than four or so of these "sting" operations on a yearly basis, and I am wondering if the resources are there to back up the statutes.

Mr. HELTERHOFF. We have no restrictions such as a number that you can only have four or only two or what. We have approximately 1,300 agents working on white-collar crime across the country, and within that, we prioritize, whether it is banking fraud or governmental fraud, you know, where the crime might be. But this certainly as an outgrowth of this case is going to be a very high priority within the white-collar crime program.

I don't see at this point, in my opinion, we have sufficient resources to keep going, and based on your fine committee, we have good documentation maybe to enhance our budget a little bit along this line.

Mr. SIKORSKI. Good.

I will ask another question in this enforcement area. There is a proposal up now to change the racketeering law, the RICO. As I understand, it is H.R. 2943. How does that affect apprehension of the diverters in this kind of situation? It is my understanding that the proposal will eliminate wire and mail fraud from being brought in under RICO. Have you been able to look at that? If not, maybe you should look at it and respond in writing to the subcommittee.

Mr. THOMPSON. Congressman, I am not aware of the specifics of that statute and how it might affect—

Mr. SIKORSKI. Well, if it does eliminate wire and mail fraud from being involved under RICO prosecution, would that affect these cases?

Mr. THOMPSON. I would think most certainly. As you know, in our prosecutions we use the wire fraud and mail fraud statutes as well as the conspiracy statutes to attack these illegal schemes involving drug diversions. I am not aware of the specifics of that piece of legislation, but I would like the opportunity, if you would

permit, for me to supplement the record with respect to the effect of that proposal on drug diversion investigations and prosecutions.

Mr. WYDEN. The gentleman from Minnesota asks an excellent question. We will leave the record open for the Department's view of the RICO statute, the racketeering statute, and also for additional comments you would like to make with respect to the adequacy of all the statutes in this area.

Mr. SIKORSKI. I have some questions on the audio tapes, but I will take that up in the next round.

Mr. OXLEY. Will the gentleman yield for a second? It was my understanding that the legislation which has been introduced regarding RICO only goes to the application of a civil nature and not in the criminal realm. I just want to put that on the record because that was my understanding, but we would certainly appreciate the comments from the two gentlemen here as to what their perception is, as well.

Mr. WYDEN. All right.

The gentleman from Minnesota.

Mr. SIKORSKI. We have had that concern being brought to us in this context. That's why I wanted to raise it.

I have some questions on the audio tapes, but I will take it up in the next round.

Thank you.

Mr. WYDEN. The gentleman from New York.

Mr. ECKERT. Thank you, Mr. Chairman.

In the course of your investigation—I want to get a feel for the most easily available source—what was your experience? Was the easiest source of drugs the not-for-profit hospitals, or was it salesmen's samples or was it doctor's samples? Could you give us a feel for where the best opportunity lies for those persons who are participating in the diversion market?

Mr. HELTERHOFF. I think it was a combination of two. I think it was the overordering by hospitals and clinics, and second, the samples which would come to, of course, the doctors. Those are the two major areas.

Mr. ECKERT. How widespread was the overordering by the not-for-profit hospitals? There is a great potential for profit there because obviously they buy them at extremely discounted prices, extremely discounted prices, and then turn around and sell it to the—

Mr. HELTERHOFF. That's correct.

Before, I answered another question regarding doctors' samples coming in smaller quantities. Well, these come in large quantities, and they are able—several ways. Either they get them in kind of ordering and not caring how much they are ordering, and then the other scheme, to slowly build up your inventory or the amount that you need in that area, and before you know it, you are getting so many that you are able to divert them.

Mr. ECKERT. But at what level is the decision made at the not-for-profit hospitals to sell? I saw in our earlier committee report way back, which you have probably read, written solicitations of some of these not-for-profit hospitals that can make \$30,000 or \$40,000 per month. All you have to do is sell us your surplus. They invited them to overorder and then sell and add to their budget

\$300,000 or \$400,000 a year, or half a million dollars a year or more.

Now, these persons making these decisions, the people administering, presumably, the administrators at the highest levels of these hospitals, they certainly are well aware of what they are into.

Mr. HELTERHOFF. Well, many times it is the pharmacy group that is once removed from the hospitals and clinics. They are relying on their pharmacy manager. The pharmacy manager might have several hospitals under his control, and many times the hospital administrators do not know what is going on because the control doesn't tell them how much they are ordering, nor do they pay any attention.

So it doesn't necessarily meet the high echelon of the hospitals or the clinics. We have had a few where there was some culpability at some level within the hospital, but generally it is one step removed, and the pharmacist gets it and he is able to divert it from that point.

We have had a few where they have even formed a bogus facility, and then, of course, they would be sent right to this bogus facility, which was actually a diverter.

Mr. ECKERT. But some of the solicitation is right out in the open.

Mr. HELTERHOFF. Yes.

Mr. ECKERT. Mr. Chairman, at this time I don't have any further questions.

Thank you.

Mr. WYDEN. I thank the gentleman.

The gentleman from Ohio.

Mr. LUKEN. I am not ready. I am sorry that I bounced in and out here, but this is an extremely important issue that you are working on that is one that we recognize and have recognized the pharmacy organizations have been working in the area for a long time.

Could I ask Mr. Thompson, although you are a U.S. attorney and not legislating in these areas, I am still interested in the FTC question or the question of the legal situation with regard to the non-profits.

Have you considered whether the nonprofits should have the exemption to the Robinson-Patman Act? Have you thought about that? Let me go on a little further while you do think about it.

There have been developments in the various laws, tort laws, and others, that exempt nonprofits or eleemosynary institutions that have various exemptions from the application of the laws. In this case, I believe it's an exemption from the application of the Robinson-Patman Act for nonprofits.

Is that perhaps an anachronism that should be modified? Have you thought about that?

Mr. THOMPSON. Congressman, I am not in a position to comment on it.

Mr. LUKEN. You mean you don't want to stick your neck out?

Mr. THOMPSON. I really haven't considered it. I would follow up on what Mr. Helterhoff said that in some instances there truly appeared a lack of knowledge of the illegal activities by the hierarchy of some of these not-for-profit hospitals; that is, some other individ-

uals within those hospitals were culpable and obviously should be subject to law enforcement pressures.

Mr. LUKEN. Well, it is not in your department, as I indicated, but I want to express my concern about that as we go into the investigation elsewhere. The problem that you have in the law enforcement field may well be caused, insofar as the nonprofits are concerned and as the occasion occurs because the nonprofits can buy these pharmaceuticals at ridiculously low prices, ridiculous compared to what the retail pharmacists who also sell to our citizens, compared to what they pay, and that law may well be revised.

It may be past time that that be brought up to date because these not-for-profit hospitals, after all, are businesses. We all recognize that today. We don't have to give a big speech about that. They are just as much in business as the corner druggist or anybody else who is in the field of dispensing of pharmaceuticals.

So we may have something which we can revise, which gets to the core of some of the problem. That is what I am bringing up.

But getting back to the issue that you have testified and presented to us so well, I believe the statement of Mr. Helterhoff that there are \$600,000 in products that have been seized, can you break that down at all as to how much would come from nonprofits or from hospitals or doctors? Is this all in the diversion area?

Mr. HELTERHOFF. Yes; it's all in the diversion. It is all on the order of what is in front of you here, where we would—anything that was tainted in the course of our undercover operation we would seize because we didn't want to force this into the marketplace, and once we were involved with it, we couldn't allow it to go. So the majority of it is from the sample pills and diversion from the wholesalers, and the smaller amounts from the doctors themselves.

Mr. LUKEN. Is most of it because it has been adulterated or misbranded or something of that kind?

Mr. HELTERHOFF. Yes.

Mr. LUKEN. So you really cannot trace it back and say how much of it came from the doctors, but you did—and I want to get to this issue—you did indicate that there were any number of professionals involved, something like 12 medical doctors who were named in the criminal indictments or informations?

Mr. HELTERHOFF. Yes.

Mr. LUKEN. Jail sentences?

Mr. HELTERHOFF. The majority of those were jail sentences, up to 5 years with the medical doctors, yes.

Mr. LUKEN. And 13 pharmacists.

Mr. HELTERHOFF. Yes.

Mr. LUKEN. Any direct hospital employees?

Mr. HELTERHOFF. No; we still have some investigations underway in this area, though.

Mr. LUKEN. Well, does that suggest that there is something about this distribution of pharmaceuticals by hospitals that also may be part of the problem? These are going through hospitals, and we have got organizations, what do we call them, what do they call themselves? Pharmacy coalitions or management? And they work for the hospitals, right?

Mr. HELTERHOFF. Yes.

Mr. LUKEN. So this stuff can go through the hospitals in name where it never probably gets to the hospitals at all.

-Mr. HELTERHOFF. That is right.

Mr. LUKEN. Well, maybe we have got a problem in getting to the hospitals, not of a criminal nature but of them tidying up their operation so that again that occasion doesn't occur. Do you have any ideas about that?

Mr. HELTERHOFF. I think that's an excellent point. I think that could be looked at. Like you say, not necessarily criminal, but what type of regulations—

Mr. LUKEN. Well, their negligence allows the criminals to operate.

Mr. HELTERHOFF. That's right. And the accountability that the pharmaceutical management organizations have now obviously is not sufficient enough to allow this to go on. Exactly what you are saying.

Mr. LUKEN. Actually, what this amounts to is a big front operation, not necessarily intentionally, but the hospital, with their nonprofit facade, orders the pharmaceuticals, and then they turn it over, in a careless manner, apparently, in a reckless manner because this is potent stuff, this is dangerous stuff, and then they turn it over to some agency that they don't control, they don't know what the agency is doing, and that agency either solicits or is solicited to become involved with the underground people who do the dirty work.

Mr. HELTERHOFF. That's correct.

Mr. LUKEN. You know, it is finally coming through to me because up until now the question in the back of my mind has always been if the origin of this is the nonprofit, the hospitals, how come we haven't been getting hospital administrators and others who are being indicted and so on? If this is the MO, maybe there are some things we ought to be doing in that area, working with the hospitals. I'm not sure what that is right now. I don't know if anybody has any idea what we should be doing.

Should we change the system or what?

Mr. THOMPSON. Of course, there were other sources of the diverted drugs other than hospitals and charitable organizations, export use, nursing homes, clinics and other—

Mr. LUKEN. Well, nursing homes would also be the nonprofits, wouldn't they? That's how they get it. Or do they get a discount, the nursing homes? Only if they are nonprofit, right?

Mr. THOMPSON. Yes.

Mr. LUKEN. They are still subject to the Robinson-Patman unless they are nonprofit.

Mr. HELTERHOFF. I think what you were focusing on in that area is very correct. And, to take it one step higher, the manufacturers themselves, sending that amount of pharmaceutical supplies, might be looked at, too, because, you know, all that is coming down from the manufacturers, so you really have a couple of levels to look at that, too, as to why they are sending so many down.

Mr. LUKEN. Well, in winding this up, could we get from you perhaps the identification—whether that needs to be public or not I don't know—but the identification of some of these pharmacy—what do we call them—pharmacy management, the ones who have

caused the problem, and maybe some others who haven't really been in the problem, so that the staff might look into this and we might have another hearing on it, or at least continue our investigation as to whether we can make some suggestions, or the staff could make some suggestions as to altering the system to cut down on the occasion for much of this.

Thank you, Mr. Chairman.

Mr. WYDEN. The time of the gentleman has expired.

The gentleman from Ohio.

Mr. OXLEY. Thank you, Mr. Chairman.

Mr. Helterhoff, could you take the committee through the procedures that the FBI, the Department of Justice, and the U.S. attorney have to go through to set up a sting operation?

Mr. HELTERHOFF. Yes; I would be very happy to.

Director William H. Webster, who has been Director of the FBI, he established a few years ago a Criminal Undercover Review Committee here at FBI headquarters. The committee is comprised of FBI officials and representatives from the U.S. Department of Justice.

The procedures used—and I will walk you through a couple of steps very briefly, of this proposal—was that our Atlanta field office started to recognize that they had an opportunity to work undercover. Some of the expenditures, the sensitive circumstances of what would need to be done with forming a company, with having it backstopped, all were very sensitive. So, they reviewed it in Atlanta with almost probable cause, specific information anyway, within the proposal—

Mr. OXLEY. Was that information brought to bear by paid informants for the most part?

Mr. HELTERHOFF. No; not in this case. We did not have paid informants.

We were able to get the cooperation of a pharmaceutical management-type person already in the business who got tired of this and came to us, and we were able to use him for the introduction. That was the core of starting it.

Then we looked at it with a principal legal adviser in the FBI field office. Then with Larry Thompson's shop and Gale McKenzie and looked at any concerns they had with the operation.

Then it came back to FBI headquarters, looked at in the white-collar crime section, and then eventually went to this undercover committee that I mentioned that Director Webster formed.

Mr. OXLEY. Did the gentleman that gave you the initial information though, did he have culpability, and was he given some type of immunity?

Mr. HELTERHOFF. He cooperated. From that time on he did not engage in any criminal activity. I believe it was worked out that he was not prosecuted because of his cooperation.

Mr. OXLEY. Thank you.

Mr. HELTERHOFF. When it came to the committee, the undercover committee, it was looked at, is this something that the FBI resources should be used for? Is the crime significant enough? Are there significant, sensitive circumstances that are involved?

The committee looked, as did Larry Thompson's shop before it came to the committee at, are there any problems with entrapment

with any of these subjects? Quite frankly, in all the cases here, we had adequate predication to contact the subjects. We didn't just go out and start contacting people. It was based on information, based on cooperation that we received.

Once that was reviewed, the undercover operation, it was sent to the Assistant Director of Criminal Investigative Division, who approved the operation. Then it was monitored at FBI headquarters from time to time. That is basically the scenario.

Mr. THOMPSON. The individual who gave us the initial information regarding this was not culpable of any criminal activity, Congressman, just to follow up on what Mr. Helterhoff said, this undercover operation was carefully scrutinized by the FBI, my office, Ms. McKenzie, and officials in the Department of Justice. There is absolutely no way we could have ferreted out these illegal activities involving a close and complex nature without having a viable, and having the freedom to undertake a viable undercover operation such as this by the FBI.

There was absolutely no way we could have identified and ferreted out this illegal activity.

Mr. OXLEY. I appreciate that. I think that is a very important point that the subcommittee should understand, that in this type of cases that an undercover operation is not only an important, but perhaps the only, as you indicated, way that that kind of an investigation can be conducted. And I appreciate your answers in that regard.

Also, Mr. Helterhoff, it appears to me that the FBI has made substantial changes in its outlook toward white-collar crime. I would suspect that as few as maybe 10 years ago, instead of 1,300 agents assigned to white-collar crime, it was far, far fewer than that. If indeed there were more than a handful, I would have been surprised.

So that has been a substantial change. Obviously, that change in focus has been very beneficial to law enforcement throughout the country. For that, the FBI is to be commended as well as the U.S. attorney's office.

I was particularly interested in the exchanges that went on in the tape that we saw, and would be interested in how much money the subject here was able to make, if you know, because there have been some indications, particularly I think from the gentleman from Minnesota, and also my friend from Oregon, as to the profitability of this activity.

Indeed, how profitable was it for this subject?

Mr. HELTERHOFF. Obviously, very profitable. We don't have the exact figures right now, but that is being looked at, and also in relation to IRS, as to trying to track all the amounts and inventories and the amount of volume in and out. So, we don't have an exact figure at this time.

Mr. WYDEN. If the gentleman would yield on that.

My understanding from the tape was that Mr. Macosky said he made \$111,000 in 1 week. Wasn't that correct?

Mr. HELTERHOFF. That's correct, yes.

But some of these—it wouldn't necessarily be constant, because, obviously, it is depending on how much you are diverting and buying and selling.

Mr. OXLEY. We don't know whether that was a good week or a bad week.

Mr. THOMPSON. Our investigation is continuing with respect to some possible tax violations.

Mr. OXLEY. Assuming that that is the case, this is an interesting dichotomy, compared to the normal drug kind of situation where you truly have a supply-demand type of situation. From a law enforcement standpoint and from a policy standpoint, it seems to be almost totally a supply situation.

It is not as if these people who are buying these drugs are demanding them as they would illegal drugs like cocaine or marijuana. This is clearly a supply situation, is it not?

The point is, as the gentleman pointed out so correctly, that it is our effort to try to dry that up, to try to eliminate that supply. In that context if we are talking about deterrence, is a 5-year, 8-year, or even a 10-year jail sentence, given the opportunity for parole, and given the relatively small fines available under current law, capable of providing the kind of deterrence? Or, should we be considering tightening up the penalties for this type of behavior, and hopefully increasing the deterrent factor as well?

Do you have any comments, either one of you gentlemen on that?

Mr. THOMPSON. Given the sentencing patterns in my district and the nature of the offenders, we are pleased with the jail sentences given to the defendants by the judges in the northern district of Georgia.

Mr. OXLEY. Were they mostly the maximum sentences, for the most part?

Mr. THOMPSON. In some instances they were, Congressman.

Mr. OXLEY. Is it my understanding that the one penalty—I know you mentioned 10 years and a fine. Was that the maximum punishment under that violation?

Mr. THOMPSON. It was.

But, following up on your question, given the amount of money that is involved in this illegal activity and the profits that are to be gained by those who might successfully engage in this, it would appear to us that the fine provisions in some of these statutes are, perhaps, too low.

Mr. OXLEY. So you think that if we are looking at jail time versus fines, that perhaps the fine side should be reconsidered when we are trying to put together legislation dealing with the issue?

Mr. THOMPSON. Yes, sir.

Mr. WYDEN. Would the gentleman from Ohio yield?

Mr. OXLEY. Yes.

Mr. WYDEN. I think the gentleman has asked some very good questions with respect to the deterrent aspects of all this. One followup is, that when there has been a criminal action, do you communicate that to the States, the State regulatory board, so that they can then go after the doctors and the pharmacists and others that they have jurisdiction over?

Mr. THOMPSON. Absolutely. That is standard operating procedure.



Mr. WYDEN. Have any doctors or pharmacists lost their license at the State level as a result of those communications that you have made back to them?

Mr. THOMPSON. Let me consult with my colleague on that.

I am informed that proceedings are just beginning with respect to those professionals, with respect to whom we have advised the State regulatory authorities. They are just beginning on those.

Mr. WYDEN. I thank the gentleman from Ohio.

Mr. OXLEY. If I may continue just briefly, Mr. Chairman, when I was back in the Legislature in Ohio, I had a good friend of mine who was literally an old country doctor. He was one of these fellows that would leave his office about 4 in the afternoon and instead of going home or going out and playing golf, he would visit and make house calls, which was, even in our area of the country, rather rare.

I can remember going over to his office. His brother happened to be a Congressman, one of my predecessors. He had an office right beside the railroad tracks in Deshler, OH, which became famous for the Richard Nixon campaign and the sign that said, "Bring us together." And it was literally right beside those railroad tracks.

It was a dumpy old office. I walked in there, and there were people waiting, who didn't have an appointment. They were just waiting to see the only doctor in that township.

I remember seeing one thing, and it always struck me as being unusual, although the significance never really dawned on me until today. I looked into the corner of his office and in that corner was a table. That table had samples of drugs that the doctor had received, I suppose years and years worth, that were literally piled up three-quarters of the way up to the ceiling. And I commented on what all these things were.

Well, he didn't have time to experiment with all these fancy new drugs, so he would just get them and toss them over there in the corner, and that would be the end of them.

And it never really occurred to me, of course—and it obviously never occurred to him—those samples could be potentially a profit-making kind of thing dealing with drug diversion. I suspect that that kind of activity maybe was going on even then, and that was 15 years ago.

So, I am just wondering what your opinion is as to the degree of culpability, if any, on the part of the manufacturers who, obviously, have a stake in providing these samples to the various hospitals and doctors, hoping, of course, that they will use these drugs and find them to be effective, and then, of course, sell more of these drugs. I don't necessarily have any objection to this process. That is what our free enterprise system is all about.

But, is there a degree of culpability? Is there an excess of that type of activity on the part of manufacturers, that at least should be considered not necessarily by law enforcement, but by perhaps peer groups or the association that these people belong to, or by the Congress at least in its oversight capacity?

Mr. HELFERHOFF. Well, in our criminal investigation, we did not get that high. Our investigation did not show any criminal culpability on the manufacturers.

Some of the sales reps of the manufacturers were, of course, culpable. But not the manufacturers themselves. Many of the manufacturers also do have very good systems of control right now. For example, they would get concerned when excessive amounts were being shipped. Some of the subjects that we monitored were concerned about manipulating the invoices, manipulating their purchase order because the manufacturer would come down on them.

Now there is another large area that we were talking about, where an awful lot does go out. And I don't know, maybe there is something there regulatory wise or administratively wise, that could be looked at. But we are just not in a position from our criminal investigation to know that.

Mr. OXLEY. I didn't mean to suggest any criminal culpability on the part of manufacturers, but just in terms of the overall scope of the problem, whether, in fact, there may be some lack of discretion in some cases in providing samples so widely.

We appreciate your testimony. Mr. Thompson, I understand you were on the "Today Show" this morning talking on this very subject.

We do appreciate your being here and highlighting this very important issue for us.

Mr. WYDEN. I thank the gentleman for his questions.

I recognize the gentleman from Minnesota.

Mr. SIKORSKI. I thank the Chairman.

If I might, I would like to enter into the record the exhibits B and C. They are transcripts from the audiotapes.

Mr. WYDEN. Without objection, so ordered.

Mr. SIKORSKI. Thank you.

Mr. Thompson or Mr. Helterhoff, referring to exhibit B, a transcript of a telephone conversation between your agent Carl Christiansen, posing as Bill Scott, and Jules Bursten, a pharmacist employed by Pharmaryl, Inc., a drug wholesaler from Pomona, NY—what was the date of this conversation?

Mr. HELTERHOFF. That was November 23, 1983.

Mr. SIKORSKI. And Bursten seems to know what is going on. He says on page 1, that he knows Bill Scott and who is supplying him.

On page 2 Bursten adds, "there is no secrets."

On page 3 he says that his company has been in business about 40 years and that everybody knows everybody else.

Did you find in your investigation that the various diverters did tend to know and interact with each other?

Mr. HELTERHOFF. Yes, pretty much so. They either knew each other personally, or telephonically, or once the bona fides were established, could talk to another diverter, and they were very closely aligned, yes.

Mr. SIKORSKI. On page 4, Bursten is asked how much volume he was interested in.

He replied, "As much as you can give me. I am insatiable."

Is this your experience, that diverters can move significant volumes of these drugs?

Mr. HELTERHOFF. Yes; it certainly is.

Mr. SIKORSKI. On page 5, Bursten says, he sells to wholesalers all over the country.

Does this appear to be one more example of a national market for the use of diverted prescription drugs?

Mr. HELTERHOFF. Yes; or very close to it, yes.

Mr. SIKORSKI. Exhibit C is another audiotape of a telephone conversation between Bill Scott and Jules Bursten.

What is the date of this conversation?

Mr. HELTERHOFF. That is December 5, 1983.

Mr. SIKORSKI. At the bottom of page 1, Bursten tells Scott how careful he is.

Near the bottom of page 2, Bursten tells Scott that the idea is to stay within his track record, not to make a large increase in his orders from a supplier so as not to arouse suspicion.

We saw a similar kind of thing in the videotapes today. If a diverter employed such a strategy, do you think that it would make it hard to discover the scheme?

Mr. HELTERHOFF. Yes; very difficult, unless somebody talked.

Mr. SIKORSKI. At the bottom of page 3, Scott says, "We know what the limits are on the six or seven hospitals."

What is he talking about there?

Mr. HELTERHOFF. He is talking to Bursten, that he has a diversion scheme going involving several hospitals.

Mr. SIKORSKI. So he is pulling in from six or seven hospitals.

Now Agent Scott has told Bursten that he has a diversion scheme going involving several hospitals. Does Bursten suggest a solution to the limitation of six or seven?

Mr. HELTERHOFF. Yes; this is a good example of the creative facility like we were talking about.

Mr. SIKORSKI. So what he does, he sets up a paper health facility for the purpose of ordering, and then diverting these drugs?

Mr. HELTERHOFF. Right.

Mr. SIKORSKI. On the video excerpt 11, there is mention of two doctors there. What happened to them?

Mr. HELTERHOFF. Which exhibit was that, sir?

Mr. SIKORSKI. Excerpt 11 in the video tapes. There are two doctors mentioned in there.

Mr. HELTERHOFF. That is still pending investigation. They are not charged yet.

Mr. SIKORSKI. In excerpt 14, there is a mention of Dyazide. Do you know what Dyazide is?

Mr. HELTERHOFF. Yes; it is used for hypertension.

Mr. SIKORSKI. Do you know where it came from?

Mr. HELTERHOFF. With the nonpublic sector, it is military or Government in some capacity. That goes to the nonpublic sector.

Mr. SIKORSKI. The reason I raised that is there is some indication to us and maybe to you, that there has been a lot of ordering through the Defense Department for military pharmacies and the rest of it. The drugs do not reach those pharmacies and then are diverted. Have you seen some evidence of this, besides maybe this Dyazide?

Mr. HELTERHOFF. In this particular case we had, there was a very limited amount in that way, but that certainly is a potential concern, that it could be diverted in that fashion.

Mr. SIKORSKI. My final question is, How can pharmacists who are victims of drug diversion, who do not know they are buying divert-

ed merchandise or they have merchandise that has been diverted, protect themselves?

Mr. HELTERHOFF. It is pretty hard for a bona fide pharmacist not to know where the material is coming from. With all the controls that are in place to buy legitimate drugs, in our experience any way, he would know in most instances whether it is diverted or legitimate.

If he is getting material like this, obviously as you know, he certainly should be suspicious.

Mr. SIKORSKI. What if they are a chain and the pharmacist is sitting down at the end, do they get it—what I am trying to discover is, from your answer, it seems to me we have a very valuable source of enforcers out there with pharmacists who have a professional and ethical concern that their people do not get ripped off, and they get antibiotics that are working and pills that are unadulterated and birth control pills that are not counterfeit and the rest of it.

It is your feeling that most pharmacists should be able to stop it right there? The Ceclor that I gave you was in fact in Minnesota. Two pharmacists independently, two different groups, a small company and then a chain company, came up. One noticed that the pills were slightly different. One noticed that the packaging was slightly different. They both reported it to the FDA.

Are you saying that other pharmacists are similarly situated?

Mr. HELTERHOFF. Yes; as you well know, the vast majority of pharmacists are totally legitimate and totally concerned like your example.

Mr. SIKORSKI. Absolutely, and are victims of this process because they are getting undersold. They have very small margins in the first place. What is happening in the marketplace independent of diversion is tough on independents and even on some chains. They get victimized in this process economically, just on their profit margin, and on their insurance and the rest of it.

Mr. HELTERHOFF. Our experience in this case, too, was they are not counterfeit. None of these are counterfeit. They are legitimate drugs diverted. In examples that you have up there, that is probably a little more difficult to determine by a pharmacist.

Mr. WYDEN. Would the gentleman yield?

Mr. SIKORSKI. Sure.

Mr. WYDEN. I appreciate the gentleman yielding.

It seems to me that the small pharmacy really doesn't have many choices, either they buy them or they don't. It is our understanding—the chairman praised Revco, one of the largest, if not the largest, chain drug store which is now testing for diverted products. That is something that I think they are in a financial position to do. The small pharmacy is not going to be able to have some kind of testing program. They either buy it or they don't.

I think the gentleman has asked a very important question about what a pharmacy, particularly a small pharmacy, is to do to protect themselves. I am not convinced there are adequate protections.

I am going to work with the gentleman as we look to legislative recommendations to make sure we have them.

Mr. SIKORSKI. It is my understanding we have FDA on the manufacturers. We have Customs on the borders. We have State licensing and similar bodies on the retail level.

Mr. HELTERHOFF. And State inspection, too.

Mr. SIKORSKI. We have a little problem in the middle on the wholesale system. What you are saying is this billion dollar business survives at the "hear no evil, see no evil, speak no evil" position of the industry? Is that a fair statement?

Mr. HELTERHOFF. No, I don't think so. I think the concern is—

Mr. SIKORSKI. We get the indication that the diversion market, a large majority of it, is this kind of diversion, not counterfeit, up to \$1 billion a year in a \$15 to \$20 billion industry. It might be larger. For that to survive I think you just told me you have to have pharmacists who look the other way. Somewhere they are getting baggies full of this stuff, pop bottles full of this stuff. Expiration dates are moved.

Something should trigger a red flag. Is that fair thus far?

Mr. HELTERHOFF. Yes.

Mr. THOMPSON. Including price.

Mr. SIKORSKI. Price would be the real give away.

Mr. THOMPSON. One of the things that was found by this investigation is there really is no difference in the price to the consumer, the ultimate consumer of these, between diverted drugs and drugs that have traveled through the legitimate distribution chain.

Mr. SIKORSKI. We have a lot of red flags there. We have to ask the professionals to be more cautious about passing this stuff through. I would guess that the deterrence of your operation and the subcommittee's investigation will increase that vigilance.

I thank you. I thank the chairman.

Mr. SIMS. Thank you, Mr. Chairman.

I think we need to clarify some aspects here that may not have been a large part of the Atlanta investigation but which are certainly part of the diversion market.

Mr. Helterhoff, as I understand the way the market works, most pharmacists buy from wholesale distributors. How does the pharmacist know where the wholesaler obtained the product?

Mr. HELTERHOFF. He wouldn't necessarily know.

Mr. SIMS. That is the point. The pharmacist doesn't really know whether the product was shipped to Egypt and came back or under what circumstances it was stored. Therein lies the problem for many pharmacists.

Wouldn't you agree that if a pharmacist bought it out of a baggie, he or she should know? If he bought it from what appeared to be a legitimate distributor and that product was improperly stored or was shipped to the United Arab Emirates and came back, that pharmacist may not know that.

Mr. HELTERHOFF. That is possible. Usually, there is repackaging at that point. Following what you said, you could have a shipment go over and come back in the original container and be stored.

Mr. SIMS. That has been the experience of this subcommittee, that the reimportations are in the original packaging and are declared to Customs as American goods returned to avoid any tariff, and in fact, the economics of the situation would be if they were not truly U.S.-produced goods, they would not be brought back.

You would agree that in those cases, it would be very difficult for most pharmacists to tell?

Mr. HELTERHOFF. Yes; in this investigation here, we did not have that type of situation. Certainly that would be a potential area of problems.

Mr. SIMS. Thank you, Mr. Chairman.

Mr. WYDEN. I have a couple of other questions.

Mr. Thompson, at your press conference in Atlanta on August 6, you indicated that the 46 criminal informations that were made public then were only part of the picture and that the investigation was continuing.

Is the investigation still active and at what stage are you in at this point?

Mr. THOMPSON. The investigation is continuing. We have approximately 40 subjects in our investigation, both individuals and corporations. Some of the corporations are large drug wholesalers.

Mr. WYDEN. Do you think the guilty pleas that you have and that we are going to get in the future because of your good work, are they going to put an end to drug diversion in this country?

Mr. THOMPSON. We think they will send a strong message of deterrence. I have no way of knowing whether or not they will put it to an end. I guess my cynicism says it will not be put to an end. We do feel it will send a strong message of deterrence, at least we hope so.

Mr. WYDEN. My concern really is what happens two or three years from now when some of the publicity is really a faint memory in the minds of some of these ripoff artists and crooks and others in the daisy chain. You think we will have the deterrent value at that point?

Mr. THOMPSON. I can assure you that the FBI is going to do its job and we are going to do our job pursuant to our responsibilities to uphold the law. We hope these prosecutions and this investigation will send a message to those who may be tempted to try this again, that this kind of activity will not be tolerated and when it comes to our attention, we will investigate the individuals involved and prosecute them to the fullest extent that we can.

Mr. WYDEN. How many individuals or companies are currently objects of your investigation?

Mr. THOMPSON. As I said, we have approximately 40 subjects involving both individuals and companies.

Mr. WYDEN. You are going to vigorously pursue all of these for possible criminal violations?

Mr. THOMPSON. Absolutely.

Mr. WYDEN. What about any new leads that are developed in the course of the continuing investigation? Is there going to be an effort to follow up on these on an ongoing basis? Has there been a cutoff date for the effort? How are these going to be handled?

Mr. THOMPSON. No, there has not been any cutoff date. We will follow up new leads or any allegations of criminal wrongdoing in the drug diversion area as we do with any other kind of criminal activity. As I mentioned earlier, we will investigate and prosecute such activity to the fullest extent that we can and to the fullest extent that our resources allow us.

Mr. WYDEN. Mr. Helterhoff, FBI headquarters, from their standpoint, they will provide all the necessary resources to follow up on the leads from the Atlanta operation and see each one of these cases to their conclusion?

Mr. HELTERHOFF. Absolutely.

Mr. WYDEN. I have no further questions. For the record, we have to put exhibits A through E, the FBI audiotapes, into the record. The transcripts of the audiotapes will be put into the record at this point.

[Testimony resumes on p. 389.]

[The audiotape transcripts referred to follow:]

EXHIBIT A

This is a telephone conversation between SA CARL F. CHRISTIANSEN, posing as BILL SCOTT, and LEONARD SCHLEIN.

BILL SCOTT (BS): My name's BILL SCOTT.

LEONARD SCHLEIN (LS): Well, okay. I know KENNY KING.

BS: Right.

LS: I don't know

BS: Okay, he's, uh, well, I guess you just sent him this stuff.

LS: Yeah.

BS: Some Diabinese is what I'm looking for.

LS: Oh yeah.

BS: Okay. And I guess you sent it to him through KENNY or something, I don't

LS: Oh, okay, I know the Atlanta connection.

BS: (Laughs slightly). Yeah, the Atlanta connection. Right.

LS: Okay. I'm, I'm cool. What's your name again?

BS: BILL SCOTT.

LS: Okay, BILL. Now I'm with you.

BS: Okay. What I'm trying, what I'm calling you for is to get some.

LS: Oh yeah?

BS: And, uh,

LS: You want to get into business with me also?

BS: Pardon me?



LS: You want to get into business with me also on this?

BS: Yeah. Let me tell you. I, I have a company here called PHARMACY SERVICES.

LS: Oh, I see.

BS: And we're buying and selling various, you know, type merchandise from time to time, uh,

LS: Uh huh.

BS: pretty much like, you know, these other fellows.

LS: Right. Where did you get my number? From KENNY or something?

BS: No, I got it from JIM, who, KENNY gave

LS: Uh huh.

BS: JIM your card.

LS: Okay, okay, okay, you know.

BS: I've got your card here in front of me.

LS: Okay.

BS: On the back, where it says, any questions, please call. I don't know if you gave that to KENNY or sent it to JIM in one of his shipments.

LS: Right. I probably did that to JIM.

BS: Yeah.

LS: Yeah. Okay. (Unintelligible).

BS: So, and we've dealt together, we're buying and selling stuff all the time.

LS: Oh yeah.

BS: Birth control pills and stuff.

LS: Okay. Great.

BS: So, what I wanted to do is just call and kinda get a feel for the kind of merchandise you had and give you an idea of what I get from time to time.

LS: Okay. Great.

BS: Right now, I'm particularly interested in the Diabinese.

LS: Okay.

BS: To buy.

LS: Like I say, that comes, you know the deal on that, don't ya?

BS: Yeah. Yeah.

LS: That comes from down under, down

BS: South.

LS: South of the border.

BS: Yeah.

LS: That's no problems, you know, it's right now, I'll, I'll sell it to you the same price I sell it to KENNY, you know.

BS: Okay.

LS: Ten fifty a bottle.

BS: Okay.

LS: And that's basically what's the deal on takes is, uh, you know, you gotta call me, it takes, depends when I can get a day to go down there and get it.

BS: Okay. How much can you

LS: That's what it's all about.

BS: How much can you get of that?

LS: I don't know. I, I've never, I've gotten more than two hundred at a time from him.

BS: You talking about bottles of a hundred or

LS: They're the bottles of a hundred.

BS: Okay.

LS: You know, they come in bottles of hundred. I can either broak the bottles or sell 'em, send 'em to you sealed.

BS: Okay.

LS: Depends. Sometimes they get 'em in glass bottles, like, when they come glass, it's real heavy to ship 'em,

BS: Yeah.

LS: that's the problem.

BS: Yeah.

LS: So it's easier to break 'em into

BS: Uh huh.

LS: I use the boxes I get from the wholesalers.

BS: Okay.

LS: And you know, I can do it either. They come, Diabinese come in bottles of hundreds.

BS: Uh huh.

LS: Okay. The Keflexes come in packs of twelve. That needs like unit doses.

BS: Oh, those are samples or what?

LS: No, no, no, they're just unit, they come in unit, that's how they sell in Mexico. Things in Mexico. Their American subsidiaries

BS: Uh huh.

LS: are in Mexico.

BS: Okay.

LS: And they just package things differently. The Diabinese is from PFIZER.

BS: Yeah.

LS: And the Vaflex is LILLY OF MEXICO.

BS: Right.

LS: They just package them in two, two fifty milligrams twelve in a box.

BS: Okay.

LS: And they pop, and they pop 'em out.

BS: Both of those are Procardia and uh,

LS: The Procardias come ninety to a bottle, is how they come.

BS: Okay.

LS: Now the Procardia comes in glass bottles so it would be advantageous to, to, to, you know, to open those bottles up.

BS: Yeah. You see actually that's, to be honest with you, the people I'm buying 'em from, uh, selling 'em to,

LS: Right.

BS: aren't gonna want 'em with that foreign label in there.

LS: They want 'em loose?

BS: Yeah.

LS: We'll take 'em out of the bottle, no problem.

BS: Okay. Okay.

LS: That's no sweat to me.

BS: What I usually do, you know, I either

LS: I'll send, hey, if you don't want the bottles, I'll send  
'em to you loose. It'll be cheaper.

BS: Yeah.

LS: And I could package it in smaller boxes.

BS: Yeah, and I feel a little safer doing it that way.

LS: That's fine. That is fine.

BS: Okay.

LS: You know with the Diabinese, though, now, have you seen  
the Diabinese?

BS: Yeah, yeah, I bought some. I

LS: Okay. Have you seen the Procardia?

BS: The Procardia, I haven't seen.

LS: Okay, the difference on the Procardia, the only thing is  
there's no writing on the tablet.

BS: Okay. That's

LS: It's a blank tablet. The color is almost exactly alike.

BS: Is that right?

LS: You want, why don't I send you right now. Give me your  
address right now.

BS: Alright. It's

LS: I'm gonna send you a couple of Keflex, a couple of  
Procardia in an envelope.

BS: Okay.

LS: You know, if I, what happens is if I see something that's real good, and I use it or not, I take it use it for myself and I turn it on to someone else.

BS: Uh huh.

LS: You know.

BS: That's good. That's about the sam

LS: You know a lot of times we get stuff here I like to send, see the thing I like is, see I get a lot of original packages on some stuff.

BS: Uh huh.

LS: And we like to send them out of the State really.

BS: Yeah. Yeah. See we do the same thing. I try

LS: Exactly, just divert them, you know.

BS: I'd rather send my stuff away from here out to the West Coast, uh

LS: Exactly. Well, then let's, you know, we could definitely work out something.

BS: Let me ask you

(Slight break).

LS: BILL, what's your last name again?

BS: SCOTT.

LS: SCOTT. Okay. I'll tell you, okay, the only thing on this is I have no problem, I mean, and you know, you call me. I'm trusting who you are guy. (Laughs slightly).

BS: Oh yeah, yeah, I know what you're saying.

LS: You know what I'm saying. I,

BS: Yeah.

- LS: you got, you, you mentioned KENNY. I never met KENNY.  
I never met any of these guys.
- BS: Okay.
- LS: Truthfully.
- BS: Well, that's the way
- LS: That don't matter to me none, uh.
- BS: Yeah.
- LS: The only thing is, that when we have to do it is,  
you know, as long as I, I, there's no real (unintelligible)  
no invoices, things like that.
- BS: Alright, that's, uh, you know, you don't know me and  
I don't know you, but that's kind of the way, you know,  
we're used to dealing down here.
- LS: You know, if you have no problems dealing that way,
- BS: Yeah.
- LS: then I certainly have no problem.
- BS: Yeah, well, see I, I appreciate your honesty, cause I'd  
rather get it out in the open. I feel a little uncomfortable  
too, but as long as we're both are dealing on the same,  
you know, same (unintelligible).
- LS: I tell ya, I do this my whole life. All the time.  
I grew up in New York doing this all the time.
- BS: Yeah. Yeah.
- LS: And, and we can make a lot of money.
- BS: Yeah, well I just
- LS: You know, and, and we could, there's a lot of money to make,  
and I look at it this way, do it now why you can.

BS: Yeah, that's right.

LS: I don't know how long this, you know, Diabinese will be around for

BS: Yeah.

LS: or what happens.

BS: Well, let me.

(Slight break).

LS: I, I gotta speak to my other guy.

BS: Okay.

LS: The guy that comes by today and see what he has, I mean we get a lot of Carafate and Cardizem.

BS: Okay.

LS: And that we like to sell at like, uh, forty off.

BS: Okay. Shoot, that's pretty good.

LS: You know, we, we'll turn it to you at forty off.

BS: How ill that come? Is that samples or

LS: Loose. That's loose.

BS: Okay.

LS: Not marked.

BS: That's not marked?

LS: No.

BS: That's fine.

LS: Are you into marked stuff?

BS: Ah,

LS: I got Tolectin-DS up the gazutski.

BS: Is it all marked?



LS: It's their sample, yeah.

BS: Uhh

LS: We get a lot of anti-arthritics.

BS: I've got one guy here

LS: Clinoril, you know, a lot of Clinoril

BS: Is that right?

LS: but all say, they all say sample.

BS: Let me check. Well, let me check with my people

LS: Check.

BS: and I'll get back with you.

LS: Find out because we do a lot of samples.

BS: Do

LS: I get a lot of samples, and the price is usually really right, you know, fifty, forty to fifty off.

BS: Yeah.

LS: I mean with your

BS: Especially with the marked stuff.

LS: Yeah, you know, and the point is, that again, it depends on your clientele. I do a lot of Workers Comp, third party. People don't, for two bucks on the PCS they're gonna save something.

BS: Hell, yes.

LS: You know what I'm saying?

BS: Yeah. Yeah.

LS: It depends on the, I guess on the store and what

BS: Yeah.

- LS: You know I have a one-person store so I could do what I wanna do.
- BS: Yeah. Well, see that's the kind of stores, I've got about fifteen retail stores that are just,
- LS: You know,
- BS: small operations, and
- LS: in a small operation, you could do whatever you wanna do and these samples is big dollars in this, BILL.
- BS: Yeah.
- LS: Really big money because I got, I work in the clinic here, I mean there's thousands of dollars in pills laying all over the place that no one uses.
- BS: Yeah.
- LS: You give it to a guy on Workmans Comp or a guy on Medicare or whatever
- BS: Yeah.
- LS: you know, the State, they, they're not gonna say it's a sample. See what I mean. It's not like you're charging them big dollars for a sample.
- BS: Nay, it never comes out. Well, lis
- LS: I'm trying to think what else, uh, those, so far those are the three items that I use extensively. See, Mexico has a lot of other stuff, but a lot of their packaging is, is weird.

BS: Yeah.

LS: You know, I got, I got Ovral Birth Control Pills for twenty cents a cycle.

BS: Are you kidding me?

LS: But the point is, they, they're weird. I'm gonna send you one of these cycles.

BS: Will they fit, uh?

LS: No, uh, they're weird, you know,

BS: Okay.

LS: they're just weird looking.

BS: Well, let, let me look at one.

LS: I'm gonna send you one.

BS: Cause I got some guys down here, I guess, just like you have out there, that, that'll just about do anything.

LS: I mean, you know, twenty cents a cycle.

BS: Jesus Christ.

LS: You know, they could charge eight bucks or whatever.

BS: Yeah, that's right.

LS: I'll throw that in.

BS: Okay.

LS: Okay.

BS: Good talking.

(End of the conversation).

EXHIBIT B

This is a telephone conversation between SA CARL F. CHRISTIANSEN, posing as BILL SCOTT, and JULES BURSTEN.

JULES BURSTEN (JB): Well, I, hum, I presume, uh, I spoke, I can't think of who I spoke down there about the brands.

BILL SCOTT (BS): Yeah, yeah, that's why I'm calling. I don't know somebody. Do, do you know RYMER?

JB: Who?

BS: RYMER RIVERS. He's, he's the guy that owns the majority of the stock in the company now. I'm a partner of his, and he told me about two weeks ago that you had talked to one of our pharmacists.

JB: Yeah.

BS: Uh, I don't which one it was.

JB: Here's the story involved.

BS: What's that?

JB: Ah, here's the story, I know see, I know who you, who's supplying you now.

BS: Okay.

JB: You follow me, BILL?

BS: Uh huh.

JB: And I can offer you a better deal.

BS: Okay.

JB: With more money. Well, the way we work it is a little differently. I, I split the profit that I sell it for with you.

BS: Okay.

JB: Rather give, than give you a, plain dollar figure, BILL, do you understand?

BS: Right.

JB: Let's say, wel, any particular product, and it costs thirty cents, for argument's sake.

BS: Okay. You're talking about like bid price.

JB: You, your net price is

BS: Right.

JB: thirty

BS: Right.

JB: and we sell it for a dollar. We return you thirty plus thirty-five, half of the seventy.

BS: Okay.

JB: So, you make, and that's how we work it.

BS: Okay.

JB: And, and we pay you immediately.

BS: What do you mean by immediately?

JB: Well, on the receipt of the goods, you got your money. And we'll, we'll, uh, we'll do the financing.

BS: Okay.

JB: In other words, there's a good flow of cash for you.

BS: Let me ask you this. How, how did you find out about us?

JB: Well, you know there's no secrets. I'm been doing this for a number of years. I'm semi-retired.

BS: Uh huh.

JB: And Hanover is uh, we've been in business about forty years, and that, this has been our function basically for many years. We, we are termed a wholesaler's wholesaler.

BS: Uh huh.

JB: And we know about the, you know, everybody knows everybody else.

BS: Well, who do you, who do you think we're buying our stuff from?

JB: Who, who do I think?

BS: You said that you knew the sou, you know

JB: I, I think you're buying it, uh, uh, who's buying your stuff?

BS: No, no. You, you said when you started that you knew, somehow you found out

JB: Taking and picking up your goods.

BS: Pardon me?

JB: Who's picking up the merc, the surplus of your merchandise.

BS: Okay.

JB: JERRY GROSSMAN.

BS: Yeah.

JB: Is that right?

BS: Well, uh,

JB: (Unintelligible) I don't care who it is.

BS: Yeah.

JB: You understand?

BS: Yeah.

JB: I know that I can give you a better deal.

BS: Okay.

JB: Better than anybody.

BS: Well, why don't we do this, uh, do you either, do you get out of that area, do you get down here much? Or,

JB: Not to any great degree.

BS: Okay.

JB: Do you get up this way at all?

BS: No, but if, if, let me ask you a few questions and try to make sure that it's worth both of our times to

JB: Alright.

BS: How much volume are we talking about?

JB: As much as you can give me. How's that?

BS: Are you, are you, you know,

JB: I'm insatiable.

BS: Okay.

JB: I

BS: What kind, what kind of products, any in particular, you

JB: What, whatever you think you can use. That, that you use. I'll give you some products that I can use, that, you know, if you can get 'em.

BS: Uh huh.

JB: But I, I, I'll take anything you got. I have tremendous sources that want the goods. Do you follow me?

BS: Yeah.

JB: And I don't get, I don't ever, and it's grown to an extent, BILL, that I don't have enough merchandise to supply.

BS: Uh huh.

JB: That's my problem.

BS: What do ya'll, do you just sell it to wholesalers?

JB: Right.

BS: Uh huh.

JB: All over the country.

BS: Yeah. Yeah. Ah,

JB: I worked for MC KESSON for many years, BILL.

BS: Did you?

JB: Yeah. I was General Manager up in Jersey. I, I will give you a list of items.

BS: Okay.

JB: Of what, what we would need. Okay?

BS: Uh huh.

JB: And then you would order them. When they come in, you'd ship 'em up and we ship you down a check immediately.

BS: Okay. Where are they shipped? Up in New Jersey?

JB: Yeah. Up in Hanover.

BS: Okay.

JB: And we, we, we, it, um, immediately upon receipt, the check goes out.



BS: Okay.

JB: If you want it certified, we'll certify it. Any way you want.

BS: Okay.

JB: And you'll find that the profit structure, BILL, is far superior to anybody's.

BS: Uh huh.

JB: By our splitting the profit, I feel everybody should have a, a share in the pie.

BS: How are you able to do that when most of these others do it differently?

JB: Look, uh, you know everybody, you know, cause the other guy is, is greedy, that doesn't mean I have to be.

BS: Yeah, I see what you're saying.

JB: BILL, listen to me, and, and I'm not trying to sell you a bill of goods, it'll be the smartest thing you ever did.

BS: Okay.

JB: Dollar wise.

BS: Yeah.

JB: Profit wise.

BS: Yeah. Well that's, that's the bottom line. Cause we

JB: I, I, I pay you the best profit on each individual when I, take an item like Tagamet, just, I'm just picking you know.

BS: Uh huh.

JB: (Clears throat). The profit may be greater than that than on, uh, uh, another product.

BS: Uh huh.

JB: Uh, uh, it'll vary with each product.

BS: Yeah, I see what

JB: You'll get more for your dollar.

BS: Have you had any problems with any, you know, the rumors, the reason I'm so cautious right now is cause there's a lot of rumors floating around her that some of the drug companies are really clamping down.

JB: The only drug company to clamp down that I know of is MERCK, completely really clamp, but BILL,

BS: We don't buy too much from MERCK anyway.

JB: I've had no trouble with SCHERING, HOFFMAN, LA ROCHE

BS: Uh huh.

JB: uh, AYERST, uh, no, nothing of those, I mean, they're coming in, it's coming in fine.

BS: Okay. Okay.

JB: The only two that create a problem is MERCK and LILLY.

BS: Yeah.

JB: And I stay away from there, you wanna know the truth.

BS: Yeah, we don't buy too much from them anyway.

JB: I, I, I, I, it doesn't pay to get involved.

BS: Yeah, well, that's, that's basically what I'm saying is,  
JB: (Unintelligible).  
BS: our philosophy is if, you know, we know what we're doing  
and we know the risks we take, but, uh, we want to  
minimize it.  
JB: To the, to the greatest degree, minimal for everybody  
concerned.  
BS: Right.  
JB: I  
BS: So, you'll catch one of us there.  
JB: Very good.  
BS: Alright?  
JB: Yeah.  
BS: Take it easy.  
JB: Thanks.  
BS: Good talking with you and I hope, you know, I hope we  
can do business.  
JB: BILL, there's no concern on my part. I, if, if, if we  
sit down, you'll see what, what transpires.  
BS: Okay.  
JB: Take care.  
BS: That's probably what it'll take then.  
JB: Okay.  
BS: We'll see ya.  
JB: Bye now.

(End of conversation).

EXHIBIT C

This is a telephone conversation between SA CARL F. CHRISTIANSEN, posing as BILL SCOTT, and JULES BURSTEN.

BILL SCOTT (BS): And he was, we were talking with him today, and he understood that, uh, he was telling us that somebody got in a jam, got indicted in Florida.

JULES BURSTEN (JB): Yeah, I'll tell you who, not in Florida.

BS: Oh, wasn't it?

JB: It was in New York.

BS: Yeah, well

JB: The indictment was due to, uh, ta, Ampicillin that was outdated and they were relabeling it.

BS: Uh huh.

JB: With the current date. It's, uh, uh, JOHN BLACKMAN from, uh, former Vice President of PRIMO.

BS: Ah, I don't know any, I don't know that, but this, I think this guy was talking about something different. I think it was in Florida, and allegedly it was the same, you know, type thing we were talking about, but, as long, all, all we want to do when we come up, you know, besides discussing the details, is make sure that

JB: Well, we got understand, let me tell ya one thing, BILL.

BS: Okay.

JB: We, or I do everything very carefully.

---

BS: That's what we're after, making sure.

JB: I don't want any problems, that, I wouldn't, I don't wanna buy too much from you.

BS: Yeah.

JB: So, to have the

BS: Any red flags.

JB: (Unintelligible) look at you and, you know,

BS: Yeah. We, there's no sense drawing any suspicion over a few extra bucks.

JB: No, I mean, ya, the minute you make yourself greedy that's when you have problems.

BS: Exactly. Okay. Well I'll tell you, it sounds like we have, you know, the same philosophies, as long as we

JB: I'd rather do less business and present it properly.

BS: Yeah. That's right. Well, that sounds good.

JB: And that's, yeah, well, uh, you have a pretty good track record as to what you've ordered.

BS: Right.

JB: The idea is, is to stay within that tra, track record at the given time.

BS: Uh huh.

JB: And then very, very gradual, not any great degree,

BS: Uh huh.

JB: increase.

BS: Okay.

JB: And there are other ways to, uh, uh, and, and I, I'll talk it over with you and I'll have CHUCK EDELSTEIN with me

BS: Okay.

JB: from the office, and we'll come up with some ideas of how to do it.

BS: That's what we're really, you know, we heard some other people doing some other things like, you know, like, well, I'd rather talk to you about it in person, but

JB: Yeah.

BS: you know what I'm talking about besides<sup>e</sup> besides the hospitals maybe having to (untelligible) another, you know, facility or something

JB: Yeah.

BS: that we could use, and because we know what the limits are on the six, seven hospitals.

JB: Alright, you can create a facility you know.

BS: Yeah, well, that's what we're not sure how to do.

JB: Yeah, well, I'll tell you how to do that.

BS: Okay.

(End of conversation).

EXHIBIT D

This is a telephone conversation between ED BURKLOW and EARL STEWART.

EARL STEWART (ES): I'll tell you what I have got though

ED BURKLOW (EB): What?

ES: that, that you can live with. I got some, uh, uh, twenty-ones of, uh, of, uh, WYETH B.C. Pills. Now you gonna have to get your cut somewhere else but I gotta have seven twenty-five for 'em and they're stock packages.

EB: Uhhh

ES: Ovral and Lo/Ovrал.

EB: Ovrал and Lo/Ovrал.

ES: Yeah. But now it'll, it'll take me a day or two to get, get those up.

EB: Take you

ES: And uh, I wouldn't even move for less than a thousand packs.

EB: A dol, a dollar a pack?

ES: What?

EB: How much a pack?

ES: Seven dollars and twenty-five cents.

EB: (Whistles) Dang you, EARL.

ES: What are you talking about

EB: Seven dollars a pack?

ES: those things now cost ten dollars a pack. Direct.

EB: Uh huh.

ES: I mean, you buy a pack of 'em, and you gonna pay ten dollars for 'em.

EB: Is that right?

ES: And these are stock. This is not a sample.

EB: Oh, they're stocked?

ES: That's what I, yeah.

EB: Hum.

ES: They stock packages.

EB: Oh, they're stock packages.

ES: That's right.

EB: Huh. Where in the world's he

ES: I don't know about that now, don't ask me that question.

EB: Don't ask you any questions. (Laughs slightly).

ES: I don't know.

EB: Alright, well, uh,

ES: They, they're yours when you get 'em.

EB: (Unintelligible).

ES: Cause I ain't want, it don't be no invoice, nothing like that. I just want the cash money.

EB: You just want

ES: Just like this

EB: cash money.

ES: there ain't gonna be no invoice. I just want the cash.

EB: You just want the cash.

ES: That's all I care about.



EB: Right. Well, listen, this guy, uh, uh, hum, well, let me figure out, let me get back in touch with you.

ES: Cause I don't want no checks.

EB: You don't want any checks, okay. I, I know what you mean. It's too near Christmas for that. And, uh,

ES: But you want me to go ahead and order this?

EB: I want you to go ahead and order that, right.

ES: I'll get on it right now.

EB: And find out, uh, listen that, uh,

ES: How about some Lasix 20 milligram?

EB: Lasix 20 milligram?

ES: I got about forty-eight thousand.

EB: Forty-eight thousand of 'em. Let me check on that and, uh, what price?

ES: It's gonna have to be seventy cents on the dollar.

EB: Seventy cents on the dollar? Is that stock package or is that

ES: No.

EB: It's

ES: They, they're baggies.

EB: Baggies?

ES: Yeah.

EB: Ah, let me get, check with him on that see him, I don't know, that's not too fast a mover I don't, but

ES: I don't even wanna know this guy

EB: you don't have any forty, you don't have any 40 milli

ES: I, I just wanna know you.

EB: Huh?

ES: I don't wanna even know the man. I just wanna know you.

EB: Yeah. Well, how much would, uh, 40 milligrams of the fastest, you don't have any Lasix 40, do you?

ES: Huh uh.

EB: Yeah. Alright. Well, let me check with him and see what

ES: Now I got, uh, a hundred and forty-four packs of, uh, Norinyl 150-28-

EB: Oh, Norinyl 1

ES: But they'll cost you five bucks a pop.

EB: Norinyl 1 what?

ES: 50-28.

EB: 150?

ES: And I, they got sample wrote on 'em, but I'll show you how to get it off there so you won't even know it's ever been on there.

EB: Sample written on.

ES: You buy an electric, electric eraser.

EB: A what, an electric eraser.

ES: Yeah, and it'll take it off of there just like you ain't never seen one.

EB: Is that right?

ES: Yes sir.

- EB: Huh. Well let me check. I don't know how he, I don't know that much about these BC's and so forth. Let me, I'll tell you what, let me check, let me take care of this Beconase and get in touch with him on this Lasix 20. Alright, and then
- ES: Now, I ain't got but a hundred and forty-four packs of that other and so it's not gonna be here long. In fact, if I leave out of here Saturday, it'll be gone Saturday,
- EB: Well
- ES: and that's what I think I'm gonna do.
- EB: Alright, on the, uh, what on the Ovrал, Lo/Ovrал?
- ES: No, on that Norinyl.
- EB: On the
- ES: I got those in my hands.
- EB: You got a hundred and fifty of those, alright, now
- ES: A hundred and forty-four.
- EB: Alright now, well, alright, on the Lo/Ovrал and Ovrал, I'm mixed up here. You said Lo/Ovrал seven dollars a pack?
- ES: No, I said seven thirty-five or seven twenty-five.
- EB: Seven thirty-five
- ES: Or seven twenty-five. It'll depend.
- EB: Alright, now how much of those can you get?
- ES: Well, I'm not gonna move 'em unless I get a thousand packs or in that neighborhood.
- EB: At least a thousand packs.
- ES: Yeah, and, and then I'll hope I'll come up with somewhere between seven hundred and fifty and twelve hundred packs.
- EB: Oh, okay. Alright, I got you.

(End of the conversation).

EXHIBIT E

SPECIAL AGENT (SA) CARL F. CHRISTIANSEN POSING AS BILLY

SCOTT (BS): This is SA Carl F. Christiansen, Special Agent  
with the FBI in Atlanta, Georgia. Today is  
Monday, May 21st, 1984. The time is approximately  
12:40 p.m. I'll be meeting with Nelson Chambliss  
at his home.

(Pause)

BS: (Sneezes)

NELSON CHAMBLISS (NC): Hey.

BS: What's goin' on?

NC: Come on in. Let me get this one thing glued  
down.

BS: What in the world, oh, are you cuttin' and  
pastin'?

NC: Yeah.

BS: (Unintel). Boy, this is a nice area.

(Dog barking)

NC: (Unintel) get this thing (unintel). I  
adjusted my telephone bill (unintel) all the times  
I've called you and Earl and other people I'm not  
supposed to call and times . . .

BS: Take, what do ya do, take it off of the bill?

NC: No. I just uh, cover it up, see. Like this.

BS: Oh, you cut somethin' off of another bill or

\* \* \* \* \*

BS: Yeah, I had a sandwich this morning. I had  
break...., late breakfast.

NC: Yeah. What the heck. I don't have to  
(unintel).

BS: Give him a couple bottles of Slow-K.

NC: Yeah, Slow-K, that's a, a anti-hypertension  
medicine, isn't it? Or is that Potassium?

BS: That's Potassium Chloride.

NC: Yeah.

BS: I tell ya, I was readin' Drug Topics the other day  
and that the number twelfth most . . .

NC: Prescribed drug.

BS: Yeah.

NC: Uh, see Leo can tell us what he uses in quantity.  
Watch it. Oh Do you see what happened?

BS: Yeah. I'll get 'em. it.

NC: (Laughs) you didn't see that guy  
stoppin'?

BS: No. I probably didn't have to stop that quick.

NC: Wait a minute. Let's see.

BS: I'll get out. Let me go in here. Just pick it up  
the best you can for right now and just bag it and  
fold it over. Don't let 'em all fall out the  
door.

NC: That's what's gonna happen I'm afraid. That's exactly what's gonna happen.

BS: That's okay. Just pick, just open it the way it is and get the bag back up straight.

NC: But if I open the door, they're gonna all fall out.

BS: (Chuckles) What else can we do?

NC: Get in the back and get 'em. Look like a couple a yo-yos. (Chuckles)

BS: Probably never know the difference. There's a lotta pills there, ya know it?

NC: (Laughs) A little dirt won't hurt anybody. Try gettin' the pine straw out.

BS: (Laughs)

NC: (Unintely)

BS: I should just leave, we'll just leave it. I'll get it when we come back.

NC: Don't step on 'em. You're steppin' on one too. You're gonna forget to open the door there Billy.

BS: I'll get a vacuum.

NC: (Unintely) ptomaine poisoning.

BS: That's okay. This is (unintely) the other day.

NC: (Laughs)

BS: Oh . . . The bag, the bag is popped. Who gave ya the bags?

NC: Hell, it wasn't popped 'til a while ago.

BS: Why don't we uh, what we should do is put it in that plastic bag.

NC: . . . watch the cops today. (Laughs)  
. . . you're . . .

BS: Let's get outa here. This guy'll never know the difference between . . .

NC: Now wait a minute. They're gonna go all behind the . . . , okay. All right.

BS: That's all we need is for the cops to come by and see us.

NC: (Laughs) Look, they're fallin' all outa the wait a minute. Hey, let's get a box or somethin'. They're gonna, we're gonna lose two thirds of 'em right here.

BS: Just leave 'em.

NC: No. Let's get a . . .

BS: What are ya gonna do?

NC: Get a bag. Get that, dump that trash out; and get that plastic bag. You're gonna have to open the door and get 'em 'cause they're gonna fall all the way down (unintel): (Unintel)

BS: What we need is a uh (unintel) put the box underneath the door (unintel).

(Unintelligible conversation - BS and NC outside vehicle talking)

BS: (Laughing)

NC: I get mixed up with the craziest people.

BS: (Chuckles) Ohhh.

NC: We don't need this other box (unintel).

BS: What's that?

NC: We don't need this other box (unintel)?

BS: Nah. Well, you can just throw it in here rather than takin' it back. Okay. Should we open this one?

NC: Wait, wait, wait. Give me that box before ya open that one. (Unintel)

BS: Now you're probably gonna hit me in the head with the door. Just pull.

NC: (Unintel)

BS: Yeah, that's it.

NC: Pine straw.

BS: Get that pine straw outa there.

NC: No extra charge for pine straw folks.

BS: Some recent research has indicated that pine straw



with your Nicobid does wonders.

NC: That's right. (Unintel). (Unintel). There's one right down there.

BS: All right. Put this bag in there.

NC: You have to hold it real gingerly.

(Chuckles)

BS: (Unintel)? Oh, here it is.

NC: (Unintel). Real bozos man, I'll tell ya.

BS: (Unintel) paid for (unintel).

NC: (Unintel)

BS: (Unintel)

NC: We were in New York, my boss and I, we started havin' breakfast. We were at Stouffer's in White Plains, and we started havin' breakfast; and, and uh, you know, how they have these little setups with coffee and juice and . . .

BS: Uh huh.

NC: . . . uh, pastries. And I said hey Dave, let's just go in here. It'd save a of a lot uh time. A little sign out there said some breakfast bar or somethin' . . .

BS: (Unintel)

NC: . . . open uh, seven 'til nine or something like that. Anyway, we went on in there.

Mr. WYDEN. I have no further questions. I recognize minority counsel, Mr. Smith, for any questions he may have.

Mr. SMITH. Thank you, Mr. Chairman. I have one question for Mr. Thompson and Mr. Helterhoff.

The subcommittee has corresponded with representatives of major retail drug chains and their trade associations. These representatives indicate to us that they purchase hospital overstocks of prescription drugs and that while these drugs basically fall within the rubric of diverted merchandise, under the circumstances that they purchase them, these drugs are monitored, they do not show an expired date, and they are all in sealed packages with a lot number, et cetera.

This leads them to tell us that they conclude it is possible to have a safe diversion market under adequate enforcement procedures.

Would you agree with that statement?

Mr. THOMPSON. It depends on how you define diversion. It can be defined broadly. We do not believe, based upon the facts uncovered by this investigation, that there really is a safe diversion market.

We feel that anyone who knowingly purchases diverted drugs is guilty of illegal activity and criminal activity. I guess I would have to ask you to explain a little further the definition, as to what would constitute diversion. We do not believe there is any legal or safe diversion practices.

Mr. SMITH. As long as a hospital purchases in actuality for other than its own use and resells, you would consider that to be diversion and illegal?

Mr. THOMPSON. As long as?

Mr. SMITH. A hospital purchases ostensibly for its own use and resells to a wholesaler.

Mr. THOMPSON. To its patients.

Mr. WYDEN. Will the gentleman yield on that point?

Mr. Thompson, did I understand you to say that anybody who knowingly buys diverted drugs is committing a felony?

Mr. THOMPSON. If they buy them under false pretenses, that would bring in the mail-fraud statute, the wire-fraud statute, title 21.

Mr. WYDEN. What if they just know they are diverted?

Mr. THOMPSON. It would depend upon the facts. You would have to look at that on a case-by-case basis. Perhaps I was overbroad. It would give rise to considerations of conspiracy, for example, and you would have to look at the particular facts of those cases.

Mr. WYDEN. I appreciate the gentleman yielding.

Mr. SMITH. Thank you.

I want to clarify this. I would like to get some sort of indication from the FBI as to how it approaches this.

A typical situation which has already been described, is that a retail drugstore or retail chain is offered merchandise by a wholesaler at a discount. The retail chain may or may not know the drugs have been acquired from a hospital or from some other source. In other words, there is no representation as to the origin of the merchandise. It is simply a lot of a particular drug which can be offered at a discount over average wholesale price.

That lot is received in the original packaging. It has not expired. However, there is no record as to where it was stored or how it was stored. But it is purchased from the same wholesaler that the drug chain or drugstore purchases its regular supplies from at regular average wholesale price.

Assuming that falls within the definition of diversion—in other words an item which has been offered at a discount by the wholesaler, and the item has come to the wholesaler from some source—we don't really know what source—do you think that procedures can be developed under which this kind of purchasing can take place legally and safely?

Or, do you think we should not be drawing a distinction between what you have found here and the kind of situation I am describing?

Mr. HELTERHOFF. No; I would say I can't see in any way how that could work legitimately.

True, they might buy a lot from the wholesaler at the lower price and say in that instance it was safely stored, et cetera, et cetera. But they are still manipulating the market. You are still going to have an overall effect on the whole drug market by affecting commerce in some aspect by lowering the price or raising the price.

From our investigative experience, I can't see any way where there really could be good diversion, at this point, anyway.

Mr. SMITH. Thank you very much.

Thank you, Mr. Chairman.

Mr. WYDEN. I thank the gentleman.

It seems to me after a lengthy hearing and your very helpful information, that we have established some important facts. Certainly, I am concerned about the national dimensions of this problem; the fact that every single community where you did your investigation you found this problem. That certainly has got to concern every American.

And while we know that the vast majority of health-care providers who work in this field are very honest and very reputable, I think American consumers have to be concerned about that small percentage that really is raising the specter of improper merchandise being put into their hands, and being sold to consumers around the country.

You have helped to give us valuable information today about the dimensions of the problem.

I know the gentleman from Minnesota and I and a number of other members are going to go forward with these hearings.

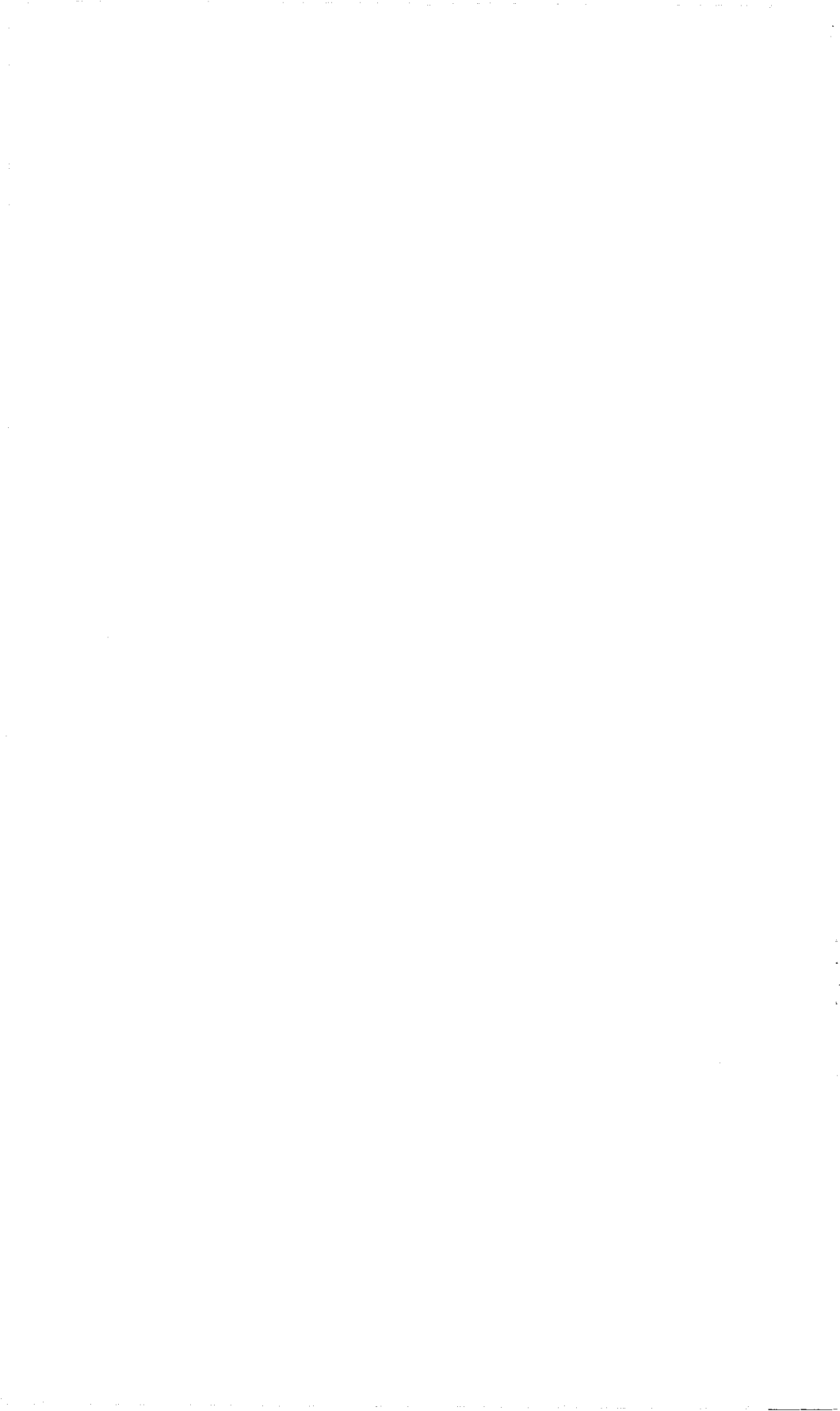
The chairman said, in particular, that we are interested in hearing from trade groups and industry groups with respect to their suggestions as to how we handle this situation. And the chairman unquestionably wants to take these hearings forward and consider legislative recommendations and other prescriptions for dealing with the situation. And because of your work, that is going to be a little bit easier.

And, unless you have any further comments, we will excuse you.  
Any further comments from the gentleman from Minnesota?

Mr. SIKORSKI. No.

Mr. WYDEN. All right, we are adjourned.

[Whereupon, at 1 p.m., the hearing was adjourned, to reconvene  
at the call of the Chair.]



## PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING

FRIDAY, DECEMBER 6, 1985

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:25 a.m., in room 2322, Rayburn House Office Building, Hon. Ron Wyden presiding (Hon. John D. Dingell, chairman).

Mr. WYDEN. The subcommittee will come to order.

Today, the Subcommittee on Oversight and Investigations conducts its fifth hearing into the threat to the public health posed by pharmaceutical drug diversions.

Our chairman, the very distinguished gentleman from Michigan, Mr. Dingell, is tied up on the floor, where the House is considering the Superfund, and unfortunately will not be able to be with us this morning, but I think this morning's hearing is an extremely important hearing that can be extremely constructive to the subcommittee.

At the last subcommittee hearing, I asked the U.S. attorney from Atlanta about the depth of the problem that we are looking at today, and the U.S. attorney from Atlanta said that virtually every community where they had looked at the drug diversion issue, had been touched by this problem, and the evidence is crystal clear that we have a serious problem on our hands.

It is my view that this situation represents a health disaster waiting to happen, and the only debate is what kind of ways can we tackle the problem in a constructive way.

We agree that there is a problem, now we open the debate as to what we might do about it. So I think with that, let us submit the remarks of the distinguished gentleman from Michigan, Mr. Dingell, into the record.

[The prepared statement of Mr. Dingell follows:]

### OPENING STATEMENT OF THE HON. JOHN D. DINGELL

This morning, the Subcommittee on Oversight and Investigations conducts its fifth hearing into the threat to the public health posed by pharmaceutical drug diversion. There can be no disagreement about the clear and present danger to the physical well-being of Americans from counterfeit, adulterated and misbranded drugs.

Perhaps the most startling statement on the extent of this problem came at our last hearing from the U.S. Attorney in Atlanta, who is conducting a nationwide criminal investigation of this problem. Mr. Larry Thompson stated that his investigation, which has reached dozens of communities throughout our country, has found

that in every "city, town and village" touched by the investigation, at least one pharmacy was dispensing diverted drugs.

The threat to the health of unsuspecting consumers must be dealt with quickly and effectively. We hope that the quality of most of the prescriptions filled in this country are fully safe and effective. We know that hundreds of millions of dollars worth of diverted drugs reach unsuspecting consumers each year.

It is clear that short of laboratory testing at each stage of the distribution chain, there is no way that even the participants can be sure that the drugs they buy and sell are safe.

Because rarely, if ever, are defective pharmaceuticals suspect in the failure of a particular treatment, we cannot rely on the potential liability of participants in the diversion market to provide adequate quality control. This leaves us with the necessity of either outlawing certain of the most dangerous practices or altering the economic incentives which give rise to the enormous profit of diversion, or both.

Today, we have asked representatives from each major segment of the pharmaceutical distribution chain to discuss, as a panel, the pros and cons of possible legislative solutions. We appreciate their attendance, some at considerable personnel inconvenience, and look forward to a lively and informative session.

Mr. WYDEN. We also have an opening statement of the Honorable Gerry Sikorski, the gentleman from Minnesota, who has also been very involved in our investigations; and the ranking Republican on our subcommittee, Mr. Broyhill of North Carolina, asked that a letter from the North Carolina Department of Human Resources be inserted into the record at this point; and from Mr. Bruce E. Vinson, director of pharmacy, Grace Hospital, Detroit, MI.

Let us insert on behalf of Chairman Dingell a letter from Mr. Vinson into the record at this point as well.

[The material referred to follows:]

STATEMENT OF HON. GERRY SIKORSKI

Thank you, Mr. Chairman. Since this subcommittee began its in-depth investigation of the dangers and sources of drug diversion some five months ago, many serious questions have been raised about the way prescription drugs are being supplied and distributed in this country. We have heard from private investigators, pharmacists, law enforcement officials, and former drug diverters. Their revealing testimony, based on inside knowledge, leads us to conclude that the growing menace of drug diversion endangers the health of every man, woman, and child in America who relies on prescription drugs.

I would like to welcome all of the witnesses today and I commend them for their efforts to work with us to eliminate this real health threat. I know that all of you share our concern about the public health and that your recommendations and assistance will help us ensure that the potential drug diversion disaster about to happen never does.



Harper-Grace Hospitals  
Grace Hospital Division

November 27, 1985

Honorable John Dingell  
Chairman, Committee on Energy and Finance  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Dingell:

I regret that I was unable to meet with you when I was in Washington in September, but I feel I did have a beneficial meeting with your professional staff member, Dr. Anthony Robbins. I expressed my opposition to the passing of any legislation that would legalize heroin. My reasons are the same as those I expressed to Senator Levin in April of 1984 (Attachment I). Basically, since heroin is metabolized to morphine to relieve pain, this represents a therapeutic redundancy to the current pain armamentarium. You can also see that educational efforts in journals and seminars are aimed at increasing the health care provider's knowledge of pain control (Attachments II-V).

I also voiced opposition to any resolution to the Bulk Resale/Drug Diversion Issue that jeopardizes the Robinson Patman Act. The impact on non-profit institution's drug budget would be significant. In my own institution my drug budget would increase by 53%. The impact on other insurers and private pay patients is obvious.

I appreciate the opportunity to bring these issues to your attention, and if I can provide you any further information, please contact me. You can also contact the Director of ASHP's Legislative and Regulatory Division, Jerry Hogan at 657-3000.

Sincerely,

Bruce E. Vinson, Pharm.D.  
Director of Pharmacy  
Grace Hospital Division

BEV/dav  
Attachments



NOV 8 1985



North Carolina Department of Human Resources  
325 North Salisbury Street • Raleigh, North Carolina 27611

James G. Martin, Governor

November 5, 1985

Phillip J. Kirk, Jr., Secretary

The Honorable James T. Broyhill  
2340 Rayburn Building  
Washington, D. C. 20515

Dear Congressman Broyhill:

Over the years, state government agencies have been able to purchase drugs at prices lower than those available to retailers. It is our understanding that this opportunity has been made possible by provisions of the federal Robinson-Patman Act, the Non-Profit Institutions Act of 1938, and/or the marketing practices of drug manufacturers.

Drugs purchased at discounted prices are used for state and local health services programs, which are federally, state, and/or locally initiated and funded. Among the programs and services that require the purchase of drug products are: tuberculosis control, sexually transmitted disease control, maternal and child care, home health, primary care, mental health and alcoholism treatment, mental retardation treatment, prison health services, and medical schools and affiliated hospitals. Depending upon the program and the need, services may be provided to the poor, the medically indigent, the categorically needy, and/or the general public. The advantage of being able to purchase drugs at discounted prices permits government agencies to provide basic services to our clients at a cost that the taxpayers can afford.

In recent months, Congressional concern has been focused upon a number of drug marketing issues, and although we share much of that concern, we fear that proposed solutions to some of the problems identified may jeopardize the favorable prices that we enjoy. In the absence of additional funding, a substantial increase in drug prices would mean a substantial reduction or discontinuation of these valuable health services.

Hearings are now being held by the House Energy and Commerce Subcommittee on Oversight and Investigation, chaired by Representative John Dingell, and the Senate Labor and Human Resources Committee,

chaired by Senator Orrin Hatch. The focus of these hearings has been the diversion and resale of low-priced drugs to unauthorized purchasers in violation of manufacturers' pricing agreements and possibly in violation of the Robinson-Patman Act. However, we are not aware that government programs have been a source of this illicit activity, hence our grave concern that we might be adversely affected by solutions offered to problems not of our making. At least two bills have been introduced to deal with these marketing issues: S. 1078 and H. 2385.

Of particular concern to us is a proposal offered by the National Association of Retail Druggists (NARD), a retail pharmacy trade group, that would limit low-priced drug sales to institutions "substantially supported by charitable contributions and whose functions are substantially limited to providing services to those financially unable to purchase services". The proposal further stipulates that the institution would not qualify for a Robinson-Patman Act (low-price) exemption "if it accepts payment for services or products provided". We are not aware that this proposal has been formally developed into proposed legislation, but we are concerned that it could happen at any time.

If enacted into law, and made applicable to government programs and services, we believe the NARD proposal would raise our drug prices since government programs and services are provided:

1. To persons other than those "financially unable to purchase such services";
2. On the basis of a co-pay arrangement and/or payments made by a third-party source, e.g., Medicaid, Medicare, private insurance, etc., thus the programs "accept payment for services or products provided";
3. With government funds that probably do not qualify as "charitable contributions".

One example of the impact of such legislation is our statewide family planning program. To absorb the anticipated increase in birth control pill prices to retail market levels, with no increase in the present level of service, the state would need an additional \$16,000,000 per year based on 1985 price differentials. By including all the other health service programs provided by the state, we believe it is safe to say that an aggregate \$25,000,000 to \$30,000,000 per year may be required just for the State of North Carolina!

In order to prevent these worthwhile government programs from being severely affected by these and other changes that may be proposed, I am respectfully requesting that you monitor these proposals and do whatever you can to assist us in maintaining our ability to protect and promote the public's health. Should you need further information or assistance in better understanding these somewhat complex issues, my staff is at your disposal.

Your efforts on our behalf are deeply appreciated.

Sincerely,

*Phillip J. Kirk, Jr.*  
Phillip J. Kirk, Jr.

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Mr. WYDEN. With that being dispensed with, we welcome all of you gentlemen representing all of the associations in this country concerned with this issue. We welcome your participation, gentlemen.

It is the practice of the subcommittee to swear all witnesses. Do any of you gentlemen have any objection to being sworn today?

Please rise and raise your right hand.

[Witnesses sworn.]

Mr. WYDEN. Let me also advise you of your right to have counsel with you throughout your appearance, and to have a copy of the subcommittee rules throughout your participation this morning, and I think also for the record, let me from left to right, beginning with you, if we go, Dr. Schlegel, just identify yourself, your name, your association, for our recorder.

Mr. SCHLEGEL. Good morning, Mr. Chairman, it is my pleasure to address the subcommittee—

Mr. WYDEN. Just for purposes of identification only right now, your name and your association for our recorder.

Mr. SCHLEGEL. John F. Schlegel, American Pharmaceutical Association.

Mr. ODDIS. Joseph A. Oddis, American Society of Hospital Pharmacists.

Mr. MAHAFFEY. Fred T. Mahaffey, executive director for the National Association of Boards of Pharmacy.

Mr. KELLEY. Ty Kelley, National Association of Chain Drug Stores.

Mr. WEST. Charles West, National Association of Retail Druggists.

Mr. STRECK. Ronald Streck, National Wholesale Druggists Association.

Mr. BRENNAN. Bruce Brennan, Pharmaceutical Manufacturers Association.

Mr. WYDEN. Gentlemen, we thank you. We will put your prepared remarks into the record in their entirety, and if you could summarize your views in 5 minutes, I think that would be particularly helpful to the committee. We could have some questions.

Let me also suggest in your 5-minute presentation if you could specifically address the questions that were asked by the subcommittee, I think that would be particularly helpful.

Each witness was asked to address nine questions, and if you could focus on those during your presentation, that would be most helpful.

Dr. Schlegel, let us begin with you.

TESTIMONY OF JOHN F. SCHLEGEL, PRESIDENT, AMERICAN PHARMACEUTICAL ASSOCIATION; JOSEPH A. ODDIS, EXECUTIVE VICE PRESIDENT, AMERICAN SOCIETY OF HOSPITAL PHARMACISTS; FRED T. MAHAFFEY, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY; TY KELLEY, NATIONAL ASSOCIATION OF CHAIN DRUG STORES; CHARLES M. WEST, EXECUTIVE VICE PRESIDENT, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; RONALD J. STRECK, VICE PRESIDENT FOR GOVERNMENT AFFAIRS, NATIONAL WHOLESALE DRUGGISTS' ASSOCIATION; AND BRUCE J. BRENNAN, SENIOR VICE PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. SCHLEGEL. Thank you, Mr. Chairman. It is my pleasure to address this committee. My name is Dr. John F. Schlegel. I am president of the American Pharmaceutical Association. APhA is the national professional society of pharmacists representing the third largest health profession comprised of over 150,000 pharmacy practitioners, pharmaceutical scientists and students.

Since its founding in 1852, APhA has been a leader in the professional and scientific advancement of pharmacy and in safeguarding the well-being of the individual patient.

We welcome the opportunity to assist the committee in dealing with the problem of potential health and safety threats posed to American consumers by prescription drug diversion and counterfeiting. It is of grave concern to the entire profession of pharmacy, and the subcommittee should be commended for its efforts in addressing this issue.

The United States currently enjoys the best system of drug delivery in the world. We are the envy of foreign nations who study our drug development, production, delivery and dispensing system. We provide patients with a safe, effective and economic therapy. All of us who have worked over these many years to develop and refine this system should indeed be proud of our efforts and should be concerned about the issue which confronts us today. Like you, Mr. Chairman, it is our goal to protect the integrity of the medications we dispense to American consumers.

APhA has analyzed the investigation reports of this committee and has conducted additional research into the problem of drug diversion. We have categorized the diversion schemes into five types: Counterfeit drugs; American goods returned; stolen merchandise; sample drugs; and violations of the Nonprofit Institutions Act.

The first three, counterfeit drugs, American goods returned and stolen merchandise, involve criminal actions which must be dealt with by law enforcement agencies. We commend the efforts of the DEA, FDA and the U.S. district attorney's office to investigate, identify and prosecute offenders.

To assist law enforcement in their efforts, we need strong laws which prohibit these acts and stiff penalties to act as stronger deterrents to these criminal actions. It is not only the public, but we as a profession, who are victimized by these activities. In seeking to protect the public and assure them safe products, we urge that the Congress act to: Ban American goods returned schemes which use the reimportation of pharmaceuticals for diversion; and stiffen pen-

alties to act as deterrents against counterfeiting and the theft of drugs.

In the cases where pharmacists are involved in these criminal activities, State boards of pharmacy, which license pharmacists to practice, should take action against those individuals. Those criminal acts are clearly unprofessional and cannot be tolerated in any way.

The health and safety of the American consumer is placed in great jeopardy by these actions. We are concerned about these crimes. Of the individuals recently convicted of these crimes in recent months, two were our members. We have resigned their memberships believing that their criminal actions reflect an abandonment of their oath as pharmacists.

The last two, sample drugs and violations of the Nonprofit Institutions Act, are abuses of well-intended ideas which sought to do good for consumers and professionals alike. It is unfortunate, but because diversion schemes have exploited these mechanisms, we are now forced to reexamine them to reconsider whether drug sampling and Nonprofit Institutions Act exemptions can continue.

Regrettably, the benefits to the many may be lost through unprofessional and criminal acts of a few, but the value of our current drug delivery system and the integrity of both our professionals and our products are too important to jeopardize. APhA encourages the committee to examine these ideas and to find a way to protect both these important parts of health care delivery and the integrity of American drug products. APhA believes that it will be possible to do this and that the recommendations we will make in this presentation will help.

In addition, the work we will continue to do with our colleague associations in pharmacy will produce refinements in those recommendations in the coming months. There are small numbers of people involved, but the risk to the American public is great.

APhA has a long-standing interest in combating potential abuses of sampling. Sample drugs are just like those dispensed by prescription and thus should have all the controls, labeling, and instructions for patient use as other prescriptions.

As early as 1941, our association was seriously concerned about the current practices associated with drug samples. It was not drug samples per se, but the unbridled use of samples which causes APhA's concern. It recommended that if drug samples could not be controlled, they should be eliminated. Numerous times since then, our house of delegates has considered the problems inherent in the distribution of drug samples. In 1968, the APhA House of Delegates, which is the largest deliberative body in American pharmacy, noted that:

Manufacturers' drug sampling, as now practiced, is the source of much waste, ill will and drug diversion. Furthermore, associated hazards of uncontrolled storage conditions, the difficulty of enacting drug recalls, drug diversion and the lack of monitoring dated drugs are of particular concern to the pharmacist.

Later, in remarks to the Pharmaceutical Manufacturers Association in 1970, our concerns were voiced when it was pointed out that sampling has been permitted to continue virtually outside the sphere of regulation, with samples frequently handed out to patients by unlicensed persons who keep no records. We were con-

cerned then with the public health and safety implications related to the hazards of drug storage and dispensing by persons neither trained nor held responsible for providing pharmaceutical products.

For over 40 years, APhA has recognized the problems that uncontrolled sampling could cause. We have sought over these many years to highlight these problems and to work within the profession and with industry to resolve the many problems we have seen in sampling. We will continue to work with the pharmaceutical industry and believe that recent efforts in conjunction with everyone's heightened awareness of today's diversion problem will, in fact, lead us toward a final successful resolution.

The only Federal laws or regulations which deal specifically with sampling relate to those regulations implemented the Controlled Substances Act, 21 CFR 1301.74(D). Those Federal regulations specify dispensing and recordkeeping requirements. State laws vary. As of 1984, only 28 States had regulations dealing with sampling; 6 ban the sampling of controlled substances, 8 require the registration of manufacturers representatives, and 7 require the prescriber requests for sample drugs before the manufacturer can provide them. Only one State, Pennsylvania, explicitly requires that sample drugs be labeled with information about the name, quantity, and instructions for taking the drugs before they are given to a patient.

Thus, few laws guide the sample drug distribution system, including the safe dispensing of sample drugs to patients. At this time, it is possible for persons not licensed or qualified to dispense drugs and unfamiliar with safe dispensing practices to acquire drug samples and dispense them to patients. Neither these laws nor others which might seek to control the current drug sampling system would be adequate to fully protect the public health.

We believe that the successful resolution of the problem lies in a total ban on drug samples as they are currently distributed. We strongly urge the subcommittee to recommend a ban on drug sampling as currently practiced in this country as dangerous to patient health and safety, health cost inflationary and, as is now explored in these hearings, contributory to drug diversion.

Since the provision of drug samples to patients does have an important role in the delivery of health services to patients, however, APhA has a replacement program to offer, one which eliminates the negative effects of drug sampling while assuring benefits to patients.

APhA proposes the establishment of a program which will provide for sample drugs to patients to be dispensed in small, starter dose quantities; offered at no product cost to the patient; and provided for the purpose of ascertaining the value of the drug effects prior to dispensing of the remaining therapeutic course.

Mr. Chairman, I wish to clarify my testimony. The Patient Starter Dose Program in our testimony is called the Trial Prescription Order Program. The Trial Prescription Order Program will allow patients to receive sample drugs directly from pharmacies through written requests from a physician or other prescriber. Such a system would continue the perceived benefits of a drug sampling program to patients without perpetuating current risks to public health.

The proper packaging, transportation and storage of drug products are the result of many years of system development and refinement by knowledgeable people. Patients will be protected best if the sample products they receive are known to be of the same quality at the time of dispensing as those they purchase in usual drug distribution channels. If a program such as this is adopted, the prescribing physician can write a prescription for a drug and attach a coupon provided by the manufacturer for the sample drug.

The pharmacist then dispenses the drug at no charge or at a reduced charge, depending on the terms established by the manufacturer. The pharmacist is later reimbursed by the manufacturer for the drugs dispensed as samples. The patient is then assured that the drug sample has been handled properly and is thus of the highest quality. Also, the patient is assured of receiving proper instruction for the proper storage, handling and use of the drug.

In 1969, our House of Delegates gave this issue extensive consideration and developed a set of guidelines to pharmacists and manufacturers for developing drug sample programs. We believe that these principles are valid today, and so they have been incorporated into this proposed program.

To recap, we believe drug samples as currently distributed should be outlawed completely and should be replaced by a Trial Prescription Order Program. Samples of drugs would then be dispensed by pharmacists in reasonable quantities containing only a few days' supply of therapy and would be dispensed to patients, as are other drugs, with appropriate labeling, patient instructions and with child-resistant safety closures. The pharmacist meets such criteria in the normal course of practice; physicians and other prescribers normally do not.

As the third hearing on drug diversion pointed out, discriminatory pricing by drug manufacturers has fed a system which encourages diversion. At the heart of this problem is the purchasing advantage enjoyed by some nonprofit institutions such as hospitals, nursing homes and HMO's, whose actions distort the original intent of their nonprofit status and place serious economic hardships on pharmacists who choose not to participate in drug diversion schemes. To make matters worse, these institutions have been major distribution centers which operate outside the normal drug distribution system and thus escape the safeguards that have made our system the envy of the world.

As nonprofit institutions create for-profit activities to aid in their expansion, the controversy over whether or not the institution can use its nonprofit purchases to compete in the community marketplace will continue to rage. As these institutions continue to diversify and expand, the distinction between them as for-profit and nonprofit entities becomes very fuzzy. It is now time for Congress to review who should qualify for status under the Nonprofit Institutions Act.

A nonprofit institution which buys at a discriminatory discount and sells large quantities of drugs other than for its own use is in violation of the Nonprofit Institutions Act. We strongly urge that discriminatory pricing be replaced with a pricing policy based on volume of purchase discounts rather than institutional profit status.

We are extremely concerned when discriminatory prices resulting from the Nonprofit Institutions Act's provisions grossly affects the ability of some pharmacies to compete. As the committee's past hearings have illustrated, differences in prices available to nonprofit and for-profit entities have been as much as one hundredfold. This type of pricing hurts community pharmacists and their patients. Fair competition in the marketplace is not feasible when the nonprofit institution is not the truly eleemosynary institution envisioned by the Nonprofit Institutions Act.

Some have suggested that the Nonprofit Institutions Act schemes may be an ethical system of diversion which actually helps the consumer. We disagree. These schemes run counter to the intent of the law and are unfair to both the pharmacist and patient as consumers. Commonsense dictates that manufacturer margins sacrificed in the nonprofit market must be recouped in the public sector. And in the long run, it is the consumer who must make up the difference. This cost shifting is antithetical to the concept of free market economics.

Apha believes the problems of discriminatory pricing promoted by the Nonprofit Institutions Act can be reduced by amending the legislation to restrict Nonprofit Institutions Act benefits to those institutions which are truly eleemosynary and utilizing the Nonprofit Institutions Act benefits strictly for their own use.

Those institutions should not be permitted to resell drug products purchased under the Nonprofit Institutions Act exemption; the purchasing advantages should be available only for drugs used by the needy patients treated by these institutions. The Nonprofit Institutions Act should be amended to prohibit nonprofit institutions from turning the buying advantage into unfair competition with for-profit entities.

The committee, in its letter of invitation, questioned whether there are other alternatives to the current multi-tiered pricing system so as to provide comparable benefits to truly eleemosynary institutions. APhA believes that the intent of the Nonprofit Institutions Act exemptions to the Robinson-Patman Act is adequate for providing benefits to those institutions and that the best solution would be to reexamine and clarify those institutions which should be allowed such exemptions.

Violators of the act should be punished with appropriate criminal or civil penalties; however, APhA does not support the termination of medicare or medicaid benefits for institutions found to violate the act. Such termination threatens the availability of needed medical services to the poor and elderly.

We believe that we must do all we can to address this problem of drug diversion. The immorality of drug diversion is deplorable and in violation of the APhA Code of Ethics. This code has been provided. Pharmacists involved with these illegal activities may well be in violation of over half of the provisions listed in the code, but two seem most applicable in this situation.

The first states that:

A pharmacist should hold the health and safety of patients to be first consideration and should render to each patient the full measure of professional ability as an essential health practitioner.



The second is more specific:

A pharmacist should never knowingly condone the dispensing, promoting or distributing of drugs or medical devices, or assist therein, that are not of good quality, that do not meet standards required by law, or that lack therapeutic value for the patient.

The actions of pharmacists who engage in diversion are in clear violation of these provisions.

When the subcommittee stated that the "American consumer can no longer purchase drugs with the certainty that the products are safe and effective," a shock wave traveled throughout the pharmacy profession. The actions of the few have threatened to deprive pharmacy of its good name. We do not intend to see the profession's integrity sullied. We urge Congress to help protect the integrity of the Nation's drug supply.

We do not wish, Mr. Chairman, to be alarmist. The drug delivery system of this Nation is intact, and we will do a great disservice to the people of this Nation if we lead them to believe otherwise. Our goal and our concern must be to keep it intact. We must all have the patience, the courage and the incentive to examine the problems you have identified in these hearings on diversion and to seek solutions.

In conclusion, I wish to pledge APhA's continued cooperation in this process and offer to work with you to assist the subcommittee in its deliberations.

#### TESTIMONY OF JOSEPH A. ODDIS

Mr. ODDIS. Mr. Chairman and members of the subcommittee, I am Dr. Joseph A. Oddis, executive vice president of the American Society of Hospital Pharmacists.

I am pleased to be before you today on behalf of the American Society of Hospital Pharmacists to present our views on a serious public health problem: The gray market for drug products. In our oral testimony, we hope to highlight our more extensive written remarks.

Our members, as pharmacists, have a special ethical and legal responsibility to ensure the safety and efficacy of drugs dispensed to our patients. ASHP has been at the forefront of the fight to protect and improve the quality of the public health through provision of innovative, comprehensive and cost-effective pharmaceutical services.

With this record in mind, we wish to assure the subcommittee of ASHP's willingness, desire and sense of obligation to help resolve some very real compromises to the integrity of the Nation's drug supply.

To date, Mr. Chairman, the subcommittee's hearings have documented a sorry tale in which all of those involved in the drug distribution system must share some blame. Hospitals, of course, cannot escape their own responsibility.

Whether the issue is sampling, reimportation, counterfeiting, or bulk resale and purchase of drugs, manufacturers, wholesalers, community pharmacies, and chain drug stores must all assume some responsibility for tolerating, permitting and, in some cases,

even actively participating in situations which may compromise the public health.

In our view, the most unsettling aspect of the evidence discussed throughout these hearings is that we face a serious health problem. In the past several months and in preparation for this morning's hearings, ASHP has endeavored to find effective solutions to the problem at hand which we would now like to address.

Without a doubt, bulk resale of drugs by hospitals and others to redistributors is an important part of the gray market problem. While our impression is that this activity is confined to relatively few institutions, and that participation in these schemes is largely an institutional and not an individual decision, precise figures are far less important than the fact that any gray market bulk resale compromises the integrity of the drug supply.

ASHP's concern about this practice is long standing. In 1983, our legal department outlined the considerable legal risks of bulk resale and published this opinion in our journal, American Journal of Hospital Pharmacy.

We believe that this was the first public statement on the issue from the profession. We have regularly advised our members of our substantial concerns about this practice and we have discussed our serious concerns about the problem with the American Hospital Association. In June of this year, our house of delegates adopted a policy relative to bulk resale of drugs calling for legislation to specifically prohibit the practice. Finally, in August of this year, the American Journal of Hospital Pharmacy carried an editorial which roundly condemned the participation of pharmacists in bulk resale.

Current statutes, while addressing this problem only indirectly, do indicate the serious legal risks attendant to gray market transactions. ASHP believes that other remedies should be examined, such as:

Revocation of the tax-exempt status of nonprofit entities who purchase large quantities of drugs for resale; use of the Racketeering Influenced and Corrupt Organization Act of 1970, as a tool to criminally sanction the entire scope of gray market activity; and use of the Criminal Fine Enforcement Act of 1984 as a possible means of imposing fines of up to \$250,000 for individuals and \$500,000 for corporations, for violations of those sections of the Federal Food, Drug and Cosmetic Act concerning trade, holding or dealing in counterfeits or adulterated or misbranded drugs.

Obviously, the strongest statutory prohibition against bulk resale is in the Nonprofit Institutions Act itself, and if increased vigilance by the FTC is needed to enforce the law, ASHP believes that the agency should be given unequivocal direction to do so.

As you know, Mr. Chairman, issues focusing on hospital purchases do not get to the heart of the problem at hand. Section 13(c) would not affect sales by nonprofits of goods purchased under traditional Robinson-Patman discounts, nor would it affect sales by proprietary institutions whose purchases are not covered by the section 13(c) exemption.

Most importantly, repeal or modification of section 13(c) would not stop the public health problem arising from samples and counterfeits finding their way into the gray market, nor would it deter purchases of gray market drug products.

We therefore urge the subcommittee to propose legislation that addresses the problem by dealing effectively and strongly with all parties who compromise our Nation's health care by dealing in gray market drug products.

Our suggestions for future legislative action include: One, application of legislation to all individuals and corporations who engage in the bulk resale and purchase of drugs or who trade or deal in drug products. Two, imposition of felony standards against those who knowingly participate in such schemes. Three, as to any participant who receives Federal assistance or medicare or medicaid payment, imposition of a substantial penalty, perhaps up to 300 percent of the retail value of the sale/purchase, of gray market drugs.

In the area of State law enforcement, we urge State regulatory boards to take strong action against physicians, wholesalers, pharmacists and pharmacies who deal in gray market drugs.

Perhaps one of the more disturbing elements of the subcommittee's hearings on drug diversion has been disclosure of numerous abusive practices associated with the practice of manufacturers' sampling. ASHP has opposed the practice of sampling for over a decade, citing these reasons: One, sampling serves no real health need for American consumers. Two, lack of control over the distribution of samples creates major health risks related to improper storage and product adulteration, legal inability to properly inspect physicians' samples, and increased risk of distributing expired products. Three, use of samples increases the costs of nonsample products. Four, samples provide access to prescription drugs by unauthorized, untrained personnel. Five, since samples are rarely provided in child-proof containers, they pose an additional health risk.

In short, while ASHP recognizes the complexities involved in other segments of the drug diversion scandal, we believe that the issue of sampling offers Congress a unique opportunity to at least eradicate this aspect of the problem. It is clear that any purported benefits of sampling are far outweighed by the public interest in eliminating the risks involved with the continuation of the practice. ASHP recommends that the subcommittee consider prohibiting distribution of sample drug products.

ASHP believes that, at a minimum, all American goods returned and all imports of pharmaceuticals should systematically be tested to assure that they are not adulterated and meet applicable standards of strength, quality and purity. We also believe that the costs of such tests should be borne by the importers themselves.<sup>9</sup>

ASHP first considered the issue of unit-of-use or treatment-size packages in 1973, and in 1975 adopted a policy encouraging such packaging. Among the reasons we adopted this policy were our belief that such packages are: One, safer for the patient; and, two, time saving for the pharmacist, thereby permitting more time to be spent on patient counseling and education and related professional activities. We believe that this form of packaging will also be useful in reducing the "gray market." Unfortunately, treatment-size packages have not been forthcoming from the industry.

The American Society of Hospital Pharmacists believes the problem of drug diversion can be solved through action within the profession and through appropriate legislation. Specifically, one, phar-

macists should assume an ethical responsibility to refuse to deal in the "gray market"; "gray market deals" should be reported to State regulatory boards. Two, State regulatory boards should move more aggressively against individual pharmacists and pharmacies who trade in "gray market" pharmaceuticals. Three, manufacturers and wholesalers should use computer technology to more effectively track products and discern unusual purchases or fluctuations in commerce which might indicate infusion of counterfeits or samples into the chain of distribution. Four, the utility of treatment size packages should be reassessed and probably voluntarily established as a standard packaging mechanism. Five, manufacturers should cease sampling.

Additionally, it is clear to us that some legislative relief is also needed. Legislation should, one, impose substantial civil and criminal penalties upon those who deal in the "gray market." Two, prohibit sampling or curtail it so that sample products are not put into the marketplace. Three, mandate that all returned goods and imports be tested for strength, quality and purity prior to admission to domestic commerce.

Mr. Chairman, we offer our fullest cooperation in working with this subcommittee and express our appreciation at being afforded the opportunity to appear before you.

Thank you.

[Testimony resumes on p. 404.]

[The prepared statement of Dr. Oddis follows:]

STATEMENT  
OF THE  
AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

The American Society of Hospital Pharmacists (ASHP) is the national professional society of pharmacists practicing in hospitals and other organized health-care settings; membership in ASHP exceeds 20,000. Our members, as pharmacists, have a special ethical and legal responsibility to ensure the safety and efficacy of drugs dispensed to our patients. Many of those basic responsibilities are set forth in various federal statutes and regulations, such as the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq., Controlled Substances Act, 21 U.S.C. 801 et seq., and Medicare Conditions of Participation 42 C.F.R. 405.1027, as well as in state laws governing the practice of pharmacy. ASHP and its members have also moved far beyond these basic standards and have been at the forefront of the fight to protect and improve the quality of the public health by providing innovative, comprehensive, and cost-effective pharmaceutical services.

The commitment of ASHP and institutional pharmacy to improving professional practice in the public interest is well documented. ASHP has fostered "innovative" pharmaceutical services that have subsequently become the norm in organized health-care settings. Some of those standards, contained in more than 50 separate documents, are published in "Practice Standards of the American Society of Hospital Pharmacists," the only work of its kind in the profession. Our standards have served as a beacon for the rest of the profession as it seeks to upgrade professional practice. Many of the ASHP standards have been incorporated into various state

laws and regulations and adopted by such quality-assurance bodies as the Joint Commission on Accreditation of Hospitals. Such improvements as the unit dose drug distribution system,<sup>1</sup> centralized intravenous admixture services,<sup>2</sup> clinical pharmacy services,<sup>3</sup> and the hospital formulary system<sup>4</sup> were all conceived by hospital pharmacists and implemented through the standard-setting activities of ASHP and the efforts of our members. With this record in mind, we wish to assure the Subcommittee of ASHP's willingness,

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<sup>1</sup>ASHP Statement on Unit Dose Drug Distribution System (1985). The unit dose drug distribution system is a pharmacy-coordinated system of medication distribution in which medication orders are reviewed by pharmacists, filled in ready-to-administer form, and sent to patient-care areas when the medication is to be administered. This system of drug distribution and control reduces medication errors and overall costs. See Comptroller General Report, "Potentially Dangerous Drugs Missing in V.A. Hospital--A Different Pharmacy System Need" (1975).

<sup>2</sup>A centralized intravenous admixture service, an extension of the unit dose drug distribution system, is one in which all intravenous fluids are prepared in the pharmacy where proper compounding and sterility can be assured. See Recommendations of the National Coordinating Council on Large Volume Parenterals.

<sup>3</sup>ASHP Statement on Clinical Functions in Institutional Pharmacy Practice (1978). Clinical pharmacy services provide a pharmacist's unique expertise on drugs and their actions to physicians, nurses, and patients through patient education, drug therapy monitoring and counseling, and drug information services.

<sup>4</sup>ASHP Statement on the Formulary System (1983). A formulary system is a method whereby an institution's medical staff, working through its pharmacy service, evaluates and selects from among numerous drug products only those most useful in patient care to assure quality and to control cost. A modern formulary system may involve selecting generic or therapeutic equivalents.

desire, and sense of obligation to help resolve some very real compromises to the integrity of the nation's drug supply; on behalf of our members, we also assure you of our collective desire to help eliminate this problem.

To date, Mr. Chairman, the Subcommittee's hearings have documented a sorry tale in which all those involved in the drug distribution system must share some blame. Whether the issue is sampling, reimportation, counterfeiting, or bulk resale and purchase of drug products, manufacturers, wholesalers, community pharmacies, and chain drugstores must all assume some responsibility for tolerating, permitting, and, in some cases, even actively participating in situations that may compromise the public health. Hospitals, of course, cannot escape their own responsibility; some hospitals--we believe a very small minority--have been a substantial source of drug products entering into the "gray market." Resolution of the problem should not focus punitively on any one group or deal with issues that do not fully address the subject of these hearings. Rather, we should strive for a resolution of the problem that is simple, effective, and comprehensive.

In our view, the most unsettling aspect of the evidence discussed throughout these hearings is the unavoidable conclusion that we face a serious health problem: the movement of drug products outside normal channels of distribution (a "gray market"), which inhibits tracking and identification of products in case of recall

and which facilitates market entry of counterfeit, adulterated, and misbranded products and their dispensing to consumers. In the past several months, and in preparation for this morning's hearings, ASHP has endeavored to find effective solutions to the problem at hand. We appreciate the opportunity to participate in the Subcommittee's efforts.

We would now like to address a number of specific issues relating to the problem of the "gray market" for prescription drug products.

#### Bulk Resale of Drug Products

Without a doubt, bulk resale of drug products by hospitals and others to redistributors is an important part of the "gray market" problem. While our impression is that this activity is confined to relatively few institutions--and that participation in these schemes is largely an institutional and not an individual decision--precise figures are far less important than the fact that any "gray market" bulk resale compromises the integrity of the drug supply. In our view, it is a nefarious practice that, though currently inhibited by law, should be explicitly prohibited by legislation containing serious criminal and civil sanctions applied to those who engage in bulk resale of drug products as well as those who purchase or deal in diverted drug products.



ASHP's concern about this practice is longstanding. In 1983, our legal department outlined the considerable legal risks of bulk resale and published this opinion in the American Journal of Hospital Pharmacy for all our members to read; we believe that this was the first public statement on the issue from the profession. We have regularly advised our members of our substantial concerns about this practice, and we have discussed our serious concerns about the problem with the American Hospital Association. (In recent months, counsel for the Chicago Hospital Council issued a legal opinion that confirms the points addressed in our 1983 publication.) In June of this year, our House of Delegates adopted the following policy relative to bulk resale of drug products:

To support legislation that would specifically prohibit bulk resale of drugs by pharmacies except for any (1) sales otherwise permitted by law to affiliated corporations in furtherance of a planned, integrated approach to delivery of health care within a health care corporate structure and (2) sales by bona fide group purchasing arrangements to members.

Finally, in August of this year the American Journal of Hospital Pharmacy carried an editorial that roundly condemned the participation of pharmacists in bulk resale.

Current statutes, while addressing this problem only indirectly, do indicate the serious legal risks attendant to "gray market" transactions. ASHP believes that the tax-exempt status of non-

profit entities purchasing large quantities of drugs for resale could be denied if the scope and extent of sales met Internal Revenue Service criteria for revocation of tax-exempt status. Carle Foundation v. Internal Revenue Service. Sections of the Racketeer Influenced Organized Crime Act of 1970, 18 U.S.C. 1961 et seq. (RICO) might also be a potent tool to criminally sanction the entire scope of "gray market" activity, if accompanied by fraud or misrepresentation; RICO might serve as a particularly effective tool for all pharmacy to privately police its activities relating to "gray market" drugs through civil litigation. The Criminal Fine Enforcement Act of 1984, Pub.L. 98-596, 98 Stat. 3134, et seq., also imposes very high fines--up to \$250,000 for individuals and \$500,000 for corporations--for violations of those sections of the Federal Food, Drug and Cosmetic Act concerning trading, holding, or dealing in counterfeits or adulterated or misbranded drugs.

Obviously, the strongest statutory prohibition against bulk resales is in the Nonprofit Institutions Act itself, 15 U.S.C. 13(c). Section 13(c) of the Robinson-Patman Act, 15 U.S.C. 13, limits drugs purchased at special prices by nonprofit institutions to the institutions' "own use." Precedents under Section 13(c) have defined the permissible scope of the phrase "own use," and, in our view, even the most liberal reading of those cases would prohibit "gray market" sales. See, e.g., Portland Retail Druggists Association v. Abbott Laboratories, 425 U.S. 1 (1976); Jefferson

County Pharmaceutical Association v. University of Alabama Hospital and Clinics, 460 U.S. 150 (1983); De Modena et al. v. Kaiser-Permanente Foundation, 743 F.2d 1388 (1984), cert. denied, 53 U.S.L.W. 3587 (U.S., February 19, 1985). Hospitals certainly can have no objection to "playing by the rules" and so should comply with the limitations and benefits of Section 13(c). If increased vigilance by FTC is needed to enforce the law, ASHP believes that the agency should be given unequivocal direction to do so.

Issues focusing on hospital purchases do not get to the heart of the problem at hand. Even if, as some have claimed, elimination or curtailment of the benefits of Section 13(c) were enacted into law it could be only partially effective. Section 13(c) would not affect sales by nonprofits of goods purchased under traditional Robinson-Patman discounts nor would it affect sales by proprietary institutions whose purchases are not covered by the Section 13(c) exemption. Most importantly, repeal or modification of Section 13(c) would not stop the public health problem arising from samples and counterfeits finding their way into the "gray market," nor would it deter purchases of "gray market" drug products.

We therefore urge the Subcommittee to propose legislation that addresses the problem by dealing effectively and strongly with all parties who compromise our nation's health care by dealing in "gray market" drug products. Our suggestions for future legislative action include:

1. Application of legislation to all individuals and corporations who engage in the bulk resale and purchase of drug products or who trade or deal in drug products that they know or reasonably should know have not passed (or will not pass) through bona fide channels of distribution. (The law would apply to individuals and to hospitals, institutions, wholesalers, manufacturers, chain and independent community pharmacies, and drug diverters/brokers.)
2. Imposition of felony standards against those who participate in such schemes with full knowledge of the scheme.
3. As to any participant who receives federal assistance or Medicare or Medicaid payment, imposition of a penalty equal to 300% of the retail value of the sale/purchase of "gray market" drug products, said penalty to be applied as absolute liability for participation; where applicable, the Department of Health and Human Services would have authority to administratively recoup such penalty from Title XVIII or XIX payments.

In our view, Mr. Chairman, such legislation would deal forcefully, effectively, and unequivocally with the problems at hand.

#### State Law Enforcement

One of the most effective means to police the "gray market" is through local enforcement of state licensing statutes. Virtually all state practice acts permit professional licenses to be revoked for "unprofessional conduct." See National Association of Boards of Pharmacy Survey of Law, 1984. Unfortunately, the lack of clarity about the legality of bulk resales and purchases appears to have precluded an aggressive policing action at the local level.

We urge state regulatory boards to take strong action against physicians, wholesalers, pharmacists, and pharmacies dealing in "gray market" drugs. We believe that these hearings and any future legislative deliberations may provide the impetus for more vigorous local enforcement of licensure laws. It is important to note that, as the Committee Report documented, some centralized purchasing agents are not pharmacists; we therefore note the need to act against both pharmacists and pharmacies dealing in the "gray market."

The National Association of Boards of Pharmacy has already started to educate its members--individuals appointed to state boards of pharmacy--about the problem. We applaud this leadership by NABP and we expect state boards, having been sensitized to this issue, to start moving to clean pharmacy's own house.

#### Sampling

Perhaps one of the more disturbing elements of the Subcommittee's hearings on drug diversion has been the disclosure of numerous abusive practices associated with manufacturers' sampling. As previous witnesses have detailed, large quantities of drug products, originally intended to be distributed as samples, have surfaced in commercial distribution channels and have been illegally resold to consumers as bona fide products. The methods by which these samples are "transformed," the health risks associated with their

entry into distribution channels, and the various laws violated by such activity have been well documented by these ongoing hearings. Although this component of the drug diversion dilemma has shocked many, ASHP has opposed the practice of sampling for some time. ASHP recognized the following as among the principal drawbacks of sampling:

1. Sampling serves no real health need for American consumers.
2. Lack of control over the distribution of samples creates major health risks related to improper storage and product adulteration, legal inability to properly inspect physicians' samples, and increased risk of distributing expired products.
3. Use of samples increases the costs of drug products.
4. Samples provide access to prescription drugs by unauthorized, untrained personnel.
5. Because samples are rarely provided in childproof containers, they pose an additional health risk.

For more than 10 years ASHP has called for elimination of sampling. In May 1979, during hearings before the Subcommittee on Health and Scientific Research of the Senate Committee on Labor and Human Resources, ASHP voiced its strong support for proposed legislation that would have substantially restricted the distribution of free drug products. This past November, in response to the resurgence of samples as a known public health risk, ASHP's Board of Directors unanimously reaffirmed the Society's decade-old policy on samples.

In short, while ASHP recognizes the complexities involved in other segments of the drug diversion scandal, we believe that the issue of sampling offers Congress a unique opportunity to eradicate at least this aspect of the problem. It is clear that any purported benefits of sampling are far outweighed by the public interest in eliminating the risks involved with the continuation of the practice. ASHP recommends that the Subcommittee consider prohibiting distribution of sample drug products.

#### Reimportation of Drugs

ASHP applauds the efforts of the Food and Drug Administration and the U.S. Customs Service to implement a program requiring the analysis of those drug products reimported to the U.S. that raise their suspicion.

ASHP believes that, at a minimum, all American goods returned and all imports of pharmaceuticals should systematically be tested to assure that they are not adulterated and that they meet applicable standards of strength, quality, and purity. Ensuring the safety and efficacy of the products and protecting the integrity of the nation's drug distribution system overshadow any cost-effectiveness analysis of such a program. Indeed, the costs should be borne by the importers who find the economic incentive of reimporting so attractive in the first place.

## Unit-of-Use Packaging

ASHP first considered the issue of unit-of-use, or treatment-size, packages in 1973 and in 1975 adopted a policy encouraging such packaging. Among the reasons we adopted this policy were our belief that such packages are (1) safer for the patient and (2) time-saving for the pharmacist, thereby freeing more time for patient counseling and education and related professional activities. Unfortunately, treatment-size packages have not been forthcoming from the industry. Aside from these profession-based reasons for such packaging, these hearings indicate new reasons why unit-of-use or treatment-size packages should be given a fresh look. We believe unit-of-use packaging could help reduce "gray market" abuses by making it far more difficult for diverted samples and counterfeit drugs to be repackaged, thus removing a major part of the economic incentive underlying such activities.

We do not feel unit-of-use should be mandated by legislation, but we hope that the utility of treatment-size packages will be favorably reevaluated by industry and pharmacy.

## Conclusion

The public health problems raised by "gray market" situations in which drugs travel outside bona fide channels of distribution is



no mere theoretical "issue" but a catastrophe waiting to happen. To the extent the associations before you have members who tolerate, participate in, or permit a "gray market" to survive, we must share the consequences of those actions; however, the task before us is not laying blame but finding solutions.

The American Society of Hospital Pharmacists believes this problem can be solved through action within the profession and through appropriate legislation. Within pharmacy's own house we believe the following things can be done:

1. Pharmacists should assume an ethical responsibility to refuse to deal in the "gray market;" gray market "deals" should be reported to state regulatory boards.
2. State regulatory boards should move more aggressively against individual pharmacists and pharmacies who trade in "gray market" pharmaceuticals.
3. Manufacturers and wholesalers should use computer technology to more effectively track products and discern unusual purchases or fluctuations in commerce that might indicate infusion of counterfeits or samples into the chain of distribution.
4. The utility of treatment-size packages should be re-assessed and probably voluntarily established as a standard packaging mechanism.
5. Manufacturers should cease sampling.

Additionally, it is clear to us that some legislative relief is also needed. Legislation should:

1. Impose substantial civil and criminal penalties upon those who deal in the "gray market."

2. Prohibit or curtail sampling so that sample products are not put into the marketplace.
3. Mandate that all returned goods and imports be tested for strength, quality, and purity before admission to domestic commerce.

We recognize that these recommendations are stringent and, unfortunately, that some hospital pharmacists may find themselves feeling the brunt of these sanctions. Our responsibility lies not in protecting hospital pharmacists but, as professionals, in protecting the public health. We believe that our recommendations, if followed through by Congress and pharmacy, will stop--unequivocally stop--an unnecessary and dangerous flaw in the integrity of the system of drug distribution and control.

Mr. Chairman, we offer our fullest cooperation in working with this Subcommittee and express our appreciation at being afforded the opportunity to appear before you.

Thank you.

Mr. WYDEN. Thank you for your statement. Gentlemen, let me caution you about the 5-minute time limit. We have a substantial number of questions we want to pursue with the witnesses. We will have to strictly enforce it, and very much appreciate your cooperation. We are going to have to observe the 5-minute rule.

Mr. Mahaffey, welcome. We will make your prepared remarks a part of our hearing record, in their entirety, and if you could summarize your views in 5 minutes.

#### TESTIMONY OF FRED T. MAHAFFEY

Mr. MAHAFFEY. Thank you, Mr. Chairman. I will try to stay within the 5 minutes.

Mr. WYDEN. We thank you.

Mr. MAHAFFEY. We thank you.

I think it should be said that NABP is the national representatives State regulatory agencies. Many of the people that you have heard prior testimony from.

Our members of the association and our description is in the fore piece of the statement. Certainly, the matters which the committee have voiced in terms of drug diversion is known, no real surprise to the association.

We have seen a number of these instances, reported to us over the years, and certainly we know and understand how drug distribution problems exist, because our people are the ones that are out there helping to enforce the pharmacy statutes.

Basically, the association several years ago took a stand on samples. We believe that they are a deterrent to the legitimate distribution of drugs, and this last year, we resolutely again to ban sample medication on prescription drugs and devices.

We cited inadequate storage, and this has come before you many times, carrying conditions of the sales representatives, and the abuse factors again and again, abuse factors of unauthorized legend drugs.

We have called attention again to the problem related to recall of a sample. Gale McKenzie and others from the Georgia situation pointed that out to you.

We had a recall on television this morning, to point this out, recalling of a product so we feel samples should be banned by the manufacturer.

The matter of exports and imports, we understand that the Food and Drug Administration—

Mr. WYDEN. Excuse me, I am not acquainted with that recall you discussed this morning, on television.

Mr. MAHAFFEY. Baby food. I am just emphasizing that recall currently over the countermarket as well as the legend drug market.

Mr. WYDEN. We weren't acquainted with that.

Mr. MAHAFFEY. In terms of the matter of imported exports, we believe that the Food and Drug Administration provides only paper control over that situation, and as other organizations have pointed out we are certainly for testing in terms of reentry, we think there should be some chemical analysis of drugs coming back into the United States.

As to the diversion and the pricing situation, we really don't take a firm stand on this, but we feel that in all conditions, the Robinson-Patman Act should be applied in terms of nonprofit sales, and certainly we support any efforts that the committee can make to make this more effective.

The regulation of wholesalers. This last year the association took a stand in terms of regulating wholesalers. About half the States regulate wholesalers, license them and inspect them, and half do not.

So, we are on record and will support State legislation to license wholesalers and repackers.

A very important of issue here is the definition of a wholesaler and a repacker and our committee on law enforcement legislation will be working with the National Wholesale Druggists Association and others this year. We will present a model statute and regulation to our next convention concerning the licensure of wholesalers, repackers, with clear definitions.

As a matter of fact, repacker needs to be better defined. We are certainly in favor of any efforts the committee could make in terms of identity and integrity of the product, Mr. Chairman. We feel that the boards of pharmacy do an adequate job in terms of policing the profession and applying sanctions.

The average board of pharmacy has five inspectors, and basically our statement calls for more stringent enforcement of the current statutes, Federal and State, and greater cooperation.

As to the unit of use packaging, we feel that the flexibility involved there is necessary to meet the demand of the public, and we also comment on the coupon system; we feel that if it would provide accountability for the prescription legend drug. We certainly would be in favor of that.

Basically, then, the NABP supports increased cooperative drug law enforcement efforts by the State and Federal agencies. Increased funding for Federal and State law enforcement agencies to permit meaningful enforcement of the existing State and Federal laws. The elimination of samples by manufacturers or as an alternative, making the recordkeeping requirements of controlled substances applicable to all parties involved in the distribution or dispensing of samples to provide for accountability.

Then, the registration of all drug outlets including wholesalers, and other distributors at the State level, with appropriate funding to permit meaningful periodic inspection of these facilities.

Five, recordkeeping requirements throughout the channels of drug distribution that require verification of the legitimacy of the drug distribution, the drug purchaser and the efficacy of the product.

And then, adequate penalties to cause compliance with existing laws, new legislation, effectuating points three, four, and five.

We call for a renewed law enforcement effort by State and Federal officials, and of course, take recognition of the fact that we do have the best drug distribution system in the world, that is de-

signed to protect the consumer, that it can be improved through public and professional education and greater State and Federal cooperation.

Thank you.

Mr. WYDEN. Mr. Mahaffey, we thank you very much.

[Testimony resumes on p. 438.]

[The prepared statement of Mr. Mahaffey follows:]

Mr. WYDEN. Mr. Kelley?

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY  
1300 Higgins Road, Suite 103  
Park Ridge, IL 60068

STATEMENT  
FOR THE SUBCOMMITTEE  
ON OVERSIGHT AND INVESTIGATION  
OF THE COMMITTEE ON ENERGY & COMMERCE

DRUG DIVERSION

I. ABOUT THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY  
(NABP or the Association)

AID TO GOVERNMENT/THE PROFESSIONS/THE PUBLIC

In each state and in other jurisdictions such as the District of Columbia, the responsibility for the licensure and regulation of pharmacists is lodged by statute (The Pharmacy Practice Act) in a governmental administrative agency known as the Board of Pharmacy. Many such Boards are also charged with criminal law enforcement duties and responsibilities as well as the licensing of manufacturers, wholesalers and other drug outlets.

In general, Board members are appointed by the governor or a state agency. The Board functions in an administrative and quasi-judicial role in state government. Boards establish standards for accreditation of colleges and entry level competence standards for the profession through the licensure examination. They monitor the continuing education of pharmacists, and carry out disciplinary functions as defined in state statutes and regulations. The average board has approximately five investigators to assist in enforcement of the Practice Act. All states license pharmacies (community, hospitals, nursing homes, etc.), about one half of the states license wholesalers, and several license manufacturers.

The National Association of Boards of Pharmacy is a Section 501(C)(3) non-profit, voluntary organization whose membership consists of each of the boards of pharmacy in the United States, the Virgin Islands, Puerto Rico, and several of the provinces in Canada (hereinafter sometimes referred to as "State Boards"). Affiliated members of the Association include four hundred twenty five individual members of the State Boards, of whom approximately thirty percent are public members.

The purpose of NABP is: 1) To provide for interstate reciprocity in pharmaceutical licensure in the United States based upon a minimum standard of education and legislation; and 2) to improve the standard of pharmaceutical education, licensure and practice by cooperating with the state, national and international agencies and associations having similar objectives.

The Association achieves its mission and goals as a facilitator by assisting state regulatory agencies in accomplishing their administrative responsibilities, particularly in regard to the reciprocity of licensure of pharmacists among the several states, and the examination of applicants for initial licensure in the profession of pharmacy. NABP produces the licensing examination known as NABPLEX used by the District of Columbia, Puerto Rico, the Virgin Islands and all states with the exception of California. It also produces a Federal Drug Law Examination used by several states, and supports the Foreign Pharmacy Graduate Examination Commission which prepares and administers an equivalency examination that is used to qualify foreign graduates for possible licensure. In addition, the Association disseminates disciplinary information on pharmacists' licenses that have been disciplined, assisting in identifying the peripatetic pharmacist law violator who moves from state to state.

The longstanding commitment of the Association to effective law enforcement and the protection of public health is evidenced by its history of cooperation with federal government agencies. The Association has served on numerous federal committees and task forces of the federal government and has acted as consultant to such agencies on many occasions. The Association answers hundreds of inquiries, written and oral, from law enforcement agencies, manufacturers, wholesalers, health professionals, hospital administrators and the public on labeling, product selection, etc. The FDA, DEA and other national associations refer many inquiries to NABP. NABP has, over the years, established a close working relationship with the Federal Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA). NABP, as the recognized representative of pharmacy regulators, enters such relationships to facilitate communications between the federal government agencies and the State Boards. This interaction of NABP and federal government agencies is an adjunct to enforcement of federal and state drug statutes.

An excellent example of cooperation is seen in National Association of Boards of Pharmacy Foundation's Bureau of Voluntary Compliance program where state newsletters are published and mailed to over 125,000 pharmacists four times yearly in an effort to keep the practitioner informed of the states' requirements for practice. FDA, DEA and the Consumer Product Safety Commission have input and provide copy for this national newsletter. Forty states now participate in this program which was initiated in 1979. NABP also has formal meeting agreements with both the FDA and the DEA to cooperate in solving state and federal enforcement policies of mutual concern to both state and federal agencies.

In reference to its role as a communicator to the public, NABP has, during the past year, called attention to the misuse and abuse of anabolic steroids, the hazards involved in the indiscriminate sale and use of veterinary legend drugs and provide information on the distribution of needles and syringes. NABP advocates the elimination of the current sampling procedures of manufacturers in the drug distribution system, and the Association has recommended clarification of definitions

concerning wholesalers and re-packers; the Association has also recommended the licensing of these entities as a means of providing greater control for the distribution of human and-veterinary legend drugs and devices. As a compliment to its MODEL PHARMACY ACT (1977) the Association is preparing model legislation and regulations for the registration of wholesalers and re-packers which, if adopted by its membership, will be recommended to the various state legislatures; it will also be made available to the Council on State Governments (CLEAR), as well as to the National Conference of Commissioners on Uniform State Laws.

It has been a longstanding belief of the Association that the education of its members is an important aspect of the services the Association provides because it fosters compliance with the law and more efficient law enforcement. The Association produces a Board Member Manual, conducts seminars at its annual and district meetings, as well as national schools and conferences all designed to make the individual board members and the board staff, consisting of administrative personnel, inspectors and attorneys more knowledgeable and efficient. As mentioned above, the Association has also produced a Model Pharmacy Practice Act which includes provisions for the licensing of various drug outlets including manufacturers, wholesalers and re-packers.

As can be seen by its purposes, the major goal of NABP is the protection of public health and welfare. The Association does not involve itself in the economics of the health care drug distribution system except where economic issues are inexorably entwined with practices that adversely affect public health and would subject a pharmacist to the disciplinary process. The Staff Report of the Subcommittee on Oversight and Investigations is replete with examples of this overlap between the economics and standards of conduct of the profession. It is from this context that many of the issues raised by the Subcommittee are discussed in this statement by NABP.

## II. ISSUES

The issues confronting the Subcommittee appear to be threefold:

1. Does drug diversion occur in the legitimate channels of distribution affecting the consumer?
2. For what reasons and at what points in commerce does such diversion occur?
3. What additional federal legislation, if any, is needed to prevent such diversion?



NABP's reactions to these issues are set forth in the following statement and in its answers to the questions propounded by the Subcommittee.

### III. STATEMENT

NABP has long been aware of the types of drug diversion outlined in the Staff Report to the Subcommittee and has spoken out against the abuses of this distribution system through its committees, its members and resolutions adopted from time to time by the Association. It has repeatedly taken forceful stands on the issues of sampling and counterfeit drugs, and has supported the institution of a system that would require manufacturers and wholesalers to identify the legitimacy of the companies and persons to whom they sell and ship drugs.

NABP has always advocated that drug diversion can be substantially reduced through the education of all persons involved in the chain of distribution and, in particular, the manufacturer, the distributor, the prescriber and the dispenser. Education fosters responsibility to one's self and ultimately to the consumer. This may require nothing more from the manufacturer, wholesaler or other distributor than the application of good ethical business practices.

The problem of drug diversion is not limited to manufacturers and wholesalers. It involves and, in as many instances, requires the cooperation of physicians, nurses, pharmacists and other health professionals. It reaches into hospitals, nursing homes and other institutions that house and distribute legend drugs. It thrives upon the uninformed professional.

Strong educational programs which begin in the health professional undergraduate degree programs, coupled with an ever-present surveillance and disciplinary system are needed. Somehow over the years, the health care professional has not been adequately informed about his responsibility in making the prescription distribution system secure, and that only those qualified to make decisions about the distribution of drugs are in strategic positions to do so. Adequate staffing and sufficient funds as well as the availability of informative continuing education should be put into place.

The cavalier attitudes of industry in an effort to secure brand name identity and public acceptance of their drugs has contributed to the problem. Through all of this, the FDA, DEA, and state boards of pharmacy have attempted to maintain the integrity of the drug distribution system, yet these law enforcement agencies together with their associations have been virtually ignored by the diagnostician in his passive belief that all is well or eventually will be corrected.

NABP does not contend that education is the "end all" in so far as drug diversion is concerned. Neither, however, is the continued adoption of patchwork legislation not geared to an even scheme of effective, cooperative law enforcement by federal and state authorities.

Several months ago NABP was asked to answer many questions posed by the FDA concerning federal/state relations. The questions were as follows: What are the problems confronting the FDA? What should be the FDA priorities? How can the states be more involved in decision making? How can we reduce unnecessary regulation? Is the FDA's educational program effective? Can we cooperate on model bills and codes? How can we reduce contaminants in food and animal feeds? Are there possibilities for contracts and voluntary agreements between the states and the federal government? Is the FDA/state communication system adequate?

One of the most important points raised by NABP was the fact that federal government agencies cannot, with limited budget and staff, be all things to all people. The responsibilities for enforcement of the Food, Drug and Cosmetic Act that cannot be adequately fulfilled by the administration should be shared with the states where legally feasible. Cooperative efforts of state and federal governmental agencies can be and, in fact on occasion have been, secured through contractual arrangements or memorandums of understanding to effectuate a more comprehensive enforcement system.

There should be no territorial or jurisdictional restrictions where the public's health is concerned. NABP suggested and the FDA concurs that there should be more contracts let by the federal government which deputize state health law officers to act appropriately in crisis situations when time is of the essence and legal mechanisms cannot be set in place quickly enough to deal with a specific problem. In general, federal government agencies cooperate with states by sharing information on investigations and audits of control substances, but the ability of the government to seek and utilize state inspection personnel who are trained and knowledgeable law enforcement personnel should be expanded. We need new ways to solve old problems.

In the view of NABP, much of the answer to drug diversion lies in a more vigorous law enforcement of existing federal and state legislation. Law enforcement at both the state and federal level is not curtailed by a lack of legislation but rather a lack of staff and funds to effectively carry out existing laws. A properly funded program involving state and federal cooperation would go a long way toward eliminating many of the problems discussed in the Staff Report to the Subcommittee.

There is a need for additional legislation to protect the consumer from diverted drugs that flow from the legitimate channels of distribution. NABP's ideas in this regard are more fully discussed in the answers to the Subcommittee's questions and in the conclusion of the Association.

## IV. QUESTIONS AND NABP ANSWERS

1. What should be done to prevent the misuse or abuse of physicians' samples? Should the issuance of samples by pharmaceutical company representatives be prescribed, replaced by a coupon system, or modified in some other way?

The position of NABP in regard to samples is clearly expressed in a resolution adopted by the Association membership at its 1985 Annual Meeting. Resolution 81-16 reads as follows:

WHEREAS, professional pharmacists of the several states are concerned with the inadequate storage and carrying conditions of medication samples by pharmaceutical manufacturer's sales representatives; and

WHEREAS, pharmacists of the several states are further concerned with the potential abuse factor of unsecured Prescription Legend Drugs and the potential for misstorage of these Prescription Legend Drugs by these manufacturer's sales representatives;

NOW, BE IT RESOLVED, by the National Association of Boards of Pharmacy that manufacturers be urged to discontinue the manufacturing and distribution of Prescription Legend Drug sample medication.

NABP takes the position that while the use of samples may be a strong marketing device for drug manufacturers, the opportunities that sampling provides for drug diversion and its consequential endangerment of public health far outweigh the economic benefits afforded to the manufacturers. Too many times samples are stored in garages, car trunks, basements or other places which afford opportunity for theft or storage conditions that affect the efficacy of the product. Too many times excess samples are thrown in the trash can and retrieved by children who know little or nothing about the dangers of these products. Too many times samples are diverted illicitly into the distribution system in an adulterated or misbranded form.

The purpose of the distribution of samples is basically to familiarize physicians, hospitals and other entities that work with drugs of the characteristics and uses of the product. These drugs have received FDA approval and can flow freely through the legitimate channels of distribution. It would appear that the drug manufacturers could release information on these products without the use of samples. No manufacturer would lose any competitive advantage if samples were barred and, in fact, such an action might well stimulate competition.

And, then, how do we effectuate a recall of samples when a specific batch shows contamination?

Short of banning the distribution of samples, the very least that should be required is that manufacturers, detail men and all recipients of samples be required to account for them by keeping sufficient records. Distributors and dispensers of samples should also be required to comply with the federal and state laws on record-keeping which are applicable to controlled substances. There should be total accountability. If necessary, legislation should be adopted which would require such a record-keeping process to avoid the diversion of samples and the endangerment of public health. The "laissez-faire" attitude of the manufacturer as it relates to the distribution of samples makes a mockery of the system of diagnosis, prescribing and dispensing.

The coupon alternative advocated by certain parties would not alleviate the problem. This system would further complicate, not simplify, the problem and lend itself to fraud. Why institute a new system that would create another administrative burden that can be easily eliminated by banning samples or applying the controlled substance requirements to their practice? If a coupon system would provide accountability it could be of some advantage.

2. What are the advantages and disadvantages that result from the reimportation of prescription drugs? Is the current system of inspection and control by the Food and Drug Administration adequate to prevent the entry of counterfeit, adulterated, misbranded, mislabeled, or subpotent pharmaceuticals? If the safety and efficacy of imported pharmaceuticals cannot be assured, should legislation be passed that bans reimports?

It is difficult to imagine under what circumstances reimportation of drugs, once exported from the United States, could be an advantage. If reasonable controls are not possible to assure safety and efficacy, reimports should be banned. This practice is generally engaged in in support of illicit schemes that result in price manipulation, but more importantly in possible endangerment of public health. The only legitimate instance for reimportation would involve the return to a manufacturer of excess quantities. This practice in and of itself should not create either a diversion or an adulteration problem.

The Staff Report by the Subcommittee on Oversight and Investigations clearly depicts the problems that can result from reimportation. Obviously, if conduct of this type is existent, the system of inspection and control exercised by the Food and Drug Administration over the entry of drugs into the United States must be inadequate, or the proper resources and staffing have not been provided to the FDA to permit it to carry out its functions. It is our understanding that present FDA regulation of reimports is only "paper control," and that the FDA relies on the exporter for that paperwork. If reimportation is to continue it is imperative that the inspection process of these drugs include batch testing or some other means of chemical analysis at various stages of their journey.

3. Under what circumstances does the resale of pharmaceuticals by for-profit and non-profit institutions violate the Robinson-Patman Act, civil or criminal fraud or other statutes? Is there such a thing as "ethical diversion" and how important are diverter/wholesalers to the operation of the distribution market for pharmaceuticals? What are the beneficial effects and harmful impacts on the market of diversion by wholesalers?

The resale of pharmaceuticals by for-profit outlets is, like all other products, subject to the Robinson-Patman Act. Where sales are in violation of the Act remedies of the Robinson-Patman Act will be applicable.

The resale of pharmaceuticals by non-profit institutions, however, has been the subject matter of two specific law suits decided by the Supreme Court of the United States. In Abbott Laboratories, et al. v. Portland Retail Druggists Association, Inc., 96 S.Ct. 1305 (1976), the court differentiated between the purchase of supplies by a hospital for its "own use," which would include dispensing pharmaceuticals to patients of the hospital and also to a patient on discharge for a limited and reasonable amount of time for personal use off the premises. Such sales would be exempt from the anti-trust laws. Refills and direct sales to consumers for use off the premises, however, may well be in violation of the proscriptions of the Robinson-Patman Act.

The concept of resale of pharmaceuticals by not-for-profit corporations to other drug outlets was limited in Jefferson County Pharmaceutical Association, Inc. v. Abbott Laboratories, 450 U.S. 150 74 L.Ed. 2d 882 103 S.Ct. 1011 (1983) in which the Supreme Court of the United States found that the sale of pharmaceutical products to state and local government hospitals for resale in competition with private pharmacies was not exempt from the provisions of the Robinson-Patman Act. The court found that such a practice created discriminatory prices in favor of not-for-profit hospitals and its purchasers, making such purchases and resale activity subject to Robinson-Patman claims.

It is not the purpose of this submission to discuss the legal aspects of the anti-trust laws in detail but merely to point out to the committee that, in the view of NABP, the purchase and resale of drugs, particularly by not-for-profit institutions, is and should be subject to the restrictions of the anti-trust laws.

The meaning of the word "diversion," when considered in a vacuum, is neutral. Webster's New World Dictionary refers to it as a diverting or turning aside or distraction of attention, or even a passtime. When used in terms of drug diversion however, at least as this term is understood by NABP, it connotes a movement in the channels of distribution of drugs which may result in adulterated, misbranded, or mislabeled drugs,

potentially endangering public health. Under the term as interpreted by NABP, it is difficult to understand how there could be an "ethical diversion" of pharmaceuticals. Drugs that are shipped in commerce for the ultimate purpose of dispensing the product under lawful conditions as provided by state law does not, in the eyes of NABP, involve diversion.

4. Is regulation and inspection by the FDA or state authorities adequate as regards the wholesale segment of the pharmaceutical market? If not, what changes in law, regulations, or practices are needed?

In 1985 the membership of NABP adopted Resolution No. 81-15 at its annual meeting pertaining to the regulation of wholesalers. This resolution reads as follows:

WHEREAS, the distribution of pharmaceuticals at the wholesaler or distributor level is unregulated in many states; and

WHEREAS, without a corresponding requirement for distributors or wholesalers, regulation of the manufacturer and dispenser fails to protect the public;

NOW, THEREFORE, BE IT RESOLVED, that NABP engage in a dialogue with the National Wholesale Druggists Association with a goal of returning to the 1986 Annual Meeting with Model Regulations for Boards of Pharmacy to apply to wholesalers or distributors of prescription drugs and devices.

NABP is convinced that appropriate regulation of wholesalers by state authorities will lessen the improper diversion of drugs if the staff and resources are made available to implement such regulations. If wholesalers are registered in the several states and made subject to periodic inspections and these inspections are carried out by competent personnel, the control of the distribution of drugs within and even outside that state may well be improved. Under any circumstances, the state will know where the wholesalers and re-packers are located and through the licensing process will be in a position to effectively regulate the wholesaler.

The FDA has the authority to inspect wholesalers but these inspections have a low priority with the agency, and therefore inspections are rare. Some states have regulatory authority concerning wholesalers, some do not. All states should have the right to license and inspect. Sufficient board staff is a problem for states also; a federal/state coordinated program should be developed.

There can be no doubt that the mere licensing of a wholesaler by state authorities in and of itself will be of little aid to prevent drug diversion, counterfeiting, adulteration, misbranding or mislabeling of products. The licensing of such an outlet, however, if properly implemented with meaningful inspections and coupled with requirements as to record-keeping, should be most effective.

Many of the states are presently investigating or have legislated programs whereby all drug outlets, including wholesalers located within or out of the state, are required to be licensed. The regulations that have been adopted to implement this legislation, when properly carried out, are geared to require all such outlets to have appropriate facilities and qualified personnel, and to deal with those persons who are in the legitimate channels of distribution of pharmaceuticals. This type of legislation can be most effective, again, if supported by proper resources.

5. Does enough accountability and control exist in the wholesale segment of the pharmaceutical market to enable wholesale and retail purchasers to identify the true source and actual movement of goods which they are offered? If not, what are the weak areas and what should be done to correct the problem? If each wholesaler were required to document the manufacturer and all subsequent purchasers or handlers of pharmaceuticals, would this provide an adequate degree of defense against potential counterfeit, adulterated or subpotent merchandise? Might this create enough liability such that the potential purchaser would take extra care in reviewing the quality and source of goods purchased in the diversion market?

It is the opinion of NABP that there is a legal system in place to assure accountability, but that there is inadequate enforcement of the system to provide practical assurance of complete product integrity. In every aspect of the distribution system each party should demand evidence that the supplier has complied with existing federal and state statutes. A reliable system of identifying and licensing reputable wholesalers and drug manufacturers should be initiated. These listings should be readily available to state agencies for surveillance and enforcement processes. It would encourage extra care in reviewing the quality and source of the drug. Wholesaler documentation of the manufacturer would not totally eradicate counterfeit, adulterated or subpotent products by itself, but such documentation could assist in identifying these drugs more quickly. A major deterrent to counterfeit, adulterated and subpotent drugs lies in the ability of the system to effectuate voluntary compliance of those health care professionals charged with the legal responsibility of distributing drugs. A good example of voluntary compliance is the instance of the pharmacist who called the FDA to alert them of the counterfeit Ovulen-21.

6. Would unit of use packaging mitigate against the distribution of outdated or adulterated pharmaceuticals? Should such a change in industry practice be mandated by law? What are the potential costs and benefits to consumers of such a change in industry practice?

Across the board use of unit of use packaging is not a solution in itself to the diversion problem. There is the ever-present problem of labeling. If the re-packer is free to adulterate, misbrand or use counterfeit materials, such a system would not eliminate many of the afore mentioned problems. If unit dose is adopted as a mandatory requirement the same violations of the law could exist unless more stringent controls are implemented over the re-packers. Flexibility in packaging is necessary to meet the pharmaceutical needs of the public.

7. What are the advantages and disadvantages of uniform pricing? Are there alternatives to the current multi-tiered pricing system which would provide comparable benefits to the truly eleemosynary institutions? What would be the impact of a government-mandated single price system on consumer prices, both those charged by non-profit institutions and for-profit pharmacies generally?

As a general premise nothing is free. In order for the manufacturer to maintain a profit structure the cost of differential pricing must be absorbed by the consumer somewhere along the distribution system. Government agencies generally pass on savings, while non-profit and now profit institutions often do not. In considering the total picture, the effect of a single price structure could result in a reduction in the average price of a prescription. Ideally this could be accomplished by voluntary actions of the manufacturer rather than by law.

NABP's basic purpose is directed toward a drug distribution system that affords the protection which prevents harm to the public. Neither NABP or its member boards involve themselves in the economic "pricing" issues of distribution. However when multi-tiered pricing, bidding systems or other marketing strategies result in or foster possible diversion and the introduction into commerce of adulterated, misbranded or counterfeit drugs, NABP would support the institution of controls necessary to protect the integrity of the drug.

8. Is state regulation of pharmacists sufficient to deter individuals from deliberately dealing in potentially adulterated or misbranded products? Should the Federal



government require the states to revoke the licenses of pharmacists who knowingly purchase or sell pharmaceuticals which do not meet FDA requirements?

All states have pharmacy practice acts which provide for the regulation and discipline of pharmacists. In order to practice pharmacy in any state, pharmacists must meet the statutory requirements and pass a licensure examination in order to receive the initial license to practice the profession. Thereafter, a pharmacist must maintain specific standards in his practice in order to maintain his license. These state statutes are broad enough in scope to permit the revocation or suspension of a pharmacist's license should he deal in potentially adulterated or misbranded products. A summarization of the many aspects of state law is set forth in the NABP Survey of Pharmacy Law, a copy of which is available for the Committee.

NABP doubts that the federal government could legally "require" the states to revoke the licenses of pharmacists who knowingly purchase or sell pharmaceuticals which do not meet FDA requirements. Most states presently have the power, under their pharmacy practice acts, to discipline a pharmacist for such activities as (1) unprofessional conduct, (2) any act involving moral turpitude and (3) violation of pharmacy and drug laws of the state or federal governments. If a state is advised of violations of the federal law, it can, under most practice acts, take disciplinary action which would include the suspension or revocation of the pharmacist's license.

The need for greater cooperative liaison between federal and state agencies is evident. Communication efforts by all sectors of the drug distribution community should be intensified. Disciplinary action of health regulatory boards needs to be more openly communicated and state agencies in the health care professions should form networks which would disseminate information to all health professionals responsible for diagnosis, prescribing and dispensing drugs and devices. Federal or state funds should be made available to assist in these cooperative information networks.

9. Should Medicare and Medicaid eligibility be automatically terminated for any hospital or other health care facility which is found to resell pharmaceuticals? Are there other sanctions available to the federal government which would be likely to deter such practices?

NABP members are not normally involved in economic questions involving Medicare and Medicaid except where pharmacists have engaged in fraud in these programs resulting in state disciplinary action against their

licenses. Certainly, however, there must be adequate penalties to prevent the obvious continuation of the diversion of pharmaceuticals to the detriment of the public health. If this can be fostered through the determination of eligibility for hospitals and other health facilities engaged in an improper resale of pharmaceuticals, such a penalty should be seriously considered. Eligibility should be terminated and should expand to those people using their medicare/medicaid benefits to divert drugs for profit.

## V. CONCLUSIONS

### NABP Supports:

1. Increased cooperative drug law enforcement efforts by state and federal agencies.
2. Increased funding for federal and state law enforcement agencies to permit meaningful enforcement of existing federal and state laws.
3. Elimination of samples by manufacturers or, as the alternative, making the record-keeping requirements of controlled substances applicable to all parties involved in the distribution or dispensing of samples to provide accountability.
4. The registration of all drug outlets including wholesalers and other distributors at the state level with appropriate funding to permit meaningful periodic inspections of the facilities.
5. Record-keeping requirements throughout the channels of drug distribution that require verification of the legitimacy of the drug distribution, the drug purchaser and the efficacy of the product.
6. Adequate penalties to cause compliance with existing laws and new legislation effectuating items 3, 4 and 5.
7. Renewed law enforcement efforts by state and federal officials.
8. Recognition that America's drug distribution system is the best in the world; that it's design is to protect the consumer; that it can be improved through public and professional education and state and federal cooperation.

Respectfully Submitted

NATIONAL ASSOCIATION OF  
BOARDS OF PHARMACY

By

*Fred T. Mahaffey*

Fred T. Mahaffey  
Executive Director

Mr. WYDEN. Mr. Kelley.

### TESTIMONY OF TY KELLEY

Mr. KELLEY. Thank you very much.

Mr. Chairman, on behalf of the National Association of Chain Drug Stores, we appreciate the opportunity to be a participant in these hearings. I will briefly go over some of the regulatory and legislative recommendations that we have in our statement, many of which have already been touched upon by some of the other organizations.

We feel our legislation recommendations and regulatory suggestions will help address some of many issues raised by the subcommittee pertaining to misuse of physician sampling, distribution, sale of expired, adulterated, misbranded, counterfeit, or improperly stored products, as well as problems associated with reimportation, and bogus charities schemes.

We strongly support greater enforcement and surveillance by FDA and U.S. Customs Service for all pharmaceutical products, either imported or brought into the United States, and we believe that these items out to be embargoed and tested to assure their safety.

Second, the National Association of Chain Drug Stores urges greater enforcements and prosecution by the Justice Department and FBI in all cases of counterfeit, misbranded, mislabeled, adulterated, pharmaceutical, and any other type of fraudulent activities involving prescription drug products.

Third, we call for clarification and revision to the Nonprofit Institutions Act. The scope of the statute must be narrowed back to where it originally was intended, to clarify and indicate that only bona-fide charitable institutions that are caring solely for indigent patients in the hospital setting may be permitted to purchase drugs at a discriminatory price.

Congress should also strictly define the term for their own use regarding prescription drugs purchased at the preferential price, so we can eliminate the abuses that are there in the marketplace. As an alternative to this need to revise the Nonprofit Institutions Act, we would like to propose the development and enactment into law of a proposal to require every nonprofit health care facility or charity desiring to purchase drugs at the discriminatory price to register, and submit detailed reports to the Food and Drug Administration.

Quite frankly, FDA has been charged with the mission of guaranteeing the safety and integrity and legitimacy of products, and this would fall right within their mission as a Federal agency. The registration reporting requirement would aid the Federal Government in verifying the nonprofit status and legitimacy of facilities and charities involved.

It would also assist pharmaceutical manufacturers in ascertaining which institutions or charities are eligible to purchase drugs at preferential prices. Our proposal would also establish standards of accountability, disclosure, and reporting that would allow the monitoring of drugs purchased at the preferential prices, to ensure that these levels are consistent with the quantities required to meet the needs of indigent patients being cared for within the facility.

We would like to have this proposal to feature strong penalty provisions to deter excessive purchasing abuses by hospitals, HMO's and nursing homes. The proposal could be entitled the National Nonprofit Health Care Institutions Registration and Reporting Act. We believe that the FTC needs to conduct a comprehensive investigation of the purchasing and resale practices of nonprofit institutions in order to determine and document the extent of the violations that are presently occurring under the Robinson-Patman Act.

We feel there has been lackadaisical enforcement by the FTC regarding anticompetitive activities by nonprofit institutions and that a full-fledged investigation is warranted at this time.

We further endorse and encourage enactment of the legislation granting the FTC specific authority over the commercial activities of nonprofit entities to go hand in hand in with our investigation.

Finally, we are inclined to very strongly favor a curtailment of all physician sampling to gain better control over the product that is in the system. We believe, in conclusion, that many of the problems related to diversion and abuses persisting under the Nonprofit Institutions Act require action by the Congress at this time. The problems can be eliminated by the implementation of our recommendations. It is also our belief that the regulatory system at both the Federal and the State level is more than adequate to police the marketplace, but it needs additional reemphasis, as indicated in our remarks.

In terms of unit of use, we take no position, but state to the subcommittee that a conversion to this system would be extremely costly. We believe that unit of use, if required by law, would provide little more than a false sense of security, in attempting to combat counterfeit drugs.

We say this with all sincerity, because as the subcommittee knows, the one documented case of a counterfeit product came in unit-of-use packaging.

This concludes my remarks.

Mr. WYDEN. Mr. Kelley, we thank you, and we will have some questions here very shortly.

[Testimony resumes on p. 450.]

[The prepared statement of Mr. Kelley follows:]

## STATEMENT OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.

INTRODUCTION

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE. MY NAME IS JAMES I. HARRISON, JR., AND I AM PRESIDENT OF HARCO DRUG, HEADQUARTERED IN NORTHPORT, ALABAMA, OPERATING 60 DRUG STORES WITH PHARMACIES AND 10 HOME HEALTH CARE CENTERS.

I AM ALSO CURRENTLY SERVING AS CHAIRMAN OF THE BOARD OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC., (NACDS). ACCOMPANYING ME IS ROBERT J. BOLGER, WHO IS PRESIDENT OF NACDS. AS CHAIRMAN OF THE BOARD OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, MY STATEMENT REFLECTS THE VIEWS OF 172 CORPORATIONS THAT ARE OPERATING IN EXCESS OF 18,000 RETAIL PHARMACIES IN THE UNITED STATES. COLLECTIVELY, THE CHAIN DRUG INDUSTRY IS RESPONSIBLE FOR APPROXIMATELY \$25 BILLION IN ANNUAL SALES AT THE RETAIL LEVEL. IN ADDITION, CORPORATE DRUG STORES ACCOUNT FOR NEARLY ONE-THIRD OF ALL OUT-PATIENT PRESCRIPTION DRUG NEEDS AND SERVICES.

ON BEHALF OF THE NACDS MEMBERSHIP, WE DEEPLY APPRECIATE THE OPPORTUNITY TO PARTICIPATE IN THESE HEARINGS. WE WOULD FURTHER LIKE TO COMMEND THE CHAIRMAN AND THE STAFF FOR THE FINE JOB THAT YOU HAVE BEEN DOING IN INVESTIGATING AND PUBLICLY DISCLOSING THE POTENTIAL DANGERS THAT CAN RESULT FROM COUNTERFEIT,

ADULTERATED AND MISLABELED MEDICATIONS. IN OUR VIEW, THE SUBCOMMITTEE'S INVESTIGATION AND HEARINGS ARE HELPING TO ENSURE THAT THE PROBLEMS POSED BY DIVERSION AND THE DISTRIBUTION OF UNSAFE PHARMACEUTICALS ARE RECEIVING CAREFUL ATTENTION BY THE CONGRESS AND THAT APPROPRIATE REMEDIES AND TIMELY SOLUTIONS CAN BE DEVELOPED TO ELIMINATE THESE PROBLEMS. IN THIS CONTEXT, IT IS OUR PURPOSE TO PRESENT WITH OUR TESTIMONY A NUMBER OF RECOMMENDATIONS THAT WE BELIEVE WILL WORK TO INSURE THE SAFETY, INTEGRITY AND EFFECTIVENESS OF PRESCRIPTION DRUG PRODUCTS IN THE COMPETITIVE MARKETPLACE.

IT IS INDEED FORTUNATE THAT INSTANCES OF COUNTERFEIT, CONTAMINATED OR MISLABELED DRUGS ACTUALLY REACHING CONSUMERS ARE VERY FEW. THIS IS BECAUSE THE PRESENT PHARMACEUTICAL DISTRIBUTION SYSTEM WORKS WELL AND EFFICIENTLY IN BRINGING SAFE, QUALITY PRESCRIPTION DRUGS TO THE AMERICAN CONSUMER. HOWEVER, AS THE SUBCOMMITTEE STAFF REPORT MAKES CLEAR, POTENTIAL PROBLEMS DO EXIST AND EVERYONE IN THE DISTRIBUTION SYSTEM, ESPECIALLY CONSUMERS, CAN BE VULNERABLE TO COUNTERFEIT, MISLABELED, MISBRANDED, ADULTERATED AND EXPIRED PHARMACEUTICALS. SUCH SITUATIONS HAVE BEEN THOROUGHLY DOCUMENTED BY THE STAFF REPORT AND FROM THE FBI INVESTIGATION IN ATLANTA.

#### THE PRIMARY PROBLEM - PREFERENTIAL PRICING

AS THE ULTIMATE PROVIDER OF THE FINAL PRODUCT TO THE CONSUMER,

OUR INDUSTRY SHARES THE CONCERNS THAT CHAIRMAN DINGELL AND OTHER SUBCOMMITTEE MEMBERS HAVE EXPRESSED WITH RESPECT TO GUARANTEEING THE LEGITIMACY AND INTEGRITY OF THE PRESCRIPTION DRUG PRODUCTS THAT OUR CORPORATE MEMBERS DISPENSE TO PATIENTS. WE FEEL THAT THE PROBLEMS AS IDENTIFIED BY THE SUBCOMMITTEE STAFF REPORT HAVE THE POTENTIAL TO ADVERSELY EFFECT THE CONFIDENCE AND PUBLIC TRUST THAT THE PHARMACY PROFESSION IS SO PROUD OF AND HAS WORKED SO HARD TO EARN. BECAUSE OF SEVERAL CONTRIBUTING FACTORS MAINLY DRIVEN BY ECONOMIC GAIN, WE BELIEVE THESE THREATENING SITUATIONS WILL PERSIST UNLESS CONGRESS ADDRESSES THE ISSUES WITH CORRECTIVE LEGISLATION.

I AM SPECIFICALLY REFERRING TO THE FOLLOWING:

- O "ILLEGAL" DRUG DIVERSION - A NATURAL RESULT DUE TO THE PROSPECTS FOR LARGE ECONOMIC GAIN.
- O A SYSTEM THAT ALLOWS "NOT-FOR-PROFIT" ENTITIES TO COMPETE IN THE RETAIL MARKETPLACE ARMED WITH THE ABILITY TO PURCHASE PHARMACEUTICALS AT AN ADVANTAGE OF SOME 60 PERCENT OR GREATER THAN DRUG STORES.
- O THE RESULTING EFFECT OF HIGHER PRICES TO THE GENERAL PUBLIC AND MEDICAID RECEIPIENTS AS WELL AS THE ELDERLY.  
IF YOU ARE A BRAND NAME COMPANY ENTRUSTED WITH THE

JOB OF MAINTAINING PROFITABILITY FOR YOUR STOCK HOLDERS, WHAT ALTERNATIVES DO YOU HAVE AS MORE AND MORE OF YOUR COMPANY'S PHARMACEUTICAL SALES GO INTO THE NON-PROFIT AREA OF DISTRIBUTION.

### BENEFITS OF ETHICAL PURCHASING

THE HEALTH AND SAFETY PROBLEMS THAT CAN ARISE FROM THE DISTRIBUTION OF COUNTERFEIT, MISBRANDED OR ADULTERATED DRUGS, SHOULD NOT BE CONFUSED WITH THE PURELY ECONOMIC ISSUES ATTENDANT UPON THE DISTRIBUTION OF PHARMACEUTICALS IN THE SO-CALLED "DIVERSION MARKET". THE CHAIN DRUG INDUSTRY STRONGLY OPPOSES ANY PRACTICE OR ACTIVITY THAT IS RELATED TO MISBRANDING, ADULTERATION OR COUNTERFEITING. HOWEVER, AS THE SUBCOMMITTEE STAFF REPORT RECOGNIZES, THERE IS AN ECONOMIC BENEFIT TO BE REALIZED FROM THE PROPER AND LEGAL OPERATION OF THE DIVERSION MARKET. ONE EXAMPLE WOULD BE WHERE THE PRIMARY MANUFACTURER OF A PRODUCT WOULD DECIDE, FOR PRUDENT REASONS, SUCH AS EXCESS INVENTORY OR A NEED TO CREATE A CASH INFLUX, TO SELL THEIR PRODUCT TO A DISTRIBUTOR AT SUBSTANTIAL SAVINGS. THE DISTRIBUTION IN TURN CAN BE MORE COMPETITIVE TO THE RETAILER AND THE RETAILER CAN PASS ALONG SOME OF THE SAVINGS TO THE CONSUMER. THIS IS ENTIRELY LEGAL, LAWFUL AND ALL PARTIES FROM THE MANUFACTURER, TO THE WHOLESALER, TO THE RETAILER, AND ULTIMATELY THE CONSUMER BENEFIT.



ON THE OTHER HAND, THERE ARE OTHER FORMS OF DIVERSION, THAT IN RECENT YEARS, HAVE COME TO MAKE UP A SIGNIFICANTLY GREATER PROPORTION OF THE SECONDARY MARKETPLACE. THIS SEGMENT OF THE DIVERSION MARKET IS GROWING AT AN ALARMING RATE AND IS FROUGHT WITH ILLEGALITIES, ABUSES AND EXCESSES, MANY OF WHICH THREATEN THE HEALTH AND SAFETY OF THE AMERICAN CONSUMER. ALL OF THESE ABUSES, INCLUDING THE MISUSE OF PHYSICIAN SAMPLES, DISTRIBUTION AND SALE OF EXPIRED, ADULTERATED, MISBRANDED, OR IMPROPERLY STORED PRODUCTS, PROBLEMS ASSOCIATED WITH FRAUDULENT EXPORTS AND IMPORTS AND BOGUS CHARITY SCHEMES MUST BE ELIMINATED.

WITH THE UNDERSTANDING THAT THE SUBCOMMITTEE IS THOROUGHLY FAMILIAR WITH THE FINDINGS OF THE STAFF REPORT AND THE PROBLEMS THAT HAVE BEEN IDENTIFIED AND DOCUMENTED, NACDS OFFERS THE FOLLOWING REGULATORY AND LEGISLATIVE RECOMMENDATIONS TO CORRECT THESE MATTERS:

1. WE STRONGLY RECOMMEND GREATER ENFORCEMENT AND SURVEILLANCE BY THE FOOD AND DRUG ADMINISTRATION (FDA) AND THE U. S. CUSTOMS SERVICE FOR ALL PHARMACEUTICAL PRODUCTS EITHER IMPORTED OR REIMPORTED INTO THE UNITED STATES. EACH ENTRY MUST BE EMBARGOED AND TESTED TO ASSURE THAT THE DRUGS ENTERING AND BEING DISTRIBUTED IN THE UNITED STATES ARE SAFE, POTENT AND PROPERLY LABELED. THIS ACTION WILL GREATLY ASSIST IN MINIMIZING

THE THREAT OF SUBSTANDARD COUNTERFEIT PHARMACEUTICALS COMING INTO OUR DISTRIBUTION SYSTEM AND ENTERING COMMERCE. NACDS UNDERSTANDS THAT FDA AND CUSTOMS HAVE ALREADY INITIATED THIS ACTION AND WE URGE THESE AGENCIES TO USE EXTREME VIGILANCE TO POLICE THE IMPORT-REIMPORT MARKET.

2. THE CHAIN DRUG INDUSTRY URGES GREATER ENFORCEMENT AND STRONGER PROSECUTION BY THE U. S. DEPARTMENT OF JUSTICE AND THE FBI IN ALL CASES OF COUNTERFEIT, MISBRANDED, MISLABELED, ADULTERATED PHARMACEUTICALS AND ANY OTHER TYPE OF FRAUDULENT ACTIVITIES INVOLVING PRESCRIPTION DRUG PRODUCTS.
3. NACDS CALLS FOR CLARIFICATION AND REVISION OF THE NONPROFIT INSTITUTIONS ACT. THE SCOPE OF THE STATUTE MUST BE NARROWED TO CLEARLY INDICATE THAT ONLY BONA FIDE CHARITABLE HOSPITALS THAT ARE CARING SOLELY FOR INDIGENT PATIENTS IN THE INSTITUTIONAL SETTING MAY BE PERMITTED TO PURCHASE DRUGS AT THE DISCRIMINATORY PRICE. CONGRESS MUST ALSO STRICTLY DEFINE THE TERM "FOR THEIR OWN USE" REGARDING PRESCRIPTION DRUGS PURCHASED AT PREFERENTIAL PRICES IF ABUSES IN THE MARKETPLACE ARE TO BE ELIMINATED.
4. AS AN ALTERNATIVE TO AMENDING THE NONPROFIT INSTITUTIONS

ACT, NACDS RECOMMENDS THE DEVELOPMENT AND ENACTMENT INTO LAW OF A PROPOSAL TO REQUIRE EVERY NON-PROFIT HEALTH CARE FACILITY OR CHARITY DESIRING TO PURCHASE DRUGS AT DISCRIMINATORY PRICES TO REGISTER AND SUBMIT DETAILED ANNUAL REPORTS TO THE FOOD AND DRUG ADMINISTRATION. THIS REGISTRATION AND REPORTING REQUIREMENT WOULD AID THE FEDERAL GOVERNMENT IN VERIFYING THE NON-PROFIT STATUS AND LEGITIMACY OF THE FACILITIES OR CHARITIES INVOLVED, IT WOULD ALSO ASSIST PHARMACEUTICAL MANUFACTURERS IN ASCERTAINING WHICH INSTITUTION OR CHARITY IS ELIGIBLE TO PURCHASE DRUGS AT PREFERENTIAL PRICES. THE PROPOSAL SHOULD ALSO ESTABLISH STANDARDS OF ACCOUNTABILITY, DISCLOSURE AND REPORTING THAT WOULD ALLOW THE MONITORING OF DRUGS PURCHASED AT PREFERENTIAL PRICES TO ENSURE THAT THESE LEVELS ARE CONSISTENT WITH THE QUANTITIES REQUIRED TO MEET THE NEEDS OF INDIGENT PATIENTS BEING CARED FOR WITHIN THE FACILITY. OUR PROPOSAL, WHICH SHOULD HAVE STRONG PENALTY PROVISIONS, COULD BE ENTITLED, "THE NATIONAL NONPROFIT HEALTH CARE INSTITUTIONS REGISTRATION AND REPORTING ACT."

5. THE CHAIN DRUG INDUSTRY URGES THE CONGRESS TO REQUIRE THE FEDERAL TRADE COMMISSION TO CONDUCT A COMPREHENSIVE INVESTIGATION OF THE PURCHASING AND RESALE PRACTICES

OF ALL NON-PROFIT INSTITUTIONS IN ORDER TO DETERMINE AND DOCUMENT, WHAT WE BELIEVE MAY BE EXTENSIVE VIOLATIONS UNDER THE ROBINSON-PATMAN ACT. NACDS IS OF THE OPINION THAT THERE HAS BEEN LACKADAISICAL ENFORCEMENT BY THE FTC REGARDING ANTI-COMPETITIVE ACTIVITY BY NON-PROFIT INSTITUTIONS AND THAT A FULL-FLEDGED INVESTIGATION OF THESE ABUSES IN RELATIONSHIP TO DIVERSION AND MISREPRESENTATION IN THE MARKETPLACE IS WARRANTED.

6. NACDS ENDORSES AND ENCOURAGES THE ENACTMENT OF LEGISLATION GRANTING THE FTC EXPLICIT AUTHORITY OVER THE COMMERCIAL ACTIVITIES OF NON-PROFIT ENTITIES. CURRENTLY, NON-PROFITS ARE OUTSIDE THE PURVIEW OF FTC JURISDICTION AND ENFORCEMENT, WHICH ALLOWS THEM TO ENGAGE IN UNFAIR, ANTI-COMPETITIVE ACTS AND PRACTICES FREE FROM CHALLENGE BY THE COMMISSION. ENACTMENT OF SUCH A LAW WOULD GIVE CLEAR DIRECTION TO THE FTC AND SHOULD GREATLY MINIMIZE THE POSSIBILITY OF ABUSES PRESENTLY OCCURRING UNDER THE NONPROFIT INSTITUTIONS ACT.
7. THE CHAIN DRUG INDUSTRY SUPPORTS CHANGES IN FEDERAL TAX LAWS RELATING TO NONPROFITS. UNRELATED BUSINESS INCOME OF A NON-PROFIT ENTITY AT THE VERY LEAST, SHOULD

BE TAXED AT THE SAME LEVEL THAT IS CURRENTLY LEVIED ON FOR-PROFIT CORPORATIONS. MANY NONPROFIT INSTITUTIONS ARE CLEARLY ENGAGED IN FOR-PROFIT BUSINESS ACTIVITIES, INCLUDING OPERATING RETAIL PHARMACIES, AND SHOULD BE SUBJECTED TO THE SAME TAX RATES ON THIS INCOME THAT CORPORATE DRUG STORES MUST PAY. FURTHERMORE, NACDS CALLS FOR GREATER DISCLOSURE TO THE IRS BY NON-PROFIT ENTITIES INCLUDING A COMPLETE BREAKDOWN OF ALL SUBSIDIARIES. IF AN INSTITUTION IS OPERATING FOR-PROFIT DEPARTMENTS OR COST-CENTERS, A SEPARATE SET OF RECORDS SHOULD BE MAINTAINED AND A MORE DETAILED REPORT FILED WITH IRS. BY THE SAME TOKEN TO COMPLIMENT THESE DISCLOSURES, SEPARATE INVENTORIES OF PRODUCTS REFLECTING THOSE PHARMACEUTICALS PURCHASED AT THE DISCRIMINATORY PRICE MUST BE MAINTAINED. SUCH A REQUIREMENT NEED NOT BE APPLIED TO CHURCHES, THE AMERICAN RED CROSS AND OTHER HIGHLY RESPECTED ORGANIZATIONS, BUT TAXING UNRELATED BUSINESS INCOME AND MANDATING FINANCIAL DISCLOSURES MUST BE APPLIED TO THOSE ENTITIES THAT ARE COMPETING UNFAIRLY AGAINST RETAIL PHARMACIES.

8. NACDS IS INCLINED TO STRONGLY FAVOR A CURTAILMENT OF ALL PHYSICIAN SAMPLING IN ORDER TO GAIN BETTER CONTROL OVER THE PRODUCT THAT IS IN THE SYSTEM,

HOWEVER, TO ALLOW CONSUMERS TO ENJOY THE BENEFIT OF A SAMPLE, WE SUPPORT AS AN ALTERNATIVE THE AVAILABILITY OF SAMPLING BY THE USE OF A COUPON OR COMPLIMENTARY PRESCRIPTION SYSTEM IN WHICH A PATIENT COULD RECEIVE A FREE "STARTER" PRESCRIPTION UPON THE PRESENTATION OF THE COUPON OR COMPLIMENTARY RX IN A RETAIL PHARMACY. THE DRUG STORE THEN WOULD BE DIRECTLY REIMBURSED BY THE MANUFACTURER FOR THE SAMPLE DISPENSED.

### CONCLUSION

TO CONCLUDE, WE BELIEVE THAT THE PROBLEMS RELATED TO ILLEGAL DIVERSION AND ABUSES PERSISTING UNDER THE NONPROFIT INSTITUTIONS ACT REQUIRE ACTION BY THE CONGRESS. WE SINCERELY BELIEVE THAT THESE PROBLEMS CAN BE VIRTUALLY ELIMINATED BY THE IMPLEMENTATION OF THE RECOMMENDATIONS THAT WE HAVE MADE TODAY. IT IS ALSO OUR BELIEF THAT THE REGULATORY SYSTEM AT BOTH THE FEDERAL AND STATE LEVEL IS MORE THAN ADEQUATE TO POLICE THE MARKETPLACE BUT NEEDS ADDITIONAL RE-EMPHASIS AS WE HAVE INDICATED IN OUR REMARKS.

IN TERMS OF UNIT-OF-USE, WE TAKE NO POSITION BUT STATE TO THE SUBCOMMITTEE THAT A CONVERSION TO SUCH A SYSTEM WOULD BE VERY COSTLY. FURTHERMORE, NACDS BELIEVES THAT UNIT-OF-USE WOULD PROVIDE LITTLE MORE THAN A FALSE SENSE OF SECURITY IN ATTEMPTING TO COMBAT COUNTERFEIT DRUGS. WE SAY THIS WITH ALL SINCERITY BECAUSE AS THE SUBCOMMITTEE KNOWS, THE OVULEN 21 BIRTH CONTROL PILLS CAME IN UNIT-OF-USE PACKAGING.

WE THANK THE CHAIRMAN AND THE SUBCOMMITTEE FOR YOUR CAREFUL CONSIDERATION OF OUR VIEWS.

Mr. WYDEN. Dr. West.

### TESTIMONY OF CHARLES M. WEST

Mr. WEST. We are pleased to appear before the subcommittee this morning and we appreciate this opportunity to bring NARD's proposals to you.

The investigation in general, and the specific matters noted by the subcommittee for discussion at today's hearing, raise numerous questions about present industry practices and appropriate roles for State and National Governments. The root of all these concerns is, in our view, clear; and, if effectively addressed, will very likely minimize or make decidedly secondary other reforms.

In our view, the principal incentive for the various illegal activities identified by the subcommittee is the industrywide practice by most pharmaceutical manufacturers of providing prescription drugs to institutional buyers, principally nonprofit entities, at prices radically below those available in the retail marketplace.

The discriminatory prices offered to such commercial nonprofits are not based on volume purchasing or frugal business practices. It is the availability of prescription drugs at such radically reduced cost or virtually no cost that entices most of the criminals identified by the subcommittee.

Without the benefit of price discrimination, a nonprofit institution would not buy in excess of its needs and illegally resell the surplus; without the benefit of price discrimination, companies or individuals would have little or no incentive to obtain pharmaceuticals from manufacturers through false or fraudulent pretenses. Without the benefit of price discrimination, what incentive would there be to reexport back to the United States pharmaceuticals produced in the United States and sold to foreign buyers? Without the benefit of price discrimination, no diversion black market would exist to facilitate the introduction into the drug distribution system of adulterated, counterfeit, and stolen prescription drugs.

Thus, in our view, drug diversion is inextricably linked to, and the product of, price discrimination. In general, it appears that such price discrimination is available through a perversion of a depression-era law that forgave price discrimination crimes which benefited charities.

For consumers, the price of subsidized prescription drugs and the resulting diversion is high. Who can put a price tag on the potential risk to their health and well-being? Additionally, consumers pay, in dollars, at least twice for such subsidized sales; first in increased taxes which subsidize commercial nonprofits; and second, in increased prescription drug prices due to cost shifting.

The variety of such illegal conspiracies is limited only by the creativity of the criminal minds. There is no such thing as ethical or good diversion.

To address the discriminatory pricing which is at the root of most of the problems the subcommittee has identified, NARD has the following recommendations: An amendment to the 1938 Nonprofit Institutions Act restating the original purpose of the act, which was to assist institutions supported by charity to aid indigents, not to establish a class of preferred competitors, albeit non-

profit competitors. Price discrimination to competitors, either for profit or nonprofit, is illegal. A joint congressional resolution would be a welcome complement to such an amendment. Legislation requiring the Federal Trade Commission to vigorously enforce the price discrimination sanctions of the Robinson-Patman Act in cases involving the resale of prescription drugs by commercial nonprofit entities.

Mandating an FTC report similar to that in the committee's bill, H.R. 2385, on predatory pricing practices would be helpful in this area of illegal conduct. Additionally, a specific set-aside of resources, both budgetary and personnel, to accomplish adequate enforcement appears necessary.

An amendment to the FTC Act which would clarify FTC jurisdiction in cases involving the commercial activities of nonprofit organizations including the selling of prescription drugs in direct competition with retail pharmacies.

A review of the Health Maintenance Organization Act to ensure that in providing incentives for nonprofit HMO's as a means to encourage competition with other forms of health care, Congress did not inadvertently provide nonprofit HMO's unfair competitive advantages over for-profit HMO's, for-profit hospitals, and other health care providers, including independent retail pharmacists. A review of H.R. 3739 which is a bill to protect consumers and certain retailers from unfair price discrimination in the sale by the manufacturer of designated products.

A comparable ban on unfair price discrimination in the sale of prescription drugs could provide an alternative means of eliminating price discrimination, except for charities.

The development by the subcommittee of a guide for consumers and pharmacists which would assist them in reporting illegal diversion activities to U.S. attorneys. A review by the subcommittee of efforts underway in the 99th Congress to amend the Racketeering Influenced and Corrupt Organizations Act, especially to determine their impact on prescription drug diversion cases involving wire and/or mail fraud.

Consideration of the establishment of Federal sanctions specifically for the resale of prescription drugs by nonprofit entities.

Consideration of an amendment to the Medicaid statute which would permit pharmacies to purchase prescription drugs for indigents covered under the program at the same prices presently extended to governmental and charitable entities.

Consideration of an amendment to the Medicare statute which would make ineligible any nonprofit entity convicted of the resale of prescription drugs.

Regarding additional issues raised by the subcommittee, we have the following comments:

The subcommittee's suggestion that a coupon system be explored in lieu of current physician sampling practices is a priority interest of NARD members.

From the evidence that the subcommittee has revealed, it appears that the current system of inspection and control to prevent entry of counterfeit, misbranded, mislabeled or subpotent pharmaceuticals is inadequate. If the safety and efficacy of such imports cannot be assured, it would seem reasonable to ban such imports.



More documentation as to the source of drug products could prove to be helpful as a deterrent to diversion. When diverted products are identified, why not destroy them as in the case of adulterated or misbranded products?

Additionally, making it illegal to knowingly possess diverted products would establish an additional deterrent and provide an alternative basis for forfeiture. If the product proves to be safe and efficacious, perhaps it would be provided to truly charitable organizations.

Unit-of-use packaging would increase the cost of prescription drugs to the consumer, would restrict the physician's right to prescribe and treat patients, and would do little to prevent distribution of outdated, adulterated, or counterfeit prescription drugs. After all, the counterfeit Ovulen 21 was in unit-of-use packaging.

In general, State laws regulating the practice of pharmacies are adequate. More vigorous enforcement in targeted cases such as the diversion of prescription drugs should be a high priority.

On behalf of the officers, executive committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to appear and to participate in the development of regulatory and legislative reform which will protect the consumer from the health consequences of drug diversion, and the economic consequences of predatory pricing and cost shifting resulting from subsidized sales to nonprofit entities.

[The prepared statement of Dr. West follows:]

Statement of Charles M. West  
Before the Oversight and Investigations Subcommittee  
Energy and Commerce Committee

December 6, 1985

Hearing on Prescription Drug Diversion

Mr. Chairman, Members of the Subcommittee\*:

I am Charles M. West of Alexandria, Virginia. I serve as the Executive Vice President of the National Association of Retail Druggists.

The National Association of Retail Druggists (NARD) represents owners of more than 30,000 independent pharmacies, where over 75,000 pharmacists dispense more than 70 percent of the nation's prescription drugs. Together, they serve 18 million persons daily and provide nearly 80 percent of the Medicaid pharmaceutical services. NARD has long been acknowledged as the sole advocate for the proprietary and professional interest of this vital component of the free enterprise system.

NARD members are primarily family businesses. They have roots in America's communities. The neighborhood independent druggist typifies the reliability, stability, yet adventuresomeness, that has made our country great.

We are pleased to appear before the Subcommittee, and we would like to express our special appreciation to the Subcommittee, its Chairman, and staff for undertaking the investigation of prescription drug diversion. The Subcommittee's endeavor has focused national attention on industry practices, principally price discrimination for nonprofit institutions and the havoc which such pricing practices have spawned, both in terms of unfair competition for the independent retail pharmacy and its customers, and the threat to consumer health and welfare posed by the risk of adulterated and substandard quality of diverted drugs.

\*Rep. John D. Dingell, (D-MI), Chairman

MAJORITY: Representatives Wyden, Eckart, Slattery, Sikorski, Scheuer, Florio, Luken, Bryant, Waxman, and Shelby.

MINORITY: Representatives Broyhill, Whittaker, Bliley, Oxley, Billirakis, Schaefer, and Eckert.

The staff report "Drug Diversion" released July 10th, and the four days of hearings held by the Subcommittee to date, have documented the extensive subterranean diversion market and the wide variety of illegal conduct which sustains this black market for prescription drugs. The variety of such illegal conspiracies is limited only by the creativity of criminal minds. There is no such thing as ethical or "good" diversion.<sup>1</sup>

The investigation in general, and the specific matters noted by the Subcommittee for discussion at today's hearing, raise numerous questions about present industry practices and appropriate roles for state and national governments. The root of all these concerns is, in our view, clear; and, if effectively addressed, will very likely minimize or make decidedly secondary, other reforms.

In our view, the principal incentive for the various illegal activities identified by the Subcommittee is the industry-wide practice by most pharmaceutical manufacturers of providing prescription drugs to institutional buyers, principally nonprofit entities, at prices radically below those available in the retail marketplace. The discriminatory prices offered to such commercial nonprofits are not based on volume purchasing or frugal business practices. Most manufacturers explain that their competitors leave them no choice but to provide drugs to commercial nonprofit organizations at such discriminatory prices. Although several companies have traditionally rejected this approach, it is encouraging that others this year have announced new pricing policies that would eliminate radical price discrimination.

It is the availability of prescription drugs at such radically reduced cost or virtually no cost that entices most of the criminals identified by the Subcommittee:

- without the benefit of price discrimination, a nonprofit institution would not buy in excess of its needs and illegally resell the surplus.
- without the benefit of price discrimination, companies or individuals would have little or no incentive to obtain pharmaceuticals from manufacturers through false or fraudulent pretenses.

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<sup>1</sup>"Pharmaceutical diversion involves a scheme wherein false and fraudulent representations are made, directly and indirectly, to drug manufacturers that pharmaceuticals are being purchased for use in hospitals, clinics, nursing homes, export and charities in order to obtain low purchase prices. The drugs so purchased are then 'diverted' from such use to resale at substantial profit for ultimate dispensing to consumers with prescriptions." Larry D. Thompson, United States Attorney, Northern District of Georgia, testimony before the Oversight Investigations Subcommittee on October 31, 1985, at page 3.

---without the benefit of price discrimination, what incentive would there be to re-export back to the United States pharmaceuticals produced in the U.S. and sold to foreign buyers?

---without the benefit of price discrimination, no diversion black market would exist to facilitate the introduction into the drug distribution system of adulterated, counterfeit, and stolen prescription drugs.

Thus, in our view, drug diversion is inextricably linked to, and the product of, price discrimination. In general, it appears that such price discrimination is available through a perversion of a depression-era law that forgave price discrimination crimes which benefited charities.

In 1936, Congress determined that large sellers and buyers in the drug and grocery marketplace were exercising substantial buying power in a way that discriminated against small buyers. Congress enacted the Robinson-Patman Act to make it unlawful for a seller to sell to a customer who would, in turn, resell in competition with another customer at a discriminatory price.

In 1938, Congress passed an exemption to the Robinson-Patman Act to address a concern that charitable institutions -- who had previously obtained goods from sellers at lower prices because they were used for eleemosynary or charitable purposes -- would not be able to do so as a result of the passage of the Act. These institutions, typified by almshouses or pauper hospitals, were supported by subscription and were making their services available to people who could not pay for the services. Today, nonprofits that are engaging in commercial activities with for-profit firms that pay Federal, state, and local taxes for the privilege of doing business, claim the protection of that exemption. That claim flies in the face of the purpose of the exemption and their method of operation. Few, if any patients, receive free care from such organizations. In order to obtain care from them, you must be a paying member, or be covered by Medicare or Medicaid. To call Kaiser, for example, a charity, is to abuse the term.

The recent decision in the ninth circuit, in which an appeals court upheld the argument by the Kaiser Foundation Health Plan that its HMO was exempt from Robinson-Patman under the Nonprofit Institutions Act, emphasizes the need for a restatement and vigorous enforcement of the original purpose of the 1938 Act.

For consumers, the price of subsidized prescription drugs and the resulting diversion is high. Who can put a price tag on the potential risk to their health and wellbeing? Additionally, consumers pay, in dollars, at least twice for such subsidized sales - first, in increased taxes which subsidize commercial nonprofits; and, secondly, in increased prescription drug prices due to cost shifting.

To address the discriminatory pricing which is at the root of most of the problems the Subcommittee has identified, NARD has the following recommendations:

- A) An amendment to the 1938 Nonprofit Institutions Act restating the original purpose of the Act, which was to assist institutions supported by charity to aid indigents, not to establish a class of preferred competitors, albeit commercial nonprofit competitors. Price discrimination to competitors, either for-profit or nonprofit, is illegal.

A joint congressional resolution would be a welcome complement to such an amendment.

- B) Legislation requiring the Federal Trade Commission to vigorously enforce the price discrimination sanctions of the Robinson-Patman Act in cases involving the resale of prescription drugs by commercial nonprofit entities. Mandating an FTC report similar to that in the Committee's Bill H.R.2385 on predatory pricing practices would be helpful in this area of illegal conduct. Additionally, a specific set-aside of resources, both budgetary and personnel, to accomplish adequate enforcement appears necessary. For the past 3 years, NARD has repeatedly urged the FTC to act in such cases. As recently as April of this year, we renewed our efforts. In that instance, we brought to the attention of the Commission the activities of a broker in California who was promoting a program in which nonprofit hospitals were requested to increase their pharmaceutical purchase orders under special hospital prices and then divert them in violation of the own-use standard, to the broker. The broker agreed to pay the hospital a percentage of the purchase price plus other methods of compensation. Interestingly, the hospital was warned not to increase its purchases too dramatically, so as to alert the manufacturer to the diversion. To this and numerous other submissions, the FTC has indicated little or no interest.
- C) An amendment to the FTC Act which would clarify FTC jurisdiction in cases involving the commercial activities of nonprofit organizations including the selling of prescription drugs in direct competition with retail pharmacies.
- D) A review of the Health Maintenance Organization Act to assure that in providing incentives for nonprofit HMO's as a means to encourage competition with other forms of health care, Congress did not inadvertently provide nonprofit HMO's unfair competitive advantages over for-profit HMO's, for-profit hospitals, and other health care providers, including independent retail pharmacists.

- E) A review of H.R.3739 which is a bill to protect consumers and certain retailers from unfair price discrimination in the sale by the manufacturer of designated products. A comparable ban on unfair price discrimination in the sale of prescription drugs could provide an alternative means of eliminating price discrimination, except for charities.
- F) The development by the Subcommittee of a guide for consumers and pharmacists which would assist them in reporting illegal diversion activities to United States Attorneys. Such a guide could include the nature and elements of the various offences, the type of evidence required for prosecutions, and an outline of steps to take once a person has become aware for example of prescription drugs for sale that are labeled "For Hospital Use Only".
- G) A review by the Subcommittee of efforts underway in the 99th Congress to amend the Racketeering Influenced and Corrupt Organizations Act, especially to determine their impact on prescription drug diversion cases involving wire and/or mail fraud.
- H) Consideration of the establishment of Federal sanctions specifically for the resale of prescription drugs by nonprofit entities. Both the civil and criminal sanctions should be adequate to deter this very lucrative conduct.
- I) Consideration of an amendment to the Medicaid statute which would permit pharmacies to purchase prescription drugs for indigents covered under the program at the same prices presently extended to governmental and charitable entities.
- J) Consideration of an amendment to the Medicare Statute which would make ineligible any nonprofit entity convicted of the resale of prescription drugs.

Regarding additional issues raised by the Subcommittee, we have the following comments:

- A) Physician Samples - The Subcommittee's suggestion that a coupon system be explored in lieu of current physician sampling practices is a priority interest of NARD members.
- B) Imports - From the evidence that the Subcommittee has revealed, it appears that the current system of inspection and control to prevent entry of counterfeit, misbranded, mislabeled, or subpotent pharmaceuticals is inadequate. If the safety and efficacy of such imports cannot be assured, it would seem reasonable to ban such imports.

- C) Wholesalers - Wholesalers are important to the operation of the distribution market for pharmaceuticals. A majority of the products acquired by retailers is obtained through wholesalers. We have no evidence that diversion has any beneficial impact on the market. The loss of control involved in diversion is not consistent with good public policy.

More documentation as to the source of drug products could prove to be helpful as a deterrent to diversion. When diverted products are identified, why not destroy them as in the case of adulterated or misbranded products? Additionally, making it illegal to knowingly possess diverted products would establish an additional deterrent and provide an alternative basis for forfeiture. If the product proves to be safe and efficacious, perhaps it could be provided to truly charitable organizations.

- D) Unit of Use - Unit of use packaging would increase the cost of prescription drugs to the consumer; would restrict the physician's right to prescribe and treat patients; and would do little to prevent distribution of outdated, adulterated, or counterfeit prescription drugs. After all, the counterfeit Ovulen 21 was in unit of use packaging.
- E) State Regulation - In general, state laws regulating the practice of pharmacy are adequate. More vigorous enforcement in targeted cases such as the diversion of prescription drugs should be a high priority.

On behalf of the Officers, Executive Committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to appear and to participate in the development of regulatory and legislative reform which will protect the consumer from the health consequences of drug diversion, and the economic consequences of predatory pricing and cost shifting resulting from subsidized sales to nonprofit entities.

Mr. WYDEN. Dr. Streck.

### TESTIMONY OF RONALD J. STRECK

Mr. STRECK. You and the members of the subcommittee should be applauded of the insight you have shown in your investigations on drug diversion.

We are concerned, however, that these investigations and hearings, as well as the grand jury investigation in Atlanta and coverage by the media, have created a misunderstanding of the entire drug distribution system by lumping diverters, secondary suppliers, and full-service drug wholesalers into the same category of "wholesaler."

Articles such as the one found in the December 2, 1985, issue of U.S. News & World Report and the December 9, 1985, issue of Newsweek, only serve to reinforce this misunderstanding.

As we describe in this testimony, full-service drug wholesalers perform an array of value-added services that are essential to the operating efficiency of retail and hospital pharmacies today. Secondary suppliers perform one function, that is to obtain a product at a low price and resell it. The many methods used by secondary-source suppliers legally to obtain drug products for resale to buyers, including many full-service drug wholesalers, should not be confused with illegal drug diversion.

The term "diverter" has become associated with the illegal procurement of drug products that are then resold into the distribution chain.

In our testimony today, we intend to make three basic points. First, the wide array of significant preferential prices has created a market which encourages secondary-source buying and selling. Second, this market climate has been abused by unlawful diverters engaged in illegal conduct. Third, we will suggest some solutions to unlawful drug diversion.

Some contend that if a buyer purchases a drug product from a secondary source at a price lower than the manufacturer's direct price, the buyer should know the product was obtained illegally. We do not agree. Market conditions in some regions of the country have persuaded some drug wholesalers to purchase part of their drug inventory from secondary sources at prices often below the manufacturer's direct price.

Below are a few examples where secondary-source suppliers may, in our opinion, legally purchase drug products and then resell to buyers: Forward buying in anticipation of price increases; forward buying on promotions; manufacturers' overruns; geographic price differences; manufacturers' price reductions prior to new package introductions or new and improved product introductions; closeouts of retailers, wholesalers, or manufacturers; and meeting competition.

Unlawful diversion includes sales, purchases and conveyances of drug products through fraud or violation of the Robinson-Patman Act and sales, purchases and conveyances of adulterated and misbranded drug products. The wide array of significant preferential prices offered by many manufacturers to nonprofit hospitals and institutions; Federal, State, and local governments; for-profit hospi-



tals and institutions; HMO's; physicians; clinics; retail pharmacy buying groups; and numerous other trade classes has created secondary-source buying and selling.

We believe that this is also the root cause for illegal drug diversion. As long as the wide array of significant preferential prices are offered by manufacturers, drug diverters will continue to thrive.

Sampling: Physician's samples should be limited to promotion of new products for a limited period of time. The use of a coupon or complimentary prescription system in which a patient may receive a free introductory prescription upon the presentation of the coupon or complimentary prescription in a retail pharmacy makes sense.

Such a complimentary prescription would eliminate opportunities for diverters to use samples in the diversion market. We believe this action will help minimize the threat of misbranded, adulterated and counterfeit pharmaceuticals entering the United States.

With regard to the Robinson-Patman Act, a more rigorous enforcement of the Robinson-Patman Act, especially with regard to the three defenses that will justify a prima facie illegal price discrimination—that is, the cost justification defense, the changing conditions defense and the good faith meeting competition defense—would, in our opinion, significantly reduce chaotic preferential pricing.

A review of the first 50 defendants involved in the Atlanta grand jury investigation does not indicate that any further regulatory requirements would have prevented the illegal activity. It is doubtful that those involved in adulterating and misbranding products would register and seek a State license in order to continue their purchase and sale of illegal drugs.

NWDA believes that inadequate information is available concerning additional storage space requirements, increased packaging costs and handling costs for unit-of-use packaging.

From a practical point, counterfeit tablets or capsules in unit-of-use packages would only be seen by the patient. This would seem to contribute to the ease with which counterfeits could enter the marketplace.

Let me say in closing that we strongly support the efforts of the subcommittee to eradicate the abuses which threaten the confidence of the American public in this Nation's drug distribution system. The integrity of drug distribution has long been a strength of our country's health care system, and we pledge you NWDA's total assistance to see that it is maintained.

[Testimony resumes on p. 472.]

[The prepared statement of Mr. Streck follows:]

## STATEMENT OF THE NATIONAL WHOLESALE DRUGGISTS' ASSOCIATION

Mr. Chairman and members of the Subcommittee, my name is Ronald J. Streck, and I am Vice President of Government Affairs for the National Wholesale Druggists' Association (NWDA). The importance of the subject matter you are covering today--diversion of drug products--cannot be overemphasized. For decades the drug distribution system in this country has been considered one of the safest and most effective in the world. Never before has the safety of over-the-counter and prescription drug products been at question. However, your hearings this year have shown that the distribution system by which products ultimately reach the consumer is now being threatened by the drug diversion market.

You and the members of this Subcommittee, as well as the staff, should be applauded for the insight you have shown in your investigation of "drug diversion". We are certain that the subcommittee's investigation has already helped the pharmaceutical industry become far more aware of the problems posed by diversion. In fact, we have already seen companies in all of the various segments of the industry taking steps to assure the safety, integrity and effectiveness of their products.

We are concerned, however, that these investigations and hearings, as well as the Grand Jury investigation in Atlanta and

coverage by the media, have created a misunderstanding of the entire drug distribution system by lumping diverters, secondary suppliers, and full-service drug wholesalers into the same category of "wholesaler." Articles such as the one found in the December 2, 1985 issue of U.S. News and World Report and the December 9, 1985 issue of Newsweek, only serve to reinforce this misunderstanding.

As I will describe later in this testimony, full-service drug wholesalers perform an array of value-added services that are essential to the operating efficiency of retail and hospital pharmacies today. Secondary suppliers perform one function -- that is to obtain a product at a low price and resell it. The many methods used by secondary-source suppliers legally to obtain drug products for resale to buyers, including many full-service drug wholesalers, should not be confused with illegal drug diversion.

The term "diverter" has become associated with the illegal procurement of drug products that are then resold into the distribution chain.

In our testimony today, we intend to make three basic points. First, the wide array of significant preferential prices has created a market which encourages secondary-source buying and selling. Second, this market climate has been abused by unlawful diverters engaged in illegal conduct. Third, we will suggest some solutions to unlawful drug diversion.

INTRODUCTION

The National Wholesale Druggists' Association (NWDA) is the national trade association of full-service drug wholesalers. Its membership of more than 324 distribution centers represents 100 U. S. drug wholesale corporations responsible for more than 90 percent of U.S. drug wholesale sales. In addition, more than 250 manufacturers of pharmaceuticals, over-the-counter drugs and health and beauty aids are affiliated with NWDA as associate members. Of the \$12.5 billion in sales by full-service drug wholesalers for 1984, \$11.65 billion were sold by NWDA members.

NWDA member wholesalers are the primary authorized distributors for pharmaceutical manufacturers and other suppliers. They inventory and distribute only sealed stock bottles or other original packaging with complete labeling, lot number and expiration dates. They are required to meet all Drug Enforcement Administration (DEA) standards pertaining to records, reports and security. They are full-service suppliers to retail and hospital pharmacies principally. The many value-added services they supply to their customers distinguish them from the low price only or below market price only strategy of other middlemen frequently referred to as secondary suppliers and diverters -- sometimes incorrectly referred to as wholesalers. Value-added services make drug products available at the right place, the right time and in the right quantities.

NWDA full-service drug wholesalers go to great lengths to protect their customers and the public through proper regard for storage conditions, temperature, cleanliness and orderliness, inventory control, dating observation, returns handling, pilferage and theft prevention, frequency of delivery, local availability of supply in "as needed" quantities, and ability to perform drug product recalls.

NWDA full-service drug wholesaler members provide other marketing functions including financing in the form of trade credit, price and shelf stickers, product movement reports, electronic-order entry, retail accounting services, store layout and design, planogramming for over-the-counter products and health and beauty aids, cooperative advertising programs and gift shows, third-party processing of prescription claims, and pharmacy computer systems. Full-service drug wholesalers provide high service levels on up to 24,000 different products to assure their pharmacy customers readily available product.

#### I. SECONDARY SOURCE PURCHASING

Some contend that if a buyer purchases a drug product from a secondary source at a price lower than the manufacturer's direct price, the buyer should know the product was obtained illegally.

We do not agree. Market conditions in some regions of the country have persuaded some drug wholesalers to purchase part of

their drug inventory from secondary sources at prices often below the manufacturer's direct price. Below are a few examples where secondary source suppliers may, in our opinion, legally purchase drug products and then resell to buyers:

FORWARD BUYING IN ANTICIPATION OF PRICE INCREASES

Many secondary-source suppliers concentrate on buying drug products directly from manufacturers in anticipation of product price increases. Either product lines or individual items may be purchased in anticipation of price increases by a manufacturer. The secondary supplier, if correct in its anticipation of price increases, will then have products available for resale to full-service drug wholesalers, chains and others at prices lower than those offered by the manufacturer.

FORWARD BUYING ON PROMOTIONS

From time to time, manufacturers offer drug products at significant promotional discounts for short periods of time. Secondary suppliers will often buy large quantities during these promotional periods at significant savings. When the manufacturer's promotion ends, secondary suppliers will offer products at substantial discounts below the manufacturer's current price.

MANUFACTURERS' OVERRUNS

For a variety of reasons, manufacturers may have excessive quantities of particular drug products. As a result, they will often sell these overruns directly to a secondary source of supply at a substantial discount for resale to full-service drug wholesalers, chains, etc.

GEOGRAPHIC PRICE DIFFERENCES

Secondary suppliers may purchase goods in areas where the manufacturer/labeler is offering special allowances or deals. The secondary supplier subsequently resells the goods in an area where such special allowances or deals are not being offered.

MANUFACTURERS' PRICE REDUCTIONS PRIOR TO NEW PACKAGE INTRODUCTIONS OR NEW AND IMPROVED PRODUCT INTRODUCTIONS

Manufacturers may wish to change the packaging or the form of some of their drug products. Rather than destroy good product in old packaging, manufacturers may wish to sell the old packaged products at price reductions to encourage the purchase and speedy resale of its old packages.

CLOSEOUTS OF RETAILERS, WHOLESALERS, OR MANUFACTURERS

Drug products held in inventory by retailers, full-service drug wholesalers or others who are discontinuing their businesses are often resold to other retailers, full-service drug wholesalers, or institutions rather than returned for credit.

MEETING COMPETITION

The Robinson-Patman Act contains a good faith meeting competition defense that will "justify" a price discrimination. Secondary sources often obtain products in competitive bidding situations or from others, purchasing at lower prices because of competitive offers. Secondary sources are able to resell these products at prices below the manufacturer's current price.

## II. UNLAWFUL DIVERSION

Unlawful diversion includes sales, purchases and conveyances of drug products through fraud or violation of the Robinson-Patman Act and sales, purchases and conveyances of adulterated and misbranded drug products.

## III. PREFERENTIAL PRICING

The wide array of significant preferential prices offered by many manufacturers to non-profit hospitals and institutions; federal, state, and local governments; for-profit hospitals and institutions; HMO's; physicians; clinics; retail pharmacy buying groups; and numerous other trade classes has created secondary-source buying and selling. We believe that this is also the root cause for illegal drug diversion. As long as the wide array of significant preferential prices are offered by manufacturers, drug diverters will continue to thrive.



Our members, full-service wholesalers, who offer a vast array of value-added services to their customers have been forced to buy drug products and other merchandise from secondary sources in order to remain competitive.

Some manufacturers, as you have heard from witnesses at previous hearings, have made great efforts to reduce preferential pricing of their products and to insure that their products remain outside the diversion market. We applaud their efforts.

#### IV. SAMPLING

Physician's samples should be limited to promotion of new products for a limited period of time. Only reasonable quantities necessary to sample patients should be permitted. The use of a coupon or complimentary prescription system in which a patient may receive a free introductory prescription upon the presentation of the coupon or complimentary prescription in a retail pharmacy makes sense. Such a complimentary prescription would eliminate opportunities for diverters to use samples in the diversion market.

#### V. IMPORT/EXPORT

NWDA understands that the Food and Drug Administration (FDA) and the U.S. Customs Service have initiated greater enforcement and surveillance for all pharmaceutical products either imported or reimported into the United States. We believe this action will help minimize the threat of misbranded, adulterated and counterfeit pharmaceuticals entering the United States distribution system. These programs should be continued.

Manufacturers can drastically reduce the demand for products they have shipped to foreign countries by simply marking the trade dress package in the official language of the foreign country to which the product is being shipped. Labels could be of a different color and could be marked "For Export Only."

#### VI. ROBINSON-PATMAN ACT

In 1967 and 1969, the House Select Committee on Small Business held extensive hearings addressing the lack of enforcement of the Robinson-Patman Act and the resulting damage to retail druggists. Enforcement of the Robinson-Patman Act, in our opinion, has not improved. A more rigorous enforcement of the Robinson-Patman Act, especially with regard to the three defenses that will "justify" a prima facie illegal price discrimination (i.e. the cost justification defense the changing conditions defense and the good faith meeting competition defense) would, in our opinion, significantly reduce chaotic preferential pricing. Any reduction in preferential pricing would reduce drug diversion.

NWDA urges strong FTC enforcement of the Robinson-Patman Act.

#### VII. ADDITIONAL STATE/FEDERAL REGULATION

A review of the first 50 defendants involved in the Atlanta Grand Jury investigation does not indicate that any further regulatory requirements would have prevented the illegal activity. It is doubtful that those involved in adulterating and misbranding products would register and seek a

state license in order to continue their purchase and sale of illegal drugs. Undercover operations such as the "pharmoney" operation in Atlanta plus the enforcement of existing laws and regulations would certainly act as a deterrent to any individual or firm considering diversion. Prescription drug products are presently regulated by the FDA as well as state boards of pharmacy. Any illegal activity with regard to those products may lead to seizure of the products as well as prosecution of those adulterating and misbranding or counterfeiting drug products.

#### VIII. UNIT OF USE PACKAGING

NWDA believes that inadequate information is available concerning additional storage space requirements, increased packaging costs and handling costs for unit-of-use packaging. We believe that the competitive marketplace is the appropriate laboratory for testing the utility acceptance and cost effectiveness of the unit-of-use concept. At this stage of development, federally mandated packaging specifications would seem premature.

From a practical point, counterfeit tablets or capsules in unit-of-use packages would only be seen by the patient. The pharmacist would never have an opportunity to visually inspect the final dosage form. This would seem to contribute to the ease with which counterfeits could enter the marketplace.

CONCLUSION

As a result of the investigations and hearings of the House Commerce Subcommittee on Oversight and Investigations, an illegal "drug diversion market" has been identified. The wide array of significant preferential prices offered by many manufacturers to numerous non-profit as well as for-profit trade classes has created conditions conducive to secondary-source buying and selling. There are many ways in which secondary-source suppliers may legally obtain drug products for resale to their customers.

The environment which encourages secondary-source buying has been abused by unlawful diverters engaged in illegal conduct. As long as this wide array of significant preferential prices is offered by many manufacturers, unlawful drug diversion will thrive.

Limiting samples to a coupon or complimentary prescription system would help eliminate opportunities for drug diversion. Programs already initiated by FDA and the U. S. Customs Service to more closely scrutinize drug products imported or reimported into the United States will do likewise.

We are convinced that vigorous FTC enforcement of the Robinson-Patman Act would significantly reduce preferential pricing. When this occurs, illegal drug diversion will also be reduced.

Active enforcement of state and federal regulations will help prevent drug diversion. Additional state and federal regulations are not needed.

Unit-of-use packaging has not been properly tested for acceptance and cost effectiveness. In fact, it is possible that unit-of-use packages might actually contribute to the ease with which counterfeit products enter the marketplace.

Let me say in closing that we strongly support the efforts of the Subcommittee to eradicate the abuses which threaten the confidence of the American public in this nation's drug distribution system. The integrity of drug distribution has long been a strength of our country's health care system, and we pledge you NWDA's total assistance to see that it is maintained.

Mr. WYDEN. Mr. Brennan.

#### TESTIMONY OF BRUCE J. BRENNAN

Mr. BRENNAN. Thank you, Mr. Chairman.

On behalf of PMA, we welcome the subcommittee's investigation into drug diversion issues, and the research-based pharmaceutical industry pledges its full cooperation in working to ensure that pharmaceutical products are dispensed to the public in the safest possible manner. Let me first note something which we term as manufacturer-dispensed packages and what the chairman, in his letter to us, indicated as unit-of-use packaging.

PMA's board of directors, in a meeting 2 days ago, again discussed the issues of drug diversion at length, and our board shares the subcommittee's concern about this important problem.

The Board at that time 2 days ago stated very emphatically that it believes that a number of the diversion problems uncovered by the subcommittee's investigation may well be overcome by the use of packages prepared by manufacturers to be dispensed directly to patients. Although this approach ultimately may not prove to be feasible or desirable, the board believes it warrants expedited study as a potential solution to a troubling problem.

Accordingly, PMA's board directed that pharmaceutical industry senior managers, scientists and manufacturing control specialists, in cooperation with pharmacy and medical groups, complete an ongoing study of manufacturer-dispensed packaging in time for the board to act on this issue at its next meeting on February 12, 1986. At that time, we will immediately convey the Board's conclusions to the subcommittee.

We believe the results of our study will be useful to any Member of Congress who may be preparing legislation. We offer PMA's assistance and cooperation in developing legislation intended to strengthen the drug delivery system. I must say that in conjunction with us in pursuance of this study, the American Pharmaceutical Association has agreed to assist, as well as the AMA.

The subcommittee's investigation was initiated because more than 2 million counterfeit birth control pills were imported into the United States from Panama as "American Goods Returned."

In general, PMA sees no benefit to permitting exported pharmaceuticals back into the country. Only in very rare cases would PMA companies seek to import a previously exported product.

We fully support increased surveillance by Food and Drug Administration and Customs officials of pharmaceutical products that are being returned. Further, it is essential to promptly notify the U.S. manufacturer, whose product allegedly is being imported, prior to its release by Customs. Shipping documentation also should be made available to the manufacturer.

This would enable the company to work with FDA and Customs officials in verifying the authenticity of the shipment by checking lot numbers and expiration dates. Through this process, the U.S. manufacturer can become an effective partner with FDA and Customs in ensuring that only legitimate products are returned.

An improved system for checking pharmaceutical imports at our borders should effectively reduce, and hopefully eliminate, improper international trafficking, particularly if manufacturers are able to work with Customs and FDA officials.

Many pharmaceutical companies provide health practitioners with samples, particularly of newly-introduced products, in response to requests. Samples enable a physician to begin immediately to evaluate the effect of a prescription product in a patient, and to identify early any side effects. If a drug is not working as intended or is not tolerated, the medication can be modified without expense to the patient. Samples also enable physicians to initiate immediate therapy in cases of severe pain or infection. And samples help defray drug costs, which is particularly important to low-income patients.

Firms that provide sample products to physicians and other health care practitioners do so pursuant to company procedures designed to prevent misuse. Some 10 States require a written request from a health care practitioner before samples may be provided, and this has become the standard practice for companies that use samples.

Some abuse has resulted from improper practices by a limited number of pharmaceutical representatives, physicians and pharmacists, but sampling is not a major cause of diversion.

Sampling serves a legitimate medical purpose and should not be severely restricted because of these limited abuses. PMA would support legislation to prohibit the buying or selling of samples. A strong Federal law prohibiting the buying or selling of samples could control the improper use of samples by the very small number of people who have engaged in such practice in the past.

The major source of drug diversion identified by the subcommittee has been the purchase and resale of pharmaceutical products by nonprofit hospitals, other charitable institutions and their buying groups.

An exemption in the Robinson-Patman Act permits companies to provide pharmaceutical products at reduced prices to nonprofit hospitals and other charitable institutions, provided those products are for their own use. The purchasing institution generally is required

by a manufacturer to certify in writing that the products are for an institution's own use.

Even though companies regularly monitor sales to institutions, there have been instances when companies have made excessive sales. Fictitious or bogus domestic nonprofit groups also have been successful on occasion in purchasing products from some manufacturers. As is the case with foreign customers, companies attempt to determine the legitimacy of such customers before a sale is made. The nonprofit exemption, which allows manufacturers to supply nonprofit hospitals with drugs at reduced prices, should not be altered or eliminated simply because some parties act fraudulently in violation of the law.

Finally, let us emphasize that pharmaceutical manufacturers seek to distribute their products to retailers promptly and efficiently through a minimum number of intermediaries.

Their products are not intended to be handled by a variety of wholesalers or brokers. We see no advantage, therefore, in allowing products to be resold by wholesalers and diverters and, in fact, see potentially significant problems, such as product contamination from excessive handling and a manufacturer's ability to recall a product, should the need occur.

Mr. Chairman, we have attempted to address the questions raised in your letter of invitation for PMA to testify. We believe you and the subcommittee are performing a very valuable public service in your investigation into drug diversion, and in your commitment to take whatever action is required to correct any deficiencies in the drug distribution process.

PMA and the research-based pharmaceutical industry will fully cooperate with your efforts in whatever way will be helpful. I will be happy to respond to any questions you and other members of the subcommittee may have.

Thank you.

[Testimony resumes on p. 487.]

[The prepared statement of Mr. Brennan follows:]

# Statement

**Pharmaceutical  
Manufacturers  
Association**

BRUCE J. BRENNAN  
SENIOR VICE PRESIDENT AND GENERAL COUNSEL  
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE  
ENERGY AND COMMERCE SUBCOMMITTEE  
ON OVERSIGHT AND INVESTIGATIONS  
U.S. HOUSE OF REPRESENTATIVES

December 6, 1985

I am Bruce J. Brennan, Senior Vice President and General Counsel of the Pharmaceutical Manufacturers Association. PMA represents over 100 research-based companies that introduce virtually all of the new drugs produced in this country.

PMA welcomes the Subcommittee's investigation into drug diversion issues, and the research-based pharmaceutical industry pledges its full cooperation in working to ensure that pharmaceutical products are dispensed to the public in the safest possible manner.

Your hearings are helping to encourage manufacturers and others to re-examine their internal controls and to tighten them where necessary. They have shown that all participants

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in the distribution chain should improve their internal procedures and better enforce existing guidelines for monitoring improper orders. In addition, manufacturers must do a better job of ensuring the accountability of samples.

MANUFACTURER-DISPENSED PACKAGES

PMA's Board of Directors, in a meeting on December 4, 1985, again discussed the issue of drug diversion at length, and shares the Subcommittee's concern about this important problem.

The Board believes that a number of the diversion problems uncovered by the Subcommittee's investigation may well be overcome by the use of packages prepared by manufacturers to be dispensed directly to patients. Although this approach ultimately may not prove to be feasible or desirable, the Board believes it warrants expedited study as a potential solution to a troubling problem.

Accordingly, PMA's Board directed that pharmaceutical industry senior managers, scientists and manufacturing-control specialists, in cooperation with pharmacy and medical groups, complete an ongoing study of manufacturer-dispensed packaging in time for the Board to act on this issue at its next meeting on February 12, 1986. We will immediately convey the Board's conclusions to the Subcommittee.

We believe the results of our study will be useful to any Member of Congress who may be preparing legislation. We offer PMA's assistance and cooperation in developing legislation intended to strengthen the drug-delivery system.

IMPORTS AND SALES TO FOREIGN CUSTOMERS

The Subcommittee's investigation was initiated because more than 2 million counterfeit birth control pills were imported into the United States from Panama as "American Goods Returned". The Subcommittee Staff Report in June identified other instances where legitimately produced drugs intended for export were returned to the United States.

In general, PMA sees no benefit to permitting exported pharmaceuticals back into the country. Only in very rare cases would PMA companies seek to import a previously exported product. The return of drugs as "American Goods Returned" has assisted counterfeiters and fraudulent diverters. We fully support increased surveillance by Food and Drug Administration and Customs officials of pharmaceutical products that are being returned. The recently-implemented agreement worked out between FDA and Customs with this Subcommittee's encouragement is a good first step to limit international counterfeiting and diversion. We agree that such shipments not returning to the

holder of the U.S. New Drug Application should be physically inspected and tested by the importer if there is any possibility of contamination or impotency. As a first step in this procedure, shipping documentation should be carefully scrutinized.

Further, it is essential to promptly notify the U.S. manufacturer, whose product allegedly is being imported, prior to its release by Customs. Shipping documentation also should be made available to the manufacturer. This would enable the company to work with FDA and Customs officials in verifying the authenticity of the shipment by checking lot numbers and expiration dates. Through this process, the U.S. manufacturer can become an effective partner with FDA and Customs in ensuring that only legitimate products are returned.

PMA companies regularly sell prescription drugs to foreign customers, including agencies of foreign governments. The companies frequently donate these products to charities when there are disasters, such as earthquakes. The Subcommittee Report detailed some of the illegal schemes that have been used to defraud U.S. companies into making shipments overseas when the purchaser intended to re-direct the products back into the United States. Fictitious foreign charities have been created. In some cases, foreign government officials have been bribed and have become active participants in the diversion. And bogus shipping-papers have been prepared by

domestic brokers as part of distribution conspiracies in which the products never leave the United States.

Under current practice, U.S. labeling generally is not included in any shipment intended for export by PMA members. If for some reason such labeling is included, it is stamped "for export only". Furthermore, PMA companies investigate foreign purchasers through their internal security departments to ascertain their legitimacy prior to shipment. However, this can prove to be a difficult assignment if, for example, representatives in a foreign embassy participate in the diversion activity. Companies also check if an unreasonably large order is placed to determine whether additional inquiry is needed. And as the Subcommittee Report indicated, PMA firms have successfully brought legal actions against foreign conspirators and their U.S. brokers when fraud is discovered.

We understand that, because of manpower limitations, FDA's border inspection procedures for imported pharmaceuticals are designed to give priority attention to importers and geographic areas that previously have been identified as sources of diversion. PMA will encourage its members to notify FDA and Customs about diverters who are defrauding them -- and known trouble spots -- so they can be given greater attention.

An improved system for checking pharmaceutical imports at our borders should effectively reduce -- and hopefully eliminate -- improper international trafficking, particularly if manufacturers are able to work with Customs and FDA officials.

#### PHARMACEUTICAL SAMPLES FOR PHYSICIANS

Many pharmaceutical companies provide health practitioners with samples, particularly of newly-introduced products, in response to requests. Samples serve a useful medical purpose and benefit both prescribing physicians and patients. Typically, a small number of doses is given to start a patient on medication before a prescription is filled at a pharmacy.

Samples enable a physician to begin immediately to evaluate the effect of a prescription product in a patient, and to identify early any side effects. If a drug is not working as intended or is not tolerated, the medication can be modified without expense to the patient. Samples also enable physicians to initiate immediate therapy in cases of severe pain or infection. And samples help defray drug costs, which is particularly important to low-income patients.

Firms that provide sample products to physicians and other health-care practitioners do so pursuant to company procedures designed to prevent misuse. Most companies have

written policies on samples that outline procedures for obtaining written requests, for storage practices and for maintaining accountability. Samples are clearly marked that they are not for sale and typically constitute a very limited number of doses. In some instances, the capsule or tablet itself is marked "sample".

Some 10 states require a written request from a health-care practitioner before samples may be provided, and this has become the standard practice for companies that use samples. Many companies also have adopted procedures to monitor the handling of samples by pharmaceutical representatives and the size of requests by individual physicians. This permits companies to identify possible misuse by its employees and practitioners, and to take corrective action when appropriate.

Some abuse has resulted from improper practices by a limited number of pharmaceutical representatives, physicians and pharmacists, but sampling is not a major cause of diversion. Sampling serves a legitimate medical purpose and should not be severely restricted because of these limited abuses. Legislative remedies to curb abuse should be directed at the root of the problem -- unscrupulous pharmaceutical representatives, health-care practitioners and pharmacists -- and should not penalize the many patients who benefit from the use of samples.

PMA would support legislation to prohibit the buying or selling of samples. Under current federal law, diverters must be proven to have adulterated or misbranded drugs or conspired to defraud manufacturers to be effectively prosecuted. We believe a federal statute making it an offense for any person to knowingly buy or sell a pharmaceutical sample would constitute a much stronger disincentive to the diversion of sample products.

Alternative distribution schemes that would permit sampling but remove the product from the physician, such as the use of coupons, would eliminate the principal benefit of patient starter packages -- prompt initiation of therapy at a physician's office. The use of coupons also would be more expensive for patients, who would have to purchase their drugs immediately without the benefit of a trial period to make sure that a particular therapy is effective, can be tolerated and does not have side effects. This is not to say, however, that the use of coupons to purchase drugs cannot be quite beneficial in some circumstances, such as when patients have already successfully used a particular medication.

PMA urges the Subcommittee to continue to permit sampling, which is of demonstrated medical value, and to provide a legal basis for punishing diverters. A strong federal law prohibiting the buying or selling of samples could control the improper use of samples by the very small number of people who have engaged in such practice in the past.

SALES TO INSTITUTIONS

The major source of drug diversion identified by the Subcommittee has been the purchase and resale of pharmaceutical products by non-profit hospitals, other charitable institutions and their buying groups. As the Subcommittee Report stated, a "whole new industry" has sprung up to induce these organizations to purchase excessive amounts of products and re-sell them to brokers, who in turn channel the products back into the distribution chain.

An exemption in the Robinson-Patman Act permits companies to provide pharmaceutical products at reduced prices to non-profit hospitals and other charitable institutions -- provided those products are for their own use. The purchasing institution generally is required by a manufacturer to certify in writing that the products are for an institution's own use. Although firms certainly could more carefully monitor purchases by non-profit institutions, a manufacturer also should be able to give substantial weight to a written declaration that the products are for an institution's own use. In fact, the Supreme Court has confirmed the propriety of a manufacturer's reliance on such a declaration by a non-profit hospital.

Even though companies regularly monitor sales to institutions, there have been instances when companies have made excessive sales. Fictitious or bogus domestic non-profit groups also



have been successful on occasion in purchasing products from some manufacturers. As is the case with foreign customers, companies attempt to determine the legitimacy of such customers before a sale is made.

There are two situations involving non-profit institutions that could result in drug diversion. A manufacturer might be induced into selling to a non-existent institution, a bogus operation or non-profit concern that purchases by means of a false certification with intent to resell. In these cases, the purchaser has acted fraudulently, and existing federal mail fraud, wire fraud and racketeering statutes can be used to bring criminal charges. In recent testimony before this Subcommittee, Department of Justice and FBI officials said that existing federal law is adequate to prosecute fraudulent drug diverters. In addition, a civil remedy against the purchaser and his broker under the Robinson-Patman Act is available.

The non-profit exemption, which allows manufacturers to supply non-profit hospitals with drugs at reduced prices, should not be altered or eliminated simply because some parties act fraudulently in violation of the law.

The second situation would be where a non-profit group is induced or duped into over-ordering by brokers who have assured the concern that such activity is not only profitable but legal. In such cases, the purchasing institution has still made a false certification and would be considered culpable under Robinson-Patman Act provisions as interpreted by the courts. A resale then would result in a violation of the Act by both the reselling institution and its broker. If there is a violation of the Robinson-Patman Act, a private action for treble damages may be brought. In addition, both the reseller and the purchasing broker could well be acting as unlicensed wholesalers under state law.

Recently drafted proposals to modify the non-profit exemption in the Robinson-Patman Act in an effort to address these problems, we feel, are unduly broad. Nevertheless, we would be pleased to work with the Subcommittee in amending the law, if it is determined that a change is necessary to restrict drug diversion.

Finally, let us emphasize that pharmaceutical manufacturers seek to distribute their products to retailers promptly and efficiently through a minimum number of intermediaries. Their products are not intended to be handled by a variety of wholesalers or brokers. We see no advantage, therefore, in allowing products to be resold by wholesalers and diverters and, in

fact, see potentially significant problems, such as product contamination from excessive handling and a manufacturer's ability to recall a product should the need occur.

STATE LICENSING LAWS

In our view, state laws on the licensing and registration of wholesale and retail drug establishments generally are adequate. However, we believe these laws need to be better enforced. The findings of this Subcommittee and the publicity generated by these hearings should help to promote more stringent enforcement.

Mr. Chairman, we have attempted to address the questions raised in your letter of invitation for PMA to testify. We believe you and the Subcommittee are performing a very valuable public service in your investigation into drug diversion, and in your commitment to take whatever action is required to correct any deficiencies in the drug distribution process. PMA and the research-based pharmaceutical industry will fully cooperate with your efforts in whatever way will be helpful. I will be happy to respond to any questions you and other Members of the Subcommittee may have. Thank you.

Mr. WYDEN. Thank you all.

I want to allow our friend and colleague from Ohio to make any opening statement or comments that he would care to make.

Mr. OXLEY. Thank you, Mr. Chairman.

I will waive opening statements and look forward to the question-and-answer period.

Mr. WYDEN. We thank the gentleman and thank all our witnesses for their cooperation, and for describing a wide variety of approaches that the subcommittee can look at to deal with the situation.

One question, and I will go right down the row and ask each of you your opinion: In general, most of you have said that you felt that State regulation of pharmacies is adequate, and yet at our last hearing, I mentioned in my opening statement, I asked the U.S. attorney for Atlanta about the dimensions of this problem, and he testified that in every single one, literally dozens of cities and towns and villages that were part of the investigation, at least one pharmacy was dealing illegally in diverted drugs.

And I just wonder how we can reconcile what the U.S. attorney said with the general feeling that I have gotten here in the last hour that you all feel State regulation of pharmacies is adequate?

We will start with you, Mr. Brennan.

Mr. BRENNAN. As we indicated, Mr. Chairman, in our fuller statement, we think there are sufficient laws and regulations on the books in almost all States, but enforcement is way below par.

More funds or more attention needs to be directed at those, at enforcing those laws, and we hoped ourselves that the efforts of this subcommittee would encourage and would light a fire under State enforcement agencies to do the job.

PMA has a rather major effort in State government relations, and a big part of our operating budget. We are close to what is happening in the States, and we certainly would encourage efforts of this subcommittee toward greater enforcement of those State laws.

Mr. WYDEN. Mr. Streck.

Mr. STRECK. We would agree with that. We believe that there is really a resource problem at the State level at this time, that inspections, perhaps a sufficient number of inspections are not occurring.

We know that State boards do from time to time work with the FDA to inspect facilities. That could be continued on a far larger scale in the future, but it requires resources and that seems to be something at this time that has not been available to State Boards of Pharmacy and their inspectors.

Mr. WYDEN. Dr. West.

Mr. WEST. I agree that the State regulation, and State statutes are adequate. Perhaps the scope of authority—who has particular authority to investigate diversion or discriminatory pricing—is an issue. In many cases, it is the State board of health and not the State board of pharmacy.

The State laws regulating the practice of pharmacy are adequate, in our opinion.

Mr. WYDEN. Mr. Kelley.

Mr. KELLEY. We have always felt that by and large, both at the Federal and State level, retail drug stores, corporate drug chains, independents and so forth are one of the most heavily regulated commercial businesses within the United States.

It is our opinion that there are more than enough laws and statutes already on the books to address the problems that this subcommittee has identified, and we feel that the State regulatory boards just need to refocus on some of the areas that perhaps they have overlooked in the past.

Mr. WYDEN. Mr. Mahaffey.

Mr. MAHAFFEY. The heart of our statement, Mr. Chairman, I believe answers the question. You cannot station an investigator at each professional's practice station in the health care system, and so we must rely on voluntary compliance.

Our programs of NABP State newsletter that are sent to 125,000 practitioners are in place and working. We need more Federal-State cooperation. We have liaison with DEA, and each year we have working with FDA and we are pursuing greater Federal-State cooperation.

That in essence is what we are trying to say again and again, FDA cannot solve all the problems. DEA cannot solve all the problems. All of the other Federal agencies cannot solve all of the problems.

There must be a network of enforcement activities which takes into consideration the very grass roots problem that you brought up about all of the communities that are involved, but that must spread, and there can be no jurisdictional, territorial guarding when we are talking about the health of the public.

Agencies must talk to each other and cooperate across the board to enforce the existing statutes, and you can't do that without funding and interstate cooperation.

Mr. WYDEN. Dr. Oddis.

Mr. ODDIS. Mr. Chairman, I also believe that there are sufficient laws on the books and regulations, and that as we heard from the other speakers, we are talking about more people, more money, and more cooperation.

Mr. WYDEN. Doctor Schlegel.

Mr. SCHLEGEL. That is just one of the problems, and the sampling and the limitations of the Nonprofit Institutions Act are two major contributors, perhaps even larger contributors to the problem than State regulation.

Mr. WYDEN. I note at the bottom of page 5 of your statement, at this time it is possible for persons not licensed or qualified to dispense drugs and unfamiliar with safe dispensing practices to acquire drug samples and dispense them to patients.

Neither these laws nor others which might seek to control the current drug sampling system would be adequate to fully protect the public health, so you certainly think that there are some problems with State laws.

Mr. SCHLEGEL. Yes; but we would feel that the greater solution is to deal with the problem of sampling rather than deal with the problem of State regulation.

Mr. WYDEN. I would only say that I think there has generally been support for more inspectors, and you look at Mr. Mahaffey's

statement about there being five in a State like California or New York, and I think it is pretty clear——

Mr. MAHAFFEY. No, 5 average; 20-some or 30 in California and New York. It depends on the population. Our survey points out a lot of these things. We provide copies to you about the inspections of each pharmacy, each year in every State and their resources.

Mr. WYDEN. Well, I am told that there are 125,000 pharmacies in the State of California, and if there are 20-some——

Mr. MAHAFFEY. 125 pharmacies?

Mr. WYDEN. Pharmacists.

Mr. MAHAFFEY. A distinction, they are both licensed.

Mr. WYDEN. If there are 20-some in California, that is certainly more than the average, and that is an improvement but my own feeling and there is great concern on the subcommittee, we are very sympathetic to the request for more manpower, but we have got to change the economic incentives that have promoted this market, and we are going to figure out a way to do it.

Mr. MAHAFFEY. Mr. Chairman, you have to remember that prescription legend drugs may go to a lot of different institutions, in a lot of different places, and our boards of pharmacy sometimes have no authority to inspect other than just pharmacies.

We are talking about hospitals, nursing homes, a variety of settings, but that authority is spread in some States, in terms of the Board of Health, and some States regarding institutions and nursing homes, and so that is why we are talking about a cooperative effort or a networking of enforcement efforts, and each individual State must look at the law enforcement system.

Mr. WYDEN. State regulation of wholesalers?

Mr. MAHAFFEY. About half the States license wholesalers and half do not. We advocate that all States should license wholesalers. We have that interim model act at the present time, and we will prepare, together with the cooperation of other organizations, a model regulation for the licensing and inspection, meaningful inspection, of wholesalers and repackers, and make this available to the committee, but—and we will also make that model act and regulation available to the Council on State Governments for dissemination to the States and the National Commissioners of Uniform State Laws.

Mr. WYDEN. Will you add some more investigators in that regard, as well?

Mr. MAHAFFEY. Depends on how the regulation is written—oh, yes, add investigators for the inspection, and training of those investigators. One of the problems with the wholesalers is oftentimes, the wholesaler repacker does not understand the statute, the State statutes, say in regard to who may possess, who may diagnose, who may prescribe a legend drug.

Mr. WYDEN. The subcommittee is very concerned that the system for monitoring wholesalers is very weak. We have been advised by the FDA, they are inspected something like once every 2 years.

Mr. MAHAFFEY. It is ineffective, and I believe the Food and Drug Administration would admit that. Those States, for instance, in Michigan, those States that do have statutory requirements to inspect wholesalers, we have some excellent regulations, and we are looking at those at the present time, talking to their inspectors, de-

termining—it is not our intent to go in and prepare a regulation that is burdensome, but to get at the heart of the legend drug, veterinary drug device distribution matter.

Mr. WYDEN. Mr. Streck was reading my mind. I was interested in his thought with respect to these comments.

Mr. STRECK. I agree. We agree that the economic incentives must be changed if you want to stop illegal diversion, but to just give you an example of the problem at the State level, I was speaking to a member of the Florida Board of Pharmacy, and he told me that they have over 820-some drug wholesalers licensed in the State of Florida.

Now, of that 820, we probably have 12 members in the State of Florida, and yet, we represent nearly 90 percent of the total sales. I think you have a real resource problem in how you are going to inspect 800-some additional facilities and inspect them fairly.

Mr. WYDEN. Mr. Streck, earlier this year, the subcommittee, with, I might add, your cooperation, surveyed your wholesaler membership regarding certain drug diversion questions, and 130 letters were mailed out, and the subcommittee only got 8 replies.

The subcommittee is interested whether or not any of your members have informed you why they were not prepared to cooperate with the investigation.

Mr. STRECK. Part of the reason may be that they may have been afraid that some of the information they would supply you would not remain proprietary information.

As a result, they may have been less willing to submit that information at this time, but I think many of them had called NWDA, their association, and asked them to convey information as well, so some of them had certainly decided that they would rather work through their association.

Mr. WYDEN. Well, others were concerned about giving up information they might have regarding proprietary, like the pharmaceutical manufacturers, and did cooperate.

Would you supply to us a list of the officers and members of the boards of directors of your association, together with the company affiliations and a notation of whether or not they responded to the subcommittee letter of request, and also any explanation they would care to offer?

Mr. STRECK. If you will supply me with a list of those names who did respond, I will be happy to.

Mr. WYDEN. I will yield to my colleague and friend, Mr. Oxley.

Mr. OXLEY. With respect to the drug sampling question, have you documented labeling and packaging problems with samples, and can you give us some examples of that?

Mr. SCHLEGEL. No, we have not. One has to only be in the health care delivery system to see the large volume of samples just around. It is frightening. These are potent medications that are often stuck in the trunk of cars, as you know, closets of physicians' offices, and it is a completely uncontrolled environment with too many very, very potent medications out there.

And we feel that they ought to be treated the way normal defensed medications ought to be treated with all the controls that are considered to be of such value that we have Federal laws regulating prescription dispensing.

Mr. OXLEY. What is your opinion how these drugs, particularly samples, are misused? Do doctors overorder them? What is the major area of abuse?

Mr. SCHLEGEL. It is very, very tough to generalize. Some pharmaceutical companies are very good about controlling the distribution of their samples, and some are not. Some engage in practices of automatic shipment to their medical representatives, which, unless the medical representatives are moving them out, begins to back up someplace, and sometimes, it is industry use by the practitioners or industry handling.

There is a great deal of pressure that providers often feel from sales representatives wanting to give them samples, and very often these are not even given to the prescriber; but given to the person at the reception desk or somebody else in the organization.

Mr. OXLEY. If we were to deal with the whole question of economic incentives, clearly it seems to me that this abuse of these give-aways is one of the keys in trying to get a handle on this whole problem.

Mr. SCHLEGEL. Absolutely, sir.

Mr. OXLEY. I pointed out in our last hearing that I had visited a family doctor, a friend of mine, in a little town in Ohio. I still can't get over the fact that he had all these samples, literally stacked up on a table in his office, and probably some of them had been years old.

It is something that I cannot get out of my mind, and it is a fascinating kind of a scenario that is being played out in various doctors' offices throughout the country.

Mr. SCHLEGEL. At a time when we are trying to control health care costs in the system, one has to question the amount of waste dedicated to that kind of practice.

Mr. MAHAFFEY. I think samples disrupt the system; we need a process of education of those who will prescribe medication, those who put in the order, those who say there is a medical need for the drug.

There is responsibility at the point of diagnosis. Those health care practitioners, the physician, the M.D., the podiatrist, the dentist, those people who can prescribe, and now we have more people with that authority at the State level, nurse practitioners, physicians' assistants, and we have more people with that authority at the State level to prescribe, but I think samples make a mockery of that system, because sometimes the office assistant or the nurse or someone who is not designated by State law to have that authority of diagnosis, and providing that order to the patient, dispenses those drugs.

They are out of channels and then, of course, the testimony of the people in Georgia certainly show the problems related to misbatched numbers, out of date medication, storage conditions that the samples are put into, temperature variations, all of these things, the type of containers.

How can you recall some of these things when they have been outdated, heart medication, thyroid, so the problem is in a sense giving away some of our prerogatives in terms of the diagnosis.



Mr. OXLEY. First of all, it appears to me that we have a supply problem, not so much a demand problem as it relates to these kinds of drugs. Is that a fair statement from everybody?

Clearly, to me at least, it is an oversupply. I don't see a standing demand by the medical profession, for example, to get all of these types of drugs. It is obviously a marketing attempt by pharmaceutical companies and distributors to get their product to the market, which I have no objection to, except when it becomes a public health threat.

Mr. BRENNAN. I think I am the only one here that had anything kind to say about samples in the current system. The pharmaceutical manufacturing industry has no interest in waste in the sampling system or any other area of its activity which might add cost to that system, and ultimately to the patient who has to pay for medication.

If there is excess, if there are excess samples out there in circumstances like the one you indicated that you ran into in Ohio, that ought to be corrected.

We have, for years, in fact since 1974, supported Federal legislation which would do two things. No. 1, require samples to be dispensed or distributed to the physician only on the written request of the physician, and we have supported that when it has come up in the States, and the 10 States that have that kind of legislation.

Mr. OXLEY. Excuse me, that legislation is on the books?

Mr. BRENNAN. In 10 States. Since 1974, we have supported the concept of Federal legislation in that area, requiring samples be dispensed only on written request and sufficient recordkeeping by pharmaceutical manufacturers and their local sales people, so that there can be accountability for where the samples are, what their status is, whether they are out of date, whatnot, so we think that is an appropriate road to go down to permit manufacturers to use appropriate marketing mechanisms, but with sufficient control, so that the system does not have a public health concern associated with it.

Mr. OXLEY. Mr. Kelley would disagree with the need for Federal legislation in that area?

Mr. KELLEY. That is right. You know, I think part of the problem is that at the physician end, and the Congress last year saw problems related to controlled drugs and sampling, and for the first time enacted legislation that requires physicians to maintain the same types of records that drug stores must maintain in terms of how they are accountable for scheduled narcotics which come into their offices.

And this is—we feel that the Congress ought to maybe just go a little bit further here in order to control, have better controls over the system in terms of sampling within the physicians' office.

Let's get the product out of that environment, and allow for sampling to take place in terms of a coupon or a complimentary prescription system.

We feel that that would really resolve some of the problems related to sampling.

Mr. OXLEY. Thank you, Mr. Chairman.

Mr. WYDEN. We will return very shortly, after a vote. Please indulge us for a few minutes.

[Brief recess.]

Mr. WYDEN. The subcommittee will come to order, and let me apologize to all of you for the inconvenience, and I think throughout this hearing, we are going to have additional votes, and hopefully we won't have too many delays.

Let me pick up, if I might, Mr. Brennan, on this question of samples, because I think, as you know, the subcommittee is particularly concerned about it, and in your discussions, samples for physicians, you note several benefits, including the ability to immediately evaluate the effect of the drug on patients, identify the side effects, a whole host of things.

Wouldn't all these benefits be available under the American Pharmaceutical Association's coupon plan?

Mr. BRENNAN. I do not think they would. I think in the terms certainly of the immediacy of treatment, in those situations I think, those of us certainly who have children have all been through the situation of the child with the ear infection, a very painful, distressing situation, is able to right in the doctor's office obtain an analgesic and antibiotic and starts therapy, and the parent is not required to go across town or make whatever trip is necessary to obtain pharmaceuticals.

I think that is particularly important in rural areas, where samples are really very widely used and sought after by physicians for those kinds of circumstances.

Mr. WYDEN. In your statement, you noted that most pharmaceutical companies have written policies to establish procedures for sample distribution to physicians.

Moreover, the samples are said to be clearly marked as such and are typically packaged in small doses. None of this prevented the wholesale abuse of samples which has recently been documented, though, recently by the U.S. attorney in Atlanta, did it?

Mr. BRENNAN. Well, you talk about wholesale abuse. I don't have the figures on how many samples are distributed by the pharmaceutical industry in this country; it is in the millions. And what proportion of that was involved in diversion of those samples into an improper area, I really can't say.

But, we certainly agree with you that that has to be dried up and we think it can be addressed by insisting on accountability. We feel that our members have appropriate procedures.

They may not, and if so, if Congress feels that it is necessary, mandate sufficient accountability, mandate how they are to be distributed. We suggest rather than coupons that written requests by the physician be the way.

As I said, we don't have a precise understanding of those company procedures because that is an important marketing area and as a trade association, we really are unable to inquire into our company's marketing policies.

Mr. WYDEN. Well, the U.S. attorney in Atlanta—you said you weren't aware of the scope of the situation—the U.S. attorney in Atlanta was very specific. He said in every single community that they looked at this was a serious problem, in every town, every city, and every village, and I think we have to start with that as a basic premise.

I just wonder if the company procedures were all that effective in the past, and things worked, why would we have organizations like APhA and ASHP concluding that sampling ought to be abolished.

Mr. BRENNAN. I don't know what their reasons are for concluding that sampling ought to be abolished beyond what they said in their statements, but I know for a fact that all the pharmaceutical manufacturing companies I have talked to, that is many, many, among our members, list as a reason for termination of employment by salesmen, improper use or misuse of samples, and that has happened on a number of occasions. I am not sure whether that is one of the questions that you asked our members when you wrote to them two or three times over the last year that you have, but I am sure they would document that if asked.

Mr. WYDEN. You note that a number of companies have adopted procedures to monitor the handling by pharmaceutical representatives and size of requests now by individual physicians. By and large, didn't these procedures predate the Atlanta investigation?

Mr. BRENNAN. Yes.

Mr. WYDEN. Well, I guess what concerns me, we have got a situation where it is almost as if we are trying to have it both ways. If the procedure has existed, they weren't effective, they didn't, the companies weren't doing what they should have been doing, that there is what, a negligent situation?

Mr. BRENNAN. I guess, I, Mr. Chairman, in summary, I would disagree with the U.S. attorney in Atlanta as to the size of the problem. It is certainly, to the extent that it exists at all, a very important problem and needs to be addressed. We want to help address it, but I think in terms of the size of the problem, I have to disagree with him.

Mr. WYDEN. That certainly is your right, and it is good to have that on the record, but I must tell you, I have sat through essentially every one of these hearings, that consumers are very concerned about all the evidence that has accumulated to this point, and we have not gotten any evidence which would contradict what the U.S. attorney in Atlanta has said.

Mr. Mahaffey.

Mr. MAHAFFEY. Yes; I would like to comment about the Georgia situation and samples. You mentioned trade associations, professional societies, and we are all voluntary associations.

The Pharmaceutical Manufacturers Association, perhaps we are talking about all of the people that are registered with the Food and Drug Administration to manufacture drugs. We are talking about an enormous number of dosage forms that are being put into the distribution system, supposedly to be given away.

We know sometimes they are not given away, they are bartered and they are traded and they are wholesaled and they are sold for profit. And the 10 States, the processes of recommendation to these companies evidently doesn't work.

If 10 States have the authority to demand accountability, it is the heart of our testimony, we need accountability of prescription legend drugs and there are mechanisms in place at the present time to provide this, but just because one association recommends to their members that this be done doesn't solve the problem.

You have a State statute, and we are in the process of providing that in terms of accountability of sample medication.

And, prior testimony received from the committee has included statements of a representative of the Georgia Board of Pharmacy, and drug and narcotics agencies, FBI, Federal Attorney's Office, all of whom are involved in the prosecution of cases in the Georgia affair.

There is one important message that these individuals have brought to the committee, it is the fact that various health professionals and individuals, corporations, have been incarcerated for committing white-collar crimes.

Testimony of Gale McKenzie is quite clear in the Georgia affair, as she delineates some of the grounds for the indictments, including mail and wire fraud, obtaining drugs under false pretenses, misrepresentation, perpetuation of a scheme, and aiding and abetting in violation of the law.

Now, there seems to be something wrong with State statutes or the Federal statutes where one State agency had to go to the Federal Trade Commission, DEA, FDA, and they could not get any relief in terms of prosecuting these people that were in violation of the law.

Mr. WYDEN. Excuse me——

Mr. MAHAFFEY. We understand that, I believe we all understand that the bottom line here really is in the price differential problem, that that economically really causes so many of the problems we are dealing with here today.

Mr. WYDEN. I want to recognize my colleague from Florida. Let me make one additional point. It seems to me we have a situation where one of the professional associations has already told us that there have been abuses for more than 40 years, and I think that that is compelling evidence that now is the time to do something about it, and I would just say that the concern about the committee, and again having sat through all these hearings, is that we want to do something about the problem before it takes place.

And I just think if we get into a situation where we are just trying to figure our remedies, either prosecute people or something of the nature, after the problem has already taken place, people are going to get injured, No. 1, and No. 2, it is going to always be an uphill game to get the problem under control, and we are very anxious to work with you, and I will have some additional questions as we go.

Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate you giving me the opportunity, particularly since I had to leave to speak on the floor on an amendment.

Dr. West, in your testimony, you very emphatically refer to the fact that much of this problem would not have taken place were it not for the price discrimination.

You did a pretty good job of that. I would agree with you, that probably your points are correct, if there weren't this price, using your term price discrimination, that probably would cut down on drug diversion.

But, are you maintaining that there should not be any price discounts? I prefer that term.

Mr. WEST. Only to those institutions that are charitable which were exempted from Robinson-Patman by the 1983 Nonprofit Institutions Act.

Mr. BILIRAKIS. Well, how about the institution, for instance, in North Carolina, which wrote this committee sometime ago, the early part of November, telling us that the types of restrictions that apparently you might be referring to would cost its health programs an additional \$25 to \$30 million per year?

Would you put those in the categories of price discounts?

Mr. WEST. I am unfamiliar with that. I really questioned that.

Mr. BILIRAKIS. I realize the Department of Human Resources and their use of the drugs apparently is not ever on a profit basis, in fact, they don't sell their drugs.

Mr. WEST. They provide these drugs to indigent at no charge.

Mr. BILIRAKIS. That is my understanding.

Mr. WEST. This is a nonprofit institution?

Mr. BILIRAKIS. Some of their programs and services that require the purchase of drug products are tuberculosis control, sexually transmitted disease control, paternal and child care, home health, primary care, mental, alcoholism treatment, prison health services, medical schools and affiliated hospitals?

Mr. WEST. Well, it certainly appears that that would fit our definition of a charitable nonprofit institution, so it would not be affected. There are nonprofit institutions that take advantage of this exemption all over the country. There are many, many of them.

Mr. BILIRAKIS. In other words, what you are saying, that they are nonprofit legally, but not nonprofit in fact?

Mr. WEST. Nonprofit charitable in fact. The public, we feel, pays twice, both in increased taxes to subsidize these institutions and then paying higher prices for drugs because of cost shifting.

Mr. BILIRAKIS. The manufacturer still makes money on the sale of these drugs on a discount basis to these groups, does it not?

Mr. WEST. I don't know the answer to that question.

Mr. BILIRAKIS. May I ask you, sir?

Mr. BRENNAN. I can't answer that in specifics, but I assume that they must.

Mr. BILIRAKIS. Do we have any report of anyone actually having been harmed by the drug diversion situation? Do we know of any specifics where anyone has been injured, any reports?

Mr. MAHAFFEY. Counterfeiting. We have had harm in terms of diversion of anabolic steroids and sale by gymnasiums being misbranded in Michigan where the gymnasium was advertising these other gymnasiums and the Food and Drug Administration after some time explored that and found that they were distributing Mexican drugs produced in Mexico and anabolic steroids.

We assume that the Food and Drug Administration's requirement or the Food, Drug and Cosmetic Act requirement as to expiration dates, labeling, and all those things in place, when we have the samples that are shucked and put into baggies and all sort of containers.

Mr. BILIRAKIS. We saw evidence of that here.

Mr. MAHAFFEY. People who are not trained to recognize the distinction between various dosage forms, when you have that happening, as to whether or not the public is harmed, it doesn't afford

the same protection for those people who take those drugs as it affords the general public.

Mr. BILIRAKIS. Amen to that. Do we know specific instances where somebody has been injured as a result of that, someone who has reported? Maybe I might ask Dr. Oddis.

Mr. ODDIS. I would just comment that aside from known cases where injury has occurred, the bigger question is the use of ineffective drugs, and what has been the impact upon those who were relying on the validity of such drugs, that didn't produce because of their ineffectiveness.

Mr. WYDEN. If my friend might yield, there have been five pregnancies and one abortion. That has been the impact. I appreciate my colleague from Florida yielding.

Mr. BILIRAKIS. Drug diversion lends itself to counterfeiting, does it not; is that correct?

Mr. MAHAFFEY. Well, counterfeiting—

Mr. BILIRAKIS. They get into the system principally as a result of the drug diversion?

Mr. MAHAFFEY. They are always those who will prey upon the system, and produce something similar to or a lookalike. We have a diversion in the lookalike market in terms of drugs on the street, the Food and Drug Administration cannot legally take off the market, because they contain nothing more than some already approved chemical substance that is for sale over the counter, but the lookalikes in terms of counterfeits and prescriptions are out there.

They have been discovered, and they will continue to be as long as people can duplicate a dosage form and make it similar.

Mr. BILIRAKIS. Do you have anything you want to add?

Mr. KELLEY. From our point of view, I would say that the only instance of counterfeiting that we have seen has resulted from the penetration of a product from abroad, and that in terms of the movement of drug purchasing and distribution within the United States, we have yet to see a counterfeit problem arise within our distribution system.

It has come from abroad.

Mr. BILIRAKIS. Can't our distribution system be improved, to use some of the terms used earlier, to possibly either prevent that or certainly lessen its chances of taking place, even from abroad?

Mr. KELLEY. Definitely, and I think many of the organizations have alluded to the ideas and recommendations that there needs to be greater surveillance at our borders, with the Food and Drug Administration and the Customs Service.

Mr. WYDEN. If my colleagues might yield, I think my colleague from Florida is making a good point, and I note that when this subcommittee asked the Food and Drug Administration to take a look at this question of entries, Customs entries, that the Food and Drug Administration, looked at 57 entries, and 4 of them were counterfeit, so I think it is clear that there is a significant problem, and the point that the gentleman makes about stepping up Customs enforcement and protecting our borders is an important one.

I thank him for yielding.

Mr. BILIRAKIS. Well, Mr. Chairman, I believe it was Mr. Mahaffey who made the comment about our great distribution system, and it is one of the best, probably the best the world has ever seen,

which is the case with our medical care system, which I certainly believe in, and we have got to be careful here.

One thing, I just sort of glanced at some of your statements, and I know that contrary to what we quite often get in our testimony from our witnesses, you have made some specific recommendations for legislation and I do commend you for that.

I haven't had a chance to go through it, and don't know whether you made specific enough recommendations on how we might improve our distribution system, and if you have, I commend you for it, and if you haven't, and you have ideas, you have the opportunity, to furnish those ideas to the committee so that we can take all of those into consideration in the process of any prospective legislation.

We all must be careful, obviously, that we do not destroy this great distribution that we have. We are all talking about enhancing it and hopefully improving it, but certainly not destroying it.

It is not all bad. I would like to think that it is practically all good. However, there are areas that need to be improved.

I represent a district of virtually 50 percent elderly. I talk about the drug diversion problem, and my part in seeking a solution to the drug diversion problem in our newsletters, yet I play that carefully, because I don't want to scare the elderly half to death and destroy their confidence in their retail drug store or their chain drug store.

This is what I am afraid is going to be happening here and already is happening. So, we have all got to be expressing the proper concern here, but at the same time, not scare these people half to death to the effect that we lose complete credibility.

Mr. MAHAFFEY. If you look at the victim impact statement of Gale McKenzie, it says so much, it is in a way pointing out what the legal processes were that she took to or the Georgia U.S. Attorney took to prosecute these cases, and it points out the holes in the system and the lack of authority in terms of State and Federal law.

In terms of the distribution system, there are a lot of health professionals out there that are doing what they are supposed to be doing. Let's talk about those.

Mr. BILIRAKIS. Let's say virtually all of them are.

Mr. MAHAFFEY. Advising, diagnosing, prescribing and dispensing. You have to cut this down in terms of the number of dosage forms that are produced in this country, the number that are consumed each day.

That is an enormous amount of dosage forms. And the size of the problem, the diversion problem in the Georgia situation. That is magnified in every doctor's office.

Mr. BILIRAKIS. I have talked to pharmacists, particularly chain drug store pharmacists who have admitted to me they have seen drugs on their counter that are expired. I won't go into anything more than that, but certainly expired drugs.

So our distribution system, as good as it is, is far from perfect in that regard. Human error, I suppose, will always be there. Dr. Oddis, it seems that everybody on this panel except for Mr. Brennan is against sampling, the furnishing of samples by manufacturers, and I am sorry I missed Mr. Brennan's explanation as to why sampling is good.

I suppose your comment went into that, and maybe I can take a look at the record to find that out. Dr. Oddis, you represent the American Society of Hospital Pharmacists, and they get samples, don't they?

Mr. ODDIS. Yes, many of our members practice at hospitals that receive samples.

Mr. BILIRAKIS. But if you all are so much against sampling, why do you not preclude samples from coming into hospitals?

Mr. ODDIS. Well, it is an institutional decision. Hospital pharmacists are employees of the institution and cannot make such decision by themselves. Samples received by hospitals arrive primarily for use by physicians.

Mr. BILIRAKIS. They come there exclusively for that reason, don't they?

Mr. ODDIS. That is right.

Mr. BILIRAKIS. All of them should be used by physicians, hopefully?

Mr. ODDIS. That is right, but the problem is that hospitals have strict control systems established by the Pharmacy Department for all drugs in the hospital. Then when it comes to samples, the whole system breaks down, because they are called samples, and so, the control system becomes less effective.

Now, we assume that they are being used properly and are given to people who can't afford medication. But one would wonder if, with the effective of control system that we have for all the other drugs that are purchased, what we are gaining by having in effect a dichotomy—

Mr. BILIRAKIS. Your organization has it, I would gather, within their purview, to just mainly stop samples from coming into the hospital, do you not?

Mr. ODDIS. I wish we had that authority. But the most we can do is advise our members, who are in most cases employees of institutions of the hazards associated with drug samples.

We also are working with the American Hospital Association to convince them of our position, and that the matter of sampling should be discontinued to hospitals.

We have not been 100 percent successful in that regard as yet, although we have sensitized AHA to the problems associated with samples, and they have issued a statement of their own, advising administrators and institutions that the issue should be reviewed, but they have not come full turn to ban sample use in the institutions, at least at the association level.

Now, at some individual hospitals where some of our members practice, then those are individual institutional matters, and I would gather some hospitals have policies that simply limit and restrict samples altogether.

Mr. BILIRAKIS. It is certainly of some benefit to the hospital if their particular hospital pharmacy belonged to the American Society of Hospital Pharmacies, is it not?

Mr. ODDIS. We like to think so.

Mr. BILIRAKIS. If your organization basically has an edict to the effect that—I am not taking a position as far as sampling, even though I have lots of questions regarding sampling, but I am basically saying that you seem to be deaf on sampling, and it seems to



me that you should have some control, that you should be able to control the members of your association in some way, and if they violate that control, or in your member hospital pharmacy, then you would basically ban them from being a member of your organization?

Mr. ODDIS. Let me respond by saying, if we surveyed our members, and this is a policy adopted by our house of delegates 10 years ago, and reaffirmed more recently, if we surveyed our members' opinions and what they have attempted to do in their institutions, my guess is that they all support fully the position of ASHP, and have attempted to bring about enforcement of that position in their institution.

Unfortunately, is not left to them alone to make that kind of policy for their hospital. It is a decision that involves the physicians, the administration of that hospital and a number of other people, so it is not simply a question of convincing our people, our members, but a question of our effectiveness in addressing that issue at the hospital level.

That is the reason we have attempted to pursue the second route, to take our position against sampling to the American Hospital Association itself, and convince them of the validity of our position, so that they in turn also will say to their members, or administrators, so on, "we oppose the use of samples."

Mr. BILIRAKIS. Mr. Chairman, this will be my last question.

Do you have a set of guidelines for your member hospitals relative to this terrible problem of drug diversion. You are obviously concerned with it and hopefully, your concern includes the overall picture of drug diversion, including sampling.

Do you furnish your member hospitals with guidelines on how to conduct business in that hospital?

The illustration of a hospital pharmacy where the pharmacist is able to divert drugs which come into that hospital physically is a good one.

How in the world could the pharmacist get away with diverting those drugs? This happens all the time, and it happens an awful lot in Florida. The hospitals basically come back with an explanation of, we didn't know what was going on.

I go back to what type of burden should be on the shoulders of the hospital, in terms of what they should not know. Does your organization furnish ground rules to your member hospitals in that regard?

Mr. ODDIS. We have practice standards, statements, and technical advisory bulletins. We issue these regularly to our members, and to all new members as a matter of course.

I might also say, right after this hearing, we are going to New Orleans, where we have our major meeting of the year, and there we will have perhaps 10,000 people, and 5,000 of them will be practitioners in hospitals.

Some of the educational sessions already scheduled deal with drug theft, drug diversion in hospitals, things of that sort. We are even previewing a videotape to be sent to our members on this subject.

Mr. BILIRAKIS. These will be pharmacists, and essentially the people who are in a sense responsible for the problem of drug diversion taking place in the hospital.

How about the administrators, the boards of the hospitals, are they being educated in any way, too?

Mr. ODDIS. Yes, sir, we have a joint committee with the American Hospital Association which meets at least once a year and these matters are discussed.

Mr. BILIRAKIS. Gentlemen, I guess I have the usual Republican philosophy of less regulation is better. But I assure you, it is a big problem, and this committee is already concerned with it.

If you don't show us ways whereby you are policing your own backyard, we are going to have to get involved with legislation. We should not have to.

Mr. MAHAFFEY. Could I make one distinction?

Mr. WYDEN. Certainly.

Mr. MAHAFFEY. We have in the professional community, and recognizing the fact that health professionals are licensed by the State, we have two types of control, voluntary control of the peer group, and that being the American Medical Association, the American Pharmaceutical Association, and American Podiatric Society, and so forth, and those are voluntary associations that I can pay my dues and join.

They have no legal control. They can throw me out if I violate their codes of ethics, standards of practice or whatever, they can dissolve my membership, but I still have to have a State license to practice, and there is a difference between professional peer-group control and legal control.

What we are talking about is still in terms of stronger State statutes augmented by Federal statutes to alleviate the problem. Legal control works, and voluntary control doesn't. It is laudable.

We need voluntary control, codes of ethics, but you don't have to belong to the American Medical Association to practice.

Mr. BILIRAKIS. You don't have to, but it would be a black mark to you if you are a member and have been thrown out. I don't have to belong to the American Bar Association. If I am a member of the Florida bar, I can practice law in Florida.

If I am thrown out, it doesn't make me look very good, so I would care. But have you shared your recommendations with the various State legislatures and the State organizations, so that their legal controls could be strengthened?

Mr. MAHAFFEY. We will be.

Mr. BILIRAKIS. Thank you very much, gentlemen.

Mr. WYDEN. I thank the gentleman from Florida.

I want to come back to this question of price differential, price discrimination, and make sure I understand it, just for the record.

It is your view that a single price policy in the market for prescription drugs when in effect, it allows us to destroy the diversion market because we would be able to take out economic incentives to divert?

Mr. WEST. Exactly.

Mr. WYDEN. I would like to explore the other side of the coin, because the committee has to look at this, the question of potential benefits of price differentials, and price discrimination.

It is my understanding that you have said that there would not be a reimport problem, if pharmaceuticals cost the same in the United States as abroad, is that right? But the pharmaceutical industry is one of the few positive contributors to our balance of trade, and I don't have to tell you that we have this enormous balance of trade deficit in this country, and I guess my question to you is, a great deal of sympathy on this issue, and as we try to work something out, do you believe that U.S. firms are getting into a situation where they cannot compete on a price basis for overseas sales if we make the changes you are talking about?

Mr. WEST. No. Perhaps in my oral testimony, I should have emphasized the bar on reimportation of diverted drugs.

Mr. WYDEN. And if it is kept just to that, you do not think that there will be a difficult situation for U.S. firms competing overseas with the one-price situation?

Mr. WEST. No; because the incentive for profit that we see with price discrimination would be eliminated.

Mr. BRENNAN. In reality, there has to be at least another price for overseas, because even in the Free world, Western Europe, pharmaceutical prices are regulated by government. The United States is the last free economy in the pharmaceutical business in the world. In Japan, Germany, and England, government health and government drug programs prices are set by government. So I don't know whatever that price might be, but if it is different from the United States, the only way we can compete with the Europeans and with the Japanese is to be able to deal with that government price.

Mr. WEST. The American consumer pays higher prices, particularly when drugs are diverted, when we have the discriminatory pricing system that exists today. We have no assurances that the better prices are passed on to the consumer.

Mr. WYDEN. One other question on this point, and maybe both of you gentlemen have an interest in it. We have got the Federal, State, and local governments all getting substantial price discounts essentially under today's kind of policy, and here we are with these \$200 billion Federal deficits, with government at every level being crunched, and out in my part of the world, schools are closing, and it is clear that government at every level is in a very tight financial situation.

My question would be, I will start with you, Dr. West, are we in a situation where if we make these changes, we have got to figure out a way to generate additional revenue? Are you all saying that taxes should be raised somewhere else to change the policy, or how do we deal with it?

Mr. WEST. There must be equity in the marketplace. There must be equity in the marketplace, because the independent retail pharmacists throughout the country are paying taxes to support the government. They must be allowed to stay in business and compete on a level playing field, so there must be equity.

Mr. BILIRAKIS. Would the gentleman yield?

Mr. WYDEN. I would be happy to yield to my colleague.

Mr. BILIRAKIS. What I understand you to say, sir, is that as a result of this price discrimination, again to use your word, and there are retail pharmacists in my district who certainly agree

with you, that it is the consumer who purchases the drugs, in a retail pharmacy who is making up that difference.

In other words, that the price is increased to the consumer who pays for the drug because of price discrimination?

Mr. WEST. Yes, that is our position.

Mr. BILIRAKIS. Is that borne out by statistics, by accounting?

Mr. WEST. I am sorry we don't have those. Commonsense would dictate that if you give it away to nonprofits, you have to make it up somewhere else.

Mr. BILIRAKIS. Even with a high markup in drugs?

Mr. WEST. At the retail level, the very latest figures are out on the net profit at the independent retail pharmacy, and it has been hovering around 3 percent for years so there is not a high markup.

Mr. BILIRAKIS. We have had prior hearings which show basically what drugs are sold for on a wholesale basis, at discount prices, and at the retail. There is quite a difference there, as I recall.

I don't have any of those statistics right here, but there seemed to be quite a markup somewhere along the line in those ranges.

Mr. WEST. The charts that I have seen, from this committee certainly, illustrate that there are tremendous markups in diverted drugs. They get into that channel, from the manufacturer to the nonprofit institution, and then certainly there are tremendous markups. In the real marketplace the retail pharmacist that purchases the drugs from the wholesalers through the legitimate channels for the public does not make an excessive profit.

We have figures and we do have statistics to bear that out.

Mr. WYDEN. Dr. Schlegel.

Mr. SCHLEGEL. It might be precisely because we have differential pricing that we have exorbitant markup in some areas to offset giveaways at the other side. That is a fundamental issue here.

Ultimately, somebody has to pay if any entity is going to remain in business, be it a retail pharmacy, a hospital, a pharmaceutical manufacturer, and I think the concern that—and I don't mean to speak for my colleagues here, that I am hearing, is when you have distorted economics out there, you have distortion in profits at various ends of the spectrum.

If we can level this thing out, ultimately it should get away from this cost shifting that you are beginning to hear about, even in many of the Government programs. We see it in the Medicaid Program.

Mr. WYDEN. Counsel would like to ask a question.

Mr. Nelson.

Mr. NELSON. This whole question of the relationship between cost and pricing, various segments of the market, it has been the subject of an awful lot of conflicting testimony. It would be very useful if we could clear that up.

Mr. Brennan, am I correct in assuming that the marginal cost of pharmaceuticals is very small, the cost involved in any single tablet?

Mr. BRENNAN. The cost of producing that individual tablet, the ingredients that go into it and the manufacturing facilities?

Mr. NELSON. Yes.

Mr. BRENNAN. Yes; I would think that would be rather small.

Mr. NELSON. Do pharmaceutical companies by and large attempt to recover their fixed costs, R&D costs, distribution system costs, all the rest of it that give rise to a substantial cost, average cost, to the pharmacy, do they attempt to recover any of that through the nonprofit distribution chain or recover that exclusively through the for-profit chain?

Mr. BRENNAN. They recover that as cost, and the entire cost of continuing to do research, promotion, manufacturing the product, the whole range of costs associated with their business, across their market line, be the customer a for-profit hospital, not-for-profit hospital or other institution or a wholesaler or direct retail account, and they try and get the best prices they can from each of those areas, I am sure. But there is not, as far as I know, any individual company program or certainly a general program throughout the industry or thought throughout the industry of only making money in one area, and as has been indicated, giving the product away in another.

The costs are attempted to be recovered throughout the system of customers.

Mr. NELSON. At least three or four of your members have in recent years gone to a single price policy.

Mr. BRENNAN. Yes.

Mr. NELSON. Has that resulted in lower or higher average prices?

Mr. BRENNAN. I have no idea on that. You know the cooperation that you have gotten from my members, and you know who those companies are. The best way to find that out is to ask them. I have no way of really inquiring about that, and that is an area I can't get into.

Mr. NELSON. Maybe Dr. West does, at presumably the highest price the pharmaceutical industry sells at. When the Merrell-Dow companies moved to one pricing policy, did average wholesale prices go up or down?

Mr. WEST. I saw the figures on the one company and the prices have decreased over the past 5 to 6 years. I can submit that to the committee.

Mr. BILIRAKIS. Would counsel yield?

One price policy meaning that they do not sell to nonprofits, at a lesser price than they sell to others.

Mr. NELSON. Yes, single price. Will you submit the average wholesale price for each of the companies that went to the one price?

Mr. WEST. I will submit the information I have today. That is all I can do.

Mr. WYDEN. I thank counsel and my colleague from Florida. This is obviously a very complicated area, and Dr. West, I am going to leave the record open and maybe you can get back to me in writing, because the question I asked, Federal, State and local governments getting significant price discounts, and absent those price discounts, somewhere in this world of deficits and tight budgets, we have to figure out how we can make up the money.

And we would be open to any suggestions that you can have to do it, and you can see that the committee is very open as to how to pursue this question. It is a complicated one, and we will be working with you in the days ahead on this.

Mr. BILIRAKIS. Mr. Chairman, I would ask that the record remain open to allow us to pose additional questions to the panel on the issue of mail order sales and physician dispensing.

Mr. WYDEN. The gentleman makes an excellent suggestion, and so ordered, and we are going to have a number of additional questions submitted in writing as well, and I will make that request shortly.

Dr. West.

Mr. WEST. I was going to request the same thing.

Mr. WYDEN. One of the things you suggested, Dr. Schlegel, was the penalties against counterfeiting and the theft of pharmaceuticals be increased. What existing penalties are you talking about, and how much would you favor increasing the penalties?

Mr. SCHLEGEL. I must confess I am not a legal expert in terms of food and drug law. Very, very recently food, drug and cosmetic violations of those laws, the penalties were increased to \$500,000, under certain circumstances, and that will help.

Our whole premise is that the system is not working very well now, and we need to stiffen the penalties, and we need to put more resources toward enforcement, as Mr. Mahaffey has pointed out, and hope that at least dries up some of the problem.

But that is only part of the problem.

Mr. WYDEN. One additional question for you, Mr. Mahaffey, the State power to lift the licenses of pharmacists who violate the law, you have stated in your statement, and continually, that you want to see greater cooperation between the Federal Government and State agencies.

Is there a centralized process, a repository or some other process which collects all violations of law or professional standards by pharmacists throughout this country?

Mr. MAHAFFEY. No centralized one source for all health professionals. You have to take the responsibility of State laws into who can prescribe, diagnose, and dispense. In the profession of medicine, dentistry, in the profession of pharmacy, and in the profession of nursing, there exists a disciplinary clearinghouse that collects data, yes, violations in terms of suspensions and revocations on the individual, the leniency, and they distribute that to all the State attorneys general, and to all other boards of that like profession.

Those exist within those four professions. There also exists a disciplinary clearinghouse through the Council of State Governments—Clear.

Mr. WYDEN. This has been of interest to the Subcommittee on Health as well, and I just ask you hypothetically, if a pharmacist violated the law in the chairman's State, in the State of Michigan, and decides that he or she wants to move a couple thousand miles away to Oregon, would the process work so that Oregon, before they gave that person a license, they would know about the violation in Michigan?

Mr. MAHAFFEY. Yes; they would under our system of licensure exchange. We have a reciprocity clearinghouse that would screen the practice record of that individual, and if there was a law violation on his record, that would be moved with his license, yes, we do have a check.

Mr. BILIRAKIS: Every State board of pharmacy is required to furnish this information on a national basis to your clearinghouse?

Mr. MAHAFFEY. Not required, volunteer.

Mr. BILIRAKIS. Do they adhere to it?

Mr. MAHAFFEY. About half of them on the disciplinary clearinghouse.

Now, another problem in terms of licensure, the boards of pharmacy license two entities, a practitioner and they also license to be outlet. They also license manufacturers and wholesalers, 50-50, but in terms of inspections, each board licenses the individual practitioner, and the pharmacy, be it community, hospital, or whatever—

Mr. BILIRAKIS. It seems to me, sir, again maybe I am throwing more onus on your association than should be there, but it seems to me you could improve that 50-percent record. What is the sense of a national association if, in fact, it is not going to perform the function of a central clearinghouse?

I know there are a lot of other significant areas that are covered in functions that are covered.

Mr. MAHAFFEY. Well, certainly, we began the disciplinary clearinghouse as a service to the States to keep down the very thing you are talking about. This is about the person who is licensed and convicted, this happens all over the place, Florida, Arizona, and they move back and forth, depending upon what violation they are under prosecution from at the current time, but the disciplinary measures that are—you have to understand that there are many, many approaches to discipline in the profession.

There are letters of reprimand, various procedures. These do not, all of these procedures in terms of law enforcement, disciplinary hearings, for instance, and enforcement, don't take the same pattern.

They vary from State to State, so we have to take those into consideration and that makes our disciplinary clearinghouse, for instance, takes two things into consideration, if a license was legally suspended or revoked, that we report.

There are various other mechanisms, and that is the bottom line. Suspension and revocation is the bottom line, and there are many things that take place before that person's license is suspended or revoked.

Mr. WYDEN. One other question, if I might.

Mr. Brennan, it is my understanding that a lot of your members have limitations in their contracts with hospitals on resale, and that this is something that you all feel is significant.

Tell me a little bit about how this works, did any of your people ever sue the hospital for breach of contract?

Mr. BRENNAN. I am not sure whether they have or not. The certifications in the contracts may well have occurred over a period of—a long period of years, but they certainly have been a common occurrence, since the Supreme Court ruled in the *Portland Retail Druggists* case, where the Supreme Court indicated that was quite an appropriate method of the manufacturer dealing with the non-profit purchasing institution.

I think it is a regular, if not almost a uniform thing now, and to what extent individual companies are trying to enforce it, I just don't know.

Mr. WYDEN. We will hold the record open and maybe you could give us additional information on the record with respect to that. If this is going to be an enforcement tool, we have got to see some evidence that it is being followed up on, if there are instances of breach of contract.

I think perhaps both my colleague from Florida and I, I on behalf of the chairman, will submit some questions in writing to our witnesses. All of you have been very patient.

This is one of a series of hearings that the subcommittee is holding to look into this. We have now all reached an agreement as to the nature of the problem.

There is still some debate as to what we should do about it, but certainly consumers who learn of the problem can't feel very confident about our current efforts to deal with drug diversion, and much needs to be done. We have had a variety of good suggestions all the way from strengthening penalties to work that professional associations can pursue, and the subcommittee will be following up on all of these matters in the days ahead.

Mr. MAHAFFEY. Could I submit a survey of pharmacy laws and our model State Pharmacy Act?

Mr. WYDEN. Without objection, for the record or for the files. Do any of our other witnesses have further comments that they would like to make?

Gentlemen, thank you for your patience, and the subcommittee is adjourned.

[Whereupon, at 1 p.m., the subcommittee was adjourned.]

[The following material was submitted for the record:]





American  
Pharmaceutical  
Association

2215 Constitution Avenue, NW  
Washington, DC 20037  
(202) 628-4410

APhA

John F. Schlegel, PharmD  
President

James A. Maln  
Chairman of the Board

January 15, 1986

The Honorable Michael Bilirakis  
Member  
Subcommittee on Oversight and Investigations  
U. S. House of Representatives  
1130 Longworth House Office Building  
Washington, DC 20515

Dear Mr. Bilirakis:

On behalf of the Board of Trustees and members of the American Pharmaceutical Association (APhA), the national professional society of pharmacists, I wish to thank you for the invitation in your December 17 letter to provide our responses to three questions related to your Subcommittee's current investigation of prescription drug diversion. The questions and APhA's responses follow:

1. Can you describe to the Subcommittee the manner and extent to which prescription drugs are sold to the public through the mail? How is this practice regulated?

In mail order prescription services, prescription orders written by prescribers are usually mailed to the facility offering the service, which is often in another state. The order is then dispensed and mailed back to the patient. Such services are offered primarily through four sources: (1) as a part of health benefit plans provided to employees by employers, (2) as a service to members of an organization, such as the American Association of Retired Persons, (3) by the Federal Government, through the Veterans Administration, and (4) increasingly as a customer service by private insurance carriers and firms serving consumers, such as Sears Roebuck & Co.

APhA does not have direct access to financial data of mail order prescription services, but according to a report which appeared in the May/June 1985 issue of In Vivo--The Business and Medicine Report published by Channing, Weinberg & Company, Inc., the twelve largest of these facilities, including the Veterans Administration, dispense an estimated 42 million prescriptions per year.

Because mail order prescription services operate across state lines, there is no simple answer to how they are regulated. However, in general, the facilities themselves are subject to the regulations of the State Board of Pharmacy in the state in which they are located. Many Boards of Pharmacy, however, maintain that they also have a

Academy of Pharmaceutical Management  
Academy of Pharmaceutical Sciences

Academy of Pharmacy Practice  
Student American Pharmaceutical Association

The National Professional Society of Pharmacists

The Honorable Michael Bilirakis  
 January 15, 1986  
 Page 2

responsibility to assure that the citizens of their state receive the highest quality of pharmaceutical services that are available, irrespective of where the firm providing them is located, and they therefore feel that it is necessary that they have regulatory control of mail order prescription services which operate outside of their state boundaries but serve state residents. You may obtain specific information regarding the regulation of mail order prescription services from: National Association of Boards of Pharmacy, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068.

2. Are you aware of a growing practice of doctors selling prescription drugs in their own office? How does this practice work? Who supplies these drugs? How are they regulated?

Although definitive data is not available to us, APhA is convinced that the dispensing of pharmaceuticals by physicians is on the increase. This practice has long been in existence in limited, more remote geographic areas where pharmaceutical services were not available, but it now appears that physician dispensing is becoming more widespread. This has been brought about, at least in part, by a change in the way such drug products are made available to physicians. Formerly, physicians who wished to dispense medications would purchase their drug supplies in bulk quantities from a pharmacy, or more commonly, from a physician supply company. Physicians would then repackage the drugs themselves for dispensing to patients. Recently, however, commercial firms have emerged which sell directly to physicians prescription drugs already repackaged and labeled in dispensing containers, making dispensing a much more attractive option for physicians. Such firms are beginning to proliferate because of the economic situation in which many physicians now find themselves due to competition from the growing oversupply of physicians and the cost of containment efforts aimed at limiting reimbursement for services.

The regulation of these services is the responsibility of the state in which the dispensing occurs, so there is no simple answer to how that regulation occurs. Ideally, dispensing practices, no matter in what setting they occur, should be subject to the same regulations, usually administered by the State Board of Pharmacy. Although this is indeed the case in some states, in others the regulatory climate becomes murky because of turf questions that arise between the State Board of Pharmacy and the State Board of Medical Examiners. In such cases, the pharmacy boards maintain they have the right to control the distribution of drug products, while the medical boards insist that only they have jurisdiction over physicians' practices. Again, you may obtain more specific information on this matter from the National Association of Boards of Pharmacy.

The Honorable Michael Bilirakis  
January 15, 1986  
Page 3

3. To your knowledge, have these two distribution channels been supplied with diverted or counterfeit drugs?

The American Pharmaceutical Association does not have access to information which would enable us to answer this question. However, it is clear that mail order prescription services and physician supply firms are no more or no less vulnerable to receipt of diverted or counterfeit drugs than are others in the distribution chain. APhA has long been concerned that such operations circumvent the traditional checks and balances that exist when a true manufacturer-prescriber-patient-pharmacist relationship exists. We believe that any weakening of this relationship raises the possibility of irregularities in a drug distribution system that has proven itself over the years as being both safe and effective.

Again, thank you for the opportunity to provide further comments, and please convey to the entire Subcommittee APhA's appreciation and thanks for the excellent work that is being done in the best interest of the public health.

Sincerely,



John F. Schlegel, Pharm.D.  
President

JFS/ajb

cc: The Honorable John D. Dingell  
Chairman, Subcommittee on Oversight and Investigations



## AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

4630 Montgomery Avenue/Bethesda, Maryland 20814/(301) 657-3000

January 15, 1986

The Honorable Michael Bilirakis  
Subcommittee on Oversight  
and Investigations  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Bilirakis,

This is in response to your letter of December 17, 1985 in which you requested additional information from the American Society of Hospital Pharmacists regarding prescription drug diversion. I am pleased to respond to your specific inquiries as follows:

1. Can you describe to the Subcommittee the manner and extent to which prescription drugs are sold to the public through the mail? How is this practice regulated?

As you know, ASHP's membership is comprised largely of pharmacists who practice their profession in hospitals or other organized health care settings. As a result, our members have little first-hand knowledge of the manner in which mail-order prescription drugs are sold to the public. However, some members do practice in our nation's veterans' hospitals where a program of mail-order prescription drugs is made available and authorized by the Veterans Administration. In addition, we understand that at least one senior citizen organization, the American Association of Retired Persons, conducts a mail order prescription drug service.

2. Are you aware of a growing practice of doctors selling prescription drugs to patients in their own office? How does this practice work? Who supplies these drugs? How are they regulated?

Yes, ASHP has witnessed the recent trend toward marketing prescription drugs directly through a physician's office. There seems to be a number of ventures that follow variations of the same method, i.e., a distributor not only stocks but completely outfits a physicians' office with all of the requisite equipment to provide prescription drug services to his patients. By doing so, the patient avoids the need to visit a pharmacist and the physician adds a profitable service to his practice. As this trend expands, the risk to consumers lies in the fact that physicians are not subject to FDA or state regulatory requirements pertaining to prescription

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January 15, 1986

drugs. Also, the degree to which physicians' samples were involved in the recent Georgia investigation strongly suggests that any expansion of dispensing services by unregulated physicians may prove to be fertile ground for gray market drugs.

3. To your knowledge, have these two distribution channels been supplied with diverted or counterfeit drugs?

ASHP has no direct knowledge that any of these distribution channels is being supplied with diverted or counterfeit drugs. However, given today's competitive market system and in light of the ease by which gray market drugs are obtained, it is not difficult to imagine that, where proprietary interests are involved, reliance upon diverted drugs may occur.

I appreciate the opportunity to respond to your questions and hope you find the information to be helpful. Should you desire any further information, please do not hesitate to call upon me.

Sincerely,



Joseph A. Oddis, Sc.D.  
Executive Vice President

JH/AF/10901



nabp

## National Association of Boards of Pharmacy

O'Hare Corporate Center • 1300 Higgins Road • Suite 103  
Park Ridge, IL 60068 • 312/698-6227

January 15, 1986

The Honorable Michael Bilirakis  
House of Representatives  
1130 Longworth House Office Building  
Washington, DC 20515

Dear Congressman Bilirakis:

First, may I express appreciation on behalf of myself, the Executive Committee and the Association for the invitation to present testimony and be heard on December 6. I enjoyed the proceedings, and, as indicated, we are at the committee's disposal should you wish to call on us.

Your letter of December 17 requested information on three topics: Prescriptions that are filled through the mail; Physicians dispensing legend drugs to patients in their office; and to what extent are these two areas of distribution subject to diversion or the dispensing of counterfeit drugs?

First of all, as indicated in the Survey of Pharmacy Laws, page 24, enclosed, all states require a "permit" for license to those outlets that distribute prescription legend drugs. There are certain pharmacies that may "specialize" in the solicitation of prescription by mail. This solicitation usually takes the form of advertising in various journals and are directed to special groups, such as labor unions or the elderly. This is not to say that any legal state recognized pharmacy cannot use the mails to distribute legend drugs. Many pharmacies do. But only for local residents.

Regulations of mail service pharmacies are the same as with any licensed pharmacy. First consideration is the state's statute covering the practice of pharmacy and the distribution of legend drugs. The pharmacy must have a permit from the state (Board), must have a licensed pharmacist present to supervise the pharmacy and provide the proper information to the patient. Some states mandate pharmacist consultation. The second consideration is the requirements of the

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Federal Food, Drug and Cosmetic Act. Within that act, regulations pertaining to the Durham-Humphrey Amendments come into play. Any individual who dispenses a prescription legend drug must determine the legitimacy of the order. If there is a physician (prescriber) patient relationship, has diagnosis occurred? Is there a medical therapeutic need for the drug or device? In general, the enforcement of this provision of the Federal Statute falls to the FDA. The extent of this enforcement is minimal at best, I believe. Enforcement is left up to state authorities. Current state boards of pharmacy spot-check for the validity and authenticity of prescriptions currently on file in licensed pharmacies. Boards of pharmacy enforce this requirement under both state and federal law.

As you know, under state statutes, various health practitioners can diagnose and prescribe. These health practitioners would be the physician (MD/DO), Dentist, Podiatrist, Veterinarian (Optometrists in some states) can prescribe diagnostic aids. Currently in some states, nurse practitioner and Physician's Assistants can diagnose and prescribe under certain conditions.

Most state acts require diagnosis and prescribing be done in the course of professional practice. An example of this is the dentist or podiatrist that prescribes birth control pills. This would not be in the course of professional practice.

Currently, the matter of registration of out-of-state pharmacies is a major concern of many states. I am not certain that all pharmacies comply with the previously mentioned conditions of Durham-Humphrey. However, those that are engaged in mail order prescription service indicate that they do comply, and it is my understanding that dispensing is monitored by state and sometimes federal drug law agencies. Some states register out-of-state pharmacies with the intent that the foreign outlet must comply with state statutes and regulations. Since the product selection laws vary from state to state, this is a very complicated issue and one which this association and many of its boards are considering at the present time. Pharmacies that "specialize" in mail solicitation of prescriptions are subject to the same conditions as any other outlet in that state.

The subject of physicians dispensing drugs has been one of interest to this association for many years. Most medical practice acts, and for that matter, pharmacy practice acts, may permit the physician to dispense medicine to his or her patient, under prescribed conditions and provided state and federal statutes and regulations are complied with. It is my understanding that there is an increased amount of physicians dispensing currently. This often happens when the economy is struggling and the physician is looking for other means of increasing income. It is generally conceded that the physician, if he dispenses, should be subject to the same requirements that currently exist for dispensing practice in both federal and state law, e.g. storage, labeling, packaging, etc.

Honorable Michael Billrakis

January 15, 1986

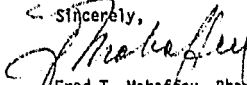
It is also conceded that, often times, the record keeping and control requirements, as well as the packaging requirements, are not adhered to by dispensing physicians.

Much of the information which your committee has reviewed indicates that haphazard dispensing and distribution practices lead to diversion. The amount of diversion that occurs in a dispensing physician's office is not known since medical boards, FDA and DEA, do not monitor these dispensing sites. Boards of pharmacies often times do not have authority to monitor physician's offices. Medical board inspections are limited or non-existent and are confined to complaints in the area of unprofessional conduct and not drug distribution. The dispensing physician, of course, should be subject to the same requirements as the pharmacist since both state and federal statutes were put in place to insure the integrity of the drug and protect the patient.

Do these two distribution channels create diversion? Evidence uncovered during the course of investigations in Georgia indicates that mail fraud can exist in wholesale amounts if you have a sufficient number of individuals who wish to secure drugs through this mechanism. Forgeries can occur in mail order prescription practices just as they can inside the community. Mail service pharmacies can use samples just as dispensing physicians can purchase counterfeit drugs just as other pharmacies can.

I hope this reply assists you and the committee in its decision making process. If it raises questions or if further explanation is needed, please let me know.

Sincerely,



Fred T. Mahaffey, Pharm. D.  
Executive Director

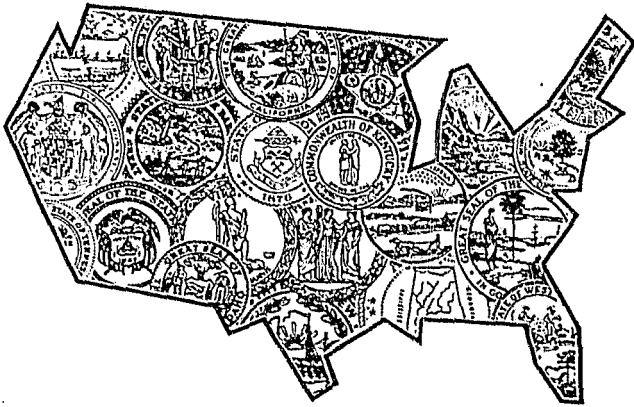
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Enclosure





**survey of  
pharmacy law**  
1985-1986



**including all 50 states,  
d.c. & puerto rico**

PREFACE TO THE SURVEY OF PHARMACY LAW

Of the 50 states, the District of Columbia and the American Territories, each Jurisdiction has statutory provisions for the regulation of the practice of pharmacy within their borders. The majority of these domains invest this responsibility in a board of pharmacy, a group of practitioners and/or public citizens who execute constitutionally dictated statutes and enforce regulations which the boards themselves may promulgate from time to time.

The National Association of Boards of Pharmacy (NABP), founded in 1904 and headquartered in Park Ridge, Illinois, serves all American boards of pharmacy in matters of interstate reciprocity of licensure, uniform examination and licensure, and other matters of mutual concern to all boards of pharmacy.

NABP is composed of 49 active members (47 states, the District of Columbia and Puerto Rico) and nine associate members (California, Florida, Hawaii, the Virgin Islands, plus five Canadian provinces, Alberta, British Columbia, Manitoba, Ontario and Saskatchewan). Active membership is based upon a reciprocal agreement with other active member states and the association.

This *Survey of Pharmacy Law* covers four main areas of responsibilities in which boards of pharmacy are concerned: Organizational Law (how the boards are constituted and their powers), Licensing Law (requirements for various states of licensure), Internship Requirements and Drug Laws. Each section contains a series of charts, fully footnoted, which are intended to serve as sources of reference providing information which is most frequently requested of the association. With each jurisdiction operating independently of all other boards, and of the association, the complexity of the various laws and regulations are often confusing, however, we hope this *Survey* will explain and simplify the laws by which pharmacy is practiced in the United States.

This *Survey* edition reflects pharmacy law updated as of September, 1985, as supplied by the state boards of pharmacy. While NABP believes the information to be complete and correct, it disclaims any liability or responsibility. This *Survey* is annually updated and will be again published in 1986, with changes which were approved by the states in the interim. For your information, a roster of all board of pharmacy secretaries (chief administrative officers) has been published in this *Survey* (back page). If you have any questions regarding specific laws or regulations, we suggest that the individual state board be contacted. This office welcomes any inquiries dealing with interstate reciprocity affairs or activities of the association.

Fred T. Mahaffey  
Executive Director

## ORGANIZATIONAL LAW

## I. BOARD ACTIVITIES

State	First Enactment	Board Year	Published Annual Report	Reprints of Laws and Regulations Available	Number of Examinations Annually	Nature of Present Act 1
Alabama	1931	A	No	Yes	3	C
Alaska	1935	B	Yes	Yes	1	C
Arizona	1903	B	Yes	Yes	2	C
Arkansas	1891	B	Yes	Yes	2 G	C
California	1891	B	No	Yes	2	C
Colorado	1887	B	No	Yes	2	C
Connecticut	1891	B	Yes	Yes	2 G	C
Delaware	1883	B	Yes	Yes	2	C
Dist. of Columbia	1908	B	No	Yes	3	C
Florida	1889	B	Yes	Yes	2	C
Georgia	1881	B	No	Yes	3	C
Hawaii	1949	B	No	Yes	2 G	C
Idaho	1889	B	Yes	Yes	3 G	C
Illinois	1881	A	Yes	Yes	2	C
Indiana	1899	B	No	Yes	At least 2	C
Iowa	1880	F	Yes	Yes	2	C
Kansas	1885	B	No	Yes	2	B
Kentucky	1874	A	No	Yes	2 G	C
Louisiana	1868	A	Yes	Yes	3 G	C
Maine	1877	B	Yes	Yes	2	C
Maryland	1902	B	Yes	Yes	2 or 3	C 1
Massachusetts	1885	B	Yes	Yes	2 G	C
Michigan	1885	B	Yes	Yes	2	C
Minnesota	1885	B	E	Yes	2	C
Mississippi	1892	B	Yes	Yes	2	C
Missouri	1881	B	Yes	Yes	2	C
Montana	1896	B	E	Yes	2	C
Nebraska	1887	B	No	Yes	3	C
Nevada	1901	B	No	Yes	2	C
New Hampshire	1875	B	No	Yes	3	C
New Jersey	1877	C	Yes	Yes	3 G	C 1
New Mexico	1889	B	No	Yes	2 G	C
New York	1884	B	Yes	Yes	2	C
North Carolina	1881	H	Yes	Yes	2	C
North Dakota	1887	B	Yes	Yes	2	C
Ohio	1884	B	Yes	Yes	2	C
Oklahoma	1899	B	Yes	Yes	2	C
Oregon	1891	B	No	Yes	2 G	C
Pennsylvania	1887	B	Yes	Yes	2 G	C
Puerto Rico	1927	B	Yes	Yes	2 G	C
Rhode Island	1870	B	Yes	Yes	3	C
South Carolina	1876	B	Yes	Yes	3	C
South Dakota	1899	B	Yes	Yes	3	C
Tennessee	1893	B	Yes	Yes	3	C
Texas	1907	D	Yes	Yes	3	C 1
Utah	1892	B	No	Yes	2	C
Vermont	1894	A	No	Yes	2	B
Virginia	1886	B	Yes	Yes	2	C
Washington	1891	B	No	Yes	2 G	C
West Virginia	1881	B	Yes	Yes	2-3	C
Wisconsin	1882	C	No	Yes	3	C
Wyoming	1888	A	Yes	Yes	3	C

## LEGEND:

A - January 1 to December 31  
 B - July 1 to June 30  
 C - June 1 to May 31  
 D - September 1 to August 31  
 E - Biennial  
 F - May 1 to April 30  
 G - At discretion of the Board

H - October 1 to September 30

1 - Compulsory (C) - Only persons holding a license are permitted to practice the occupation, and unlicensed persons are prohibited from working in the field. Some laws and regulations do include exceptions which may invalidate compulsory provisions.

ORGANIZATIONAL LAW

II. ADMINISTRATIVE AGENCIES

State	Designation (See Legend)	Board Members	Examining Committee of Pharmacists	Board or Committee Appointed by	Rules and Regulations Made by	Licenses Issued by	Licenses Revoked by
Alabama	B	5		K		B	B
Alaska	A	7**	3	K	B	T	A
Arizona	B	7**		K	B	B	B
Arkansas	B	7**		K	B	B	B
California	B, Q	10***	11	K	B	B	B
Colorado	B, U	7**		K	B	B	B
Connecticut	C, S	6**		K	C, S	C, S	C
Delaware	B	6*		K	B	D-1	B
Dist. of Columbia	A	7**		L	A, L	A	A, L
Florida	A	7**		K	A	A	A
Georgia	B, R	8*	8*	K	B	B	B
Hawaii	B, T	7	5	K	B	B	B
Idaho	B	5		K	B	B	B
Illinois	B, D	7	7	D	D	D	D
Indiana	A	6*	6	K	A	A	A
Iowa	V	7**	5	K	V	V	V
Kansas	B	6*		K	A	A	A
Kentucky	A	6		K	A	A	A
Louisiana	A	21	21	K	A	A	A
Maine	F	6*		K	F	F	B, P
Maryland	A	8**		K	A	A	A
Massachusetts	G, W	7*		K	G, N	G	G
Michigan	A, X	8**	6	K	A	X	A
Minnesota	A	7**		K	A	A	A
Mississippi	B	7		K	B	B	B
Missouri	A, W	7*		K	A	A	A
Montana	A	5**		K	A	T	A
Nebraska	H, N	5*	4	N	H, N	N	M
Nevada	B	6		K	B	B	B
New Hampshire	A	6*		K	A	A	A
New Jersey	B	9**		K	B	B	B
New Mexico	A	6		K	A	A	A
New York	A, I	19****	15	O	O	I	O
North Carolina	A	6		K	A	A	A
North Dakota	B	5		K	B	B	B
Ohio	B	8		K	B	B	B
Oklahoma	B	5		K	B	B	B
Oregon	B	7**		K	B	B	B
Pennsylvania	B, Z	7**	5	K	B	B	B
Puerto Rico	B	5		K	A	A	A
Rhode Island	A, N	5		M	A	A	CC
South Carolina	A	8*		K	A	A	A
South Dakota	B	4*		K	B	B	B
Tennessee	A, J	6		K	A	A	A
Texas	B	9**		K	B	B	B
Utah	EE	5*	4	K	EE	EE	EE
Vermont	A	7		K	B	D-1	B
Virginia	DD	5		K	A	A	A
Washington	B	7**		K	B	B	B
West Virginia	A	7**		K	A	A	A
Wisconsin	V, X	7**		K	V	V	V
Wyoming	B	3		K	B	B	B

\* . . . 1 member a layperson  
 \*\* . . . 2 layperson members  
 \*\*\* . . . 3 layperson members  
 \*\*\*\*. . . 4 layperson members

LEGEND:

All examinations given by Board or Examining Committee of Pharmacists.  
 A - Board of Pharmacy  
 B - State Board of Pharmacy  
 C - Commission of Pharmacy  
 D - Dept. of Registration & Education  
 D-1 - Division of Licensing & Registration and approval of Board

E - State Pharmacy Examiners  
 F - Board of Commissioners of Pharmacy  
 G - Board of Registration in Pharmacy  
 H - Board of Examiners in Pharmacy  
 J - Dep't. of Education  
 J - Dep't. of Commerce & Insurance  
 K - Governor of State (in NC pharmacist members elected; in CA, Senate Rules Committee & Speaker of Assembly each appoint 1 public member)  
 L - Mayor  
 M - Director of Department  
 N - Department of Health  
 O - Board of Regents  
 P - Court Proceedings only

Q - Dep't. of Professional and Vocational (Calif.—Dept. of Consumer Affairs) Standards  
 R - Secretary of State  
 S - Dep't. of Consumer Protection  
 T - Dep't. of Commerce  
 U - Dep't. of Regulatory Agencies  
 V - Pharmacy Examining Board  
 W - Dep't. of Consumer Affairs  
 X - Dep't. of Licensing and Regulation  
 Y - Dep't. of Law and Public Safety  
 Z - Dep't. of State  
 CC - Health Dep't. Adjudication Officer  
 DD - Dep't. of Health Regulatory Boards  
 EE - Division of Occupational Professional Licensing

## ORGANIZATIONAL LAW

## III. MEMBERSHIP OF BOARDS, COMMISSIONS AND COMMITTEES

State	Resident of State	Years of Practice as R.Ph.	Qualifications For			Compensation	
			Member State Ph. Association	Graduate Recognized College of Pharmacy	Term Length In Years	Per Diem	Expense Incurred
Alabama	A	10		A	5	\$ 40.00	F
Alaska	A	3			4	\$ 80.00	F
Arizona	A	10		A	5	\$ 40.00	F
Arkansas	A	5			5	\$ 45.00	F
California	A				4	\$ 50.00	F
Colorado	A	5			5	\$ 50.00	H
Connecticut	I				E*	J	J
Delaware	I			A	5	\$ 60.00*	H
Dist. of Columbia		5			3	\$ 25.00	
Florida	I	4			4	\$ 60.00	F
Georgia	A	5			5	\$ 59.00	F
Hawaii	I	5		A	4	\$ 00.00	F
Idaho	A	5		A	5	\$ 60.00	F
Illinois	A	5		A	5	\$ 60.00	F
Indiana	A			A	4	\$ 35.00	F
Iowa	I	5		A	3	\$ 40.00	J
Kansas	A	5		A	3	\$ 35.00	F, L
Kentucky	A	5		A	3	\$ 75.00	F
Louisiana	I	5			6	\$ 35.00	F
Maine	A	5		B	5	\$ 25.00	F
Maryland	I	5		A	5	\$ 45.00	F
Massachusetts	A	10			5	\$1050.00 C	F
Michigan	A	2			4	\$ 50.00	F
Minnesota	A	5			4	\$ 35.00	F
Mississippi	I	5		I	5	\$ 40.00	J
Missouri	I				5	\$ 50.00	F
Montana	I	5		A	5	\$ 50.00	F
Nebraska	I	5		A	5	\$ 15.00	F
Nevada	I	5 A			3	\$ 60.00	K
New Hampshire	I	10		A	5	\$ 50.00	F
New Jersey	I	5 A.		A	5	\$ 50.00	J
New Mexico	A	8			5	\$ 58.00	F
New York	I	5			5	\$ 75.00	F
North Carolina	A				3	\$ 35.00	F
North Dakota			I	I	5	\$ 45.00	F
Ohio				A	4	\$ 108.00	J
Oklahoma		5	A		5	\$ 50.00	F
Oregon	I	5		A	4	\$ 30.00	F
Pennsylvania	A	10		A	8	\$ 30.00	F
Puerto Rico	A	5			3	\$ 15.00	F
Rhode Island	A	5		A	4	\$ 600.00 C	F
South Carolina	A			A	6**	\$ 35.00	F
South Dakota	A		A		3	\$ 60.00	F
Tennessee	I	5		I	8	\$ 50.00	F
Texas	A	5		A	8	\$ 100.00	K
Utah	I	5		A	5	\$ 25.00	F
Vermont		5			5	\$ 30.00	F
Virginia				A	5	\$ 50.00	F
Washington	I	5		A	4	\$ 50.00	F
West Virginia	A			A	5	\$ 35.00	F
Wisconsin	A			A	4	\$ 25.00	F
Wyoming	I	5			6	\$ 50.00 G	F

\* - no more than \$500 annually

\*\* - pharmacist-at-large and lay member serve coterminously with governor

## LEGEND:

A - Required of all, except public members

B - Required of majority

C - Annually

D - Fixed by director

E - Expires with term of governor (\* or until replaced)

F - In addition to per diem: mileage

G - Wyoming \$60 out of state

H - Per diem includes expenses

I - Required of all

J - Mileage and "approved" expenses only

K - In addition to per diem: travel (transportation) expenses

L - In addition to "P" \$10.00 per quarter subsistence

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**LICENSING LAW**

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**IV. QUALIFICATIONS FOR LICENSURE**

Laws in all states, including the District of Columbia and Puerto Rico, require applicants for licensure to: 1) be of good moral character, 2) be 21 years of age (note exceptions in Table V — Requirements for Examination and Registration), 3) have graduated from an accredited first professional degree program of a college of pharmacy, and 4) have passed an examination given by the board of pharmacy. All states, the District of Columbia, Puerto Rico and the Virgin Islands use the National Association of Boards of Pharmacy Licensure Examination (NABPLEX), except California.

All jurisdictions require candidates for licensure to have a record of practical experience or internship training acquired under the supervision and instruction of a licensed practitioner.

All jurisdictions that grant licensure by reciprocity require that a pharmacist who applies for such licensure shall furnish evidence of having acquired a license by examination in a state that grants licensure by reciprocity. It is necessary that this license be in good standing, as the original license is the basis for transferring the license to other reciprocal states.

An increasing number of jurisdictions have established continuing competency requirements for licensure. States with currently operating "CE" requirements are: Alabama, Alaska, Arizona, Arkansas, California, Delaware, Florida, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Puerto Rico, South Dakota, Tennessee, Washington, and Wyoming.

There are no jurisdictions that issue original licenses to "assistant pharmacists" or pharmacy tech (aides). Examination and issuance of new certificates has been abolished in all states, but certificates previously issued and now in effect may be renewed in the following states: Alabama, Connecticut, Delaware, Illinois, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, New Jersey, North Carolina, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Virginia, Wisconsin and Puerto Rico.

Publications concerning the NABPLEX licensure examination and Internship/Preceptor Experience are available from the NABP Publications Desk, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068. The American Council on Pharmaceutical Education, the nationally recognized accrediting agency for professional degree programs in pharmacy, is also the national agency for approval of continuing education providers. A list of approved professional degrees and continuing education providers is published annually. Information regarding the Council's activities may be obtained by writing to the ACPE at 311 West Superior Street, Chicago, IL 60610.

## LICENSING LAW

## V. REQUIREMENTS FOR EXAMINATION AND REGISTRATION

(For former requirements in lieu of college prerequisite, see Requirements for Reciprocal Licensure)

State	Personal Qualifications		Education and Experience		
	Age	Citizenship*	H.S. Graduation Since	Graduate College of Pharmacy Since**	Prior Practical Experience
Alabama	19		1927	1927	F, H, S, M
Alaska			1955	1955	R, S
Arizona	none			1935	F, S, Z
Arkansas	21	x	1925	1936	1 Yr. F, H, Z
California	18		1928	1928	1500 Hrs.
Colorado	21		1929	1929	1 Yr. H, M, AA
Connecticut	18		1923	1926 D	1 Yr. M, S
Delaware	21		1927	1949	S
Dist. of Columbia	18		1928	1928	1500/1000 M
Florida	18		1928	1928	2080 Hrs. F, M, Y
Georgia	18		1927	1934 D	S
Hawaii	18			1949	1 Yr.
Idaho	majority		1925	1930	M, S
Illinois	21		1917	1917 D	J
Indiana	18		1923	1920	6 Mo. F, H, M, U
Iowa	legal			1936	F, M
Kansas			1921	1929	1 Yr. M, S
Kentucky	18	x	1926	1924	F, M - 1600 Hrs.
Louisiana	21	xx	1928	1928	1500 Hrs. F, H, M
Maine	21	x	1927	1931	1500 Hrs.
Maryland	18		1920	1920	1 Yr. F, S
Massachusetts	18		1948	1948	S
Michigan	18		1924	1938	1000 Hrs. M
Minnesota	21		1920	1929 D	F, S, CC
Mississippi	21		1921	1921 D	1500 Hrs. F, K
Missouri	21		1923	1937	1500 Hrs.
Montana			1926	1939	C, F, K, L, M, S
Nebraska	21		1920	1942	F, S
Nevada			1914	1948	C, H, S
New Hampshire	18		1927	1939 D	C, F, K, L, S
New Jersey	21	xx	1923	1920	9 Mo. C, F, H, M
New Mexico			1935	1940	M, W
New York	21	xx	1925	1905	6 Mo. M
North Carolina	18		1922	1922	F, M, S, V
North Dakota	18		1913	1915	F, K, M, S
Ohio	18		1920	1915	F, M, S
Oklahoma			1921	1923	1 Yr. F, M
Oregon	18		1919	1922 D	1 Yr. H, M
Pennsylvania	21		1925	1906	1500 Hrs.
Puerto Rico	21		1927	1927	1 Yr. (1000 Hrs.)
Rhode Island	18			1910	F, S (1500 Hrs.)
South Carolina			1918	1918	M, S, BB
South Dakota	18		1927	1933	9 Mo. F
Tennessee	18		1919	1930	F, K, L, P, S, V
Texas	18		1926	1934	S, X
Utah			1925	1927	1500 Hrs.
Vermont	18		1929	1956	1500 Hrs.

## LICENSING LAW

## V. REQUIREMENTS FOR EXAMINATION AND REGISTRATION -- (cont.)

(For former requirements in lieu of college prerequisite,  
see Requirements for Reciprocal Licensure)

State	Personal Qualifications		Education and Experience		
	Age	Citizenship*	H.S. Graduation Since	Graduate College of Pharmacy Since**	Prior Practical Experience
Virginia	18		1922	1922	6 Mo. M
Washington	18	xx	1914	1914 D	1500 Hrs. F, K, M
West Virginia	18		1923	1923	9 Mo. F, M
Wisconsin	18		1926	1927 D	1 Yr. F, H, M
Wyoming	adult	xx-not resident alien	1925	1936	S

\* A reference attesting to good moral character is required in all States; Physical examination is required in South Dakota.

\*\* Five-year program required for graduation in all colleges. Six-year program offered by several colleges.

x = full citizenship.

xx = full citizenship, or legal declaration of intention, or resident alien.

## LEGEND:

- A - Examination required in all states.  
 B - Legal age required in all states except South Carolina.  
 C - Good moral character required of all applicants (not mentioned in statute of sixteen states).  
 D - Exemptions provided for apprentices, assistants or those having experience at that time.  
 E - Experience must be in community pharmacy (hospital pharmacy experience not accepted).  
 F - Experience must be obtained in either hospital pharmacy or retail pharmacy licensed by the Board.  
 G - Credit allowed for experience in hospital pharmacy not to exceed one-half time required.  
 H - Some experience must be acquired after graduation.  
 J - Internship gained in conjunction with academic credit (externship, clerkship, clinical rotation) 400 hours required by statute.  
 K - Board may approve special internship and externship program.  
 L - Passing grade specified in Law. In Tennessee as determined by the Board, in New Hampshire and South Carolina by regulation and in Montana by Rule.  
 M - Intern registration required to validate experience.  
 N - Apprentice registration permitted (optional).  
 C - Experience subsequent to graduation after 1939.  
 P - Experience subsequent to graduation after 1938.
- Q - Failure to secure citizenship within five years automatically annuls license.  
 R - Alaska-160 of total 1500 must be completed after graduation; Connecticut-1000 hrs. (apprentice training).  
 S - 1500 hours.  
 U - Indiana-Structured externship program. No "H" required.  
 V - North Carolina-600 hours; Tennessee-500 hours.  
 W - 2000 hrs. (1 yr. practical experience). All hours may be concurrent with school. 400 hrs. of which may be acquired in clinical pharmacy option courses or demonstration projects by the board. 1500 hrs. in approved program of supervised training.  
 X - Texas-1500 hours as of 9/1/81.  
 Y - Or 1500 if Internship program has been approved.  
 Z - No more than 500 hours practical experience may be granted for training received in any pharmacy specialty other than a retail or hospital pharmacy.  
 AA - Experience must be gained under a CO licensed pharmacist.  
 BB - A minimum of 500 hrs. must be in retail or institutional pharmacy. A maximum of 500 hrs. may be given for externship, clerkship, clinical rotation. A maximum of 1000 hrs. may be given for practice related education after 5th yr. in Pharm.D. program.  
 CC - Passing of Internship competency exam required.



## LICENSING LAW

## VI. REQUIREMENTS FOR INITIAL STATE LICENSURE AND CONTINUED LICENSURE OF PHARMACISTS

State	Examination*			NABP Score Transfer Program	Examination Fee	Initial Certificate Fee	Annual Fee Renewal***
	NABPLEX®	FDLE	Other**				
Alabama	Yes				\$100.00	None	\$ 45.00 2
Alaska	Yes			Yes	\$ 50.00	\$200.00 7	\$200.00 2
Arizona	Yes			Yes	\$100.00	\$ 20.00	\$ 60.00 A,2
Arkansas	Yes				\$ 25.00 5	\$ 10.00	\$ 25.00 2
California					\$110.00	\$100.00	\$100.00 A,2
Colorado	Yes				\$122.00	\$ 29.00	\$ 91.00 A
Connecticut	Yes			Yes	\$ 50.00	None	\$ 15.00
Delaware	Yes			Yes	\$100.00	None	\$ 30.00 A,2
Dist. of Columbia	Yes	Yes			\$ 60.00	\$ 20.00	\$ 95.00 A
Florida	Yes				\$250.00	None	\$ 25.00 A,2
Georgia	Yes		Yes		\$ 50.00 8	None	\$ 50.00 A
Hawaii	Yes	Yes			\$100.00	None	\$ 70.00 A
Idaho	Yes			Yes	\$100.00	\$ 25.00	\$ 75.00 2
Illinois	Yes	Yes		Yes	\$ 95.00 5	\$ 25.00	\$ 50.00 A
Indiana	Yes	Yes	Yes		\$125.00	None	\$ 25.00 A,2
Iowa	Yes	Yes		Yes	\$100.00	None	\$ 60.00 A,2
Kansas	Yes			Yes	\$125.00	None	\$ 50.00 2
Kentucky	Yes		Yes		\$100.00 5	None	\$ 50.00 2
Louisiana	Yes				\$ 50.00 5	None	\$ 50.00 2
Maine	Yes				\$100.00	None	\$ 30.00 2
Maryland	Yes	Yes		Yes	\$ 95.00	None	\$ 50.00 A
Massachusetts	Yes			Yes	\$ 75.00	None	\$ 50.00 A,2
Michigan	Yes				\$ 80.00	None	\$ 20.00 A,2
Minnesota	Yes	Yes	Yes	Yes	\$ 90.00	\$ 50.00	\$ 50.00 2
Mississippi	Yes				\$100.00	\$ 70.00	\$ 70.00 A,2
Missouri	Yes			Yes	\$150.00	None	\$ 35.00 2
Montana	Yes		Yes		\$100.00	\$ 50.00	\$ 40.00 2
Nbraska	Yes		Yes	Yes	\$150.00	None	\$ 70.00 A,2
Nevada	Yes			Yes	\$ 85.00	\$ 60.00	\$ 50.00 A,2
New Hampshire	Yes			Yes	\$ 70.00 5	None	\$ 40.00 2
New Jersey	Yes		Yes	Yes	\$ 50.00 5	None	\$ 80.00 A,2
New Mexico	Yes				\$ 75.00	\$ 10.00	\$ 35.00 1,2
New York	Yes		Yes	Yes	\$100.00 3	None	\$ 90.00 B
North Carolina	Yes		Yes	Yes	\$ 75.00	None	\$ 40.00 2
North Dakota	Yes	Yes	Yes	Yes	\$110.00	\$ 25.00	\$ 50.00 4
Ohio	Yes				\$110.00 5	None	\$ 30.00 2
Oklahoma	Yes				\$150.00	None	\$ 40.00 2
Oregon	Yes				\$100.00	\$ 45.00	\$ 45.00 2,8
Pennsylvania	Yes			Yes	\$ 90.00	\$ 25.00	\$ 25.00 A
Puerto Rico	Yes				\$ 10.00	\$ 10.00	\$ 2.00 2
Rhode Island	Yes			Yes	\$100.00	None	\$ 25.00 10
South Carolina	Yes			Yes	\$110.00	\$ 10.00	\$ 25.00
South Dakota	Yes			Yes	\$100.00	\$ 15.00	\$ 25.00 2
Tennessee	Yes				\$100.00	\$ 30.00	\$ 30.00 2
Texas	Yes		Yes		\$124.00	\$ 48.00	\$ 48.00
Utah	Yes			Yes	\$ 75.00 11	None 11	\$ 25.00 A
Vermont	Yes	Yes		Yes	\$100.00	None	\$ 32.00 A
Virginia	Yes	Yes			\$200.00	None	\$ 20.00
Washington	Yes			Yes	\$100.00	\$ 75.00	\$ 60.00 2
West Virginia	Yes		Yes		\$125.00 5	\$ 5.00	\$ 30.00
Wisconsin	Yes	Yes	Yes	Yes	\$ 50.00	None	\$ 35.00 A
Wyoming	Yes			Yes	\$ 70.00	None	\$ 25.00 2

\* All states except California utilize the National Association of Boards of Pharmacy License Examination (NABPLEX®)

\*\* Candidates should contact the appropriate board of pharmacy to identify additional examinations.

\*\*\* For detailed CE requirements see page 11, Continuing Pharmaceutical Education Requirements.

## LEGEND:

A- Biennially

B- Triennially

1- Non-resident active pharmacist \$35; non-resident active and inactive \$25.

2- Continuing Education required for licensure.

3- Must be accompanied by \$30 fee for initial registration (NY-\$90).

4- Non-resident fee \$25.

5- Plus cost of exam material.

6- Continuing Education required for relicensure with \$10 fee.

7- Sliding scale; \$50 less each year up to 4, then \$50 per year.

8- Plus one-time application fee, (GA-\$75.)

9- Proposed changes.

10- Inactive and retired fee \$50.00.

11- Must be accompanied by separate fee for licensure (UT-\$80).

This fee is subject to annual review and change.

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**CONTINUING PHARMACEUTICAL EDUCATION REQUIREMENTS**


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Thirty-four (34) boards of pharmacy currently require (or will soon require) that pharmacists participate in continuing education activities as a prerequisite for relicensure. There are fairly uniform requirements regarding the types of programs which are recognized and the prescribed range of acceptable content matter.

Two (2) additional boards of pharmacy have been granted the authority to promulgate regulations requiring continuing pharmaceutical education as a prerequisite for relicensure.

Eight (8) states report various degrees of related continuing pharmaceutical education activity.

NOTE: One (1) continuing education unit, CEU, is equivalent to ten (10) contact hours (1 contact hour = 0.1 CEU).

**Boards Requiring Participation in Continuing Pharmaceutical Education for Relicensure**
**ALABAMA**

By January 1 of each year, every pharmacist must furnish proof of participation in not less than 15 hours of approved continuing education during the preceding year, 3 hours of which must be live exposure. Carry-over of credit is not allowed.

**ALASKA**

Each pharmacist seeking renewal of a license shall obtain an average of 15 credit hours of continuing education per year during the previous licensure period.

**ARIZONA**

Pharmacists must satisfactorily complete 3.0 CEUs of continuing professional education activities sponsored by ACPE-approved providers. Satisfactory proof of participation is required for biennial renewal of the certificate of registration. No carry-over of credit is allowed.

**ARKANSAS**

Requires that pharmacists participate in at least 6 contact hours (0.6 CEUs) of approved continuing education annually. Nursing home consultant pharmacists are required to obtain three additional hours specifically related to consultation.

**CALIFORNIA**

Pharmacists must obtain 30 hours of continuing education during the biennial renewal period. Pharmacists who live in California must obtain at least 15 hours in the "accredited" category; the additional 15 hours may be in the "acceptable" category. Pharmacists who live out of state may obtain all 30 hours in the "acceptable" category. A1 providers must be recognized by the California Board of Pharmacy. No carry-over of credit is allowed.

**DELAWARE**

Pharmacists renewing their license in 1985 will be expected to have acquired 15 hours (1.5 CEUs) of continuing pharmaceutical education credit. Thereafter, pharmacists must obtain 30 hours of continuing pharmaceutical education during each biennial renewal period. No carry-over of credit is allowed.

**FLORIDA**

Biennial renewal certificates require satisfactory proof that during the 2 years prior to the renewal application the licensee has participated in not less than 15 hours PER YEAR in approved continuing professional education programs. In addition, 12 hours of consultant pharmacist coursework is required for *annual* renewal of a consultant license.

**IDAHO**

Requires certification of participation in 15 hours (1.5 CEUs) of approved continuing pharmacy education programs for annual license renewal. A minimum of 10 hours (1.0 CEU) must be from ACPE-approved providers, and a minimum of 1 hour (.1 CEU) must be in Pharmacy Law (can be ACPE or Board approved). Carry-over of credit is not allowed.

**INDIANA**

Pharmacists are required to complete 30 hours of approved continuing education each biennium. No carry-over of credit is allowed.

**IOWA**

Requires 3.0 CEUs (30 hours) of continuing pharmaceutical education every two years as a condition for license renewal. Carry-over of credit is not allowed.

**KANSAS**

Requires 1.5 CEUs (15 clock hours) of approved continuing pharmaceutical education for annual registration. Up to 10 clock hours may be carried over to the next registration period when excess hours are needed.

**KENTUCKY**

Each licensee is required to complete a minimum of 1.5 CEUs (15 contact hours) annually in accredited programs. Non-ACPE programs must contain the Kentucky Board of Pharmacy I.D. number. Credit must be obtained between January 1 and December 31 each year. Carry-over credit is not permitted.

**LOUISIANA**

Requires that 1.5 CEUs (15 hours) of continuing pharmaceutical education in approved programs be completed annually as a prerequisite for relicensure. A minimum of 0.3 CEUs (3 hours) must be obtained through contact participation and a maximum of 0.6 CEUs (6 hours) may be obtained by reading Approved Journals. No carry-over of credit is allowed.

**MAINE**

Requires that pharmacists submit satisfactory proof of participation in not less than 15 hours of approved programs of continuing pharmaceutical education during the preceding calendar year. No carry-over of credit is allowed.

**MASSACHUSETTS**

Requires that pharmacists complete 3.0 CEUs (30 contact hours) of continuing pharmaceutical education for biennial license renewal. Because the rule became effective on January 1, 1984, only 1.5 CEUs (15 contact hours) will be required for the first renewal period in 1985. No carry-over of credit is allowed.

**MICHIGAN**

To qualify for biennial license renewal, pharmacists must have accumulated 30 hours of continuing education credit in approved programs. No carry-over of credit is allowed.

**MINNESOTA**

Requires at least 30 hours of credit from accredited continuing education programs every 2 years. Carry-over and splitting of program hours are not allowed.

**CONTINUING PHARMACEUTICAL EDUCATION REQUIREMENTS (Continued)****MISSISSIPPI**

Requires pharmacists to submit to the Board of Pharmacy evidence of completion of 2.0 CEUs (20 hours) in approved programs every 2 years, along with application for biennial license renewal. No carry-over of credit is allowed.

**MISSOURI**

Requires that pharmacists submit proof of 10 hours (1.0 CEUs) of continuing pharmaceutical education for annual license renewal.

**MONTANA**

Requires that pharmacists certify participation in 15 hours (1.5 CEUs) of approved programs each year following the first renewal license. A minimum of 5 hours (0.5 CEUs) is to be obtained in approved group (i.e., live) programs. One year carry-over of credit is allowed.

**NEBRASKA**

Effective January 1, 1984, every 2 years pharmacists will be required to complete 30 hours of continuing pharmaceutical education sponsored by ACPE-approved providers. Each pharmacist is responsible for keeping his or her own records.

**NEVADA**

Pharmacists must submit proof of receiving 30 hours of continuing education credit within the two years preceding the current renewal period. In-state registrants must have 15 hours in accredited programs. Out-of-state registrants may submit 30 hours of acceptable continuing education. Carry-over of credits is not allowed.

**NEW HAMPSHIRE**

1.5 CEUs (15 contact hours) are required for annual relicensure. A minimum of 0.5 CEUs (5 contact hours) must be didactic (live presentation) hours. No carry-over of credit is allowed.

**NEW JERSEY**

Requires that pharmacists complete 30 hours (3.0 CEUs) of continuing pharmaceutical education between May 1 and April 30 of each biennial review period. No carry-over of credit is allowed.

**NEW MEXICO**

Requires that pharmacists submit evidence of 1.5 CEUs (15 contact hours) of continuing pharmaceutical education offered by ACPE-approved providers, to renew their annual registration. A maximum of 1.5 CEUs or 1 year of credit may be accrued in excess and carried over to the next licensure year.

**NORTH CAROLINA**

Effective January 1, 1985, for the 1988 renewal year the Board of Pharmacy requires 10 hours (1.0 CEUs) of continuing pharmaceutical education per year, with no more than 5 hours (0.5 CEUs) of non-contact (i.e., correspondence or home-study) program credit.

**OHIO**

Requires that evidence of 4.5 CEUs of continuing pharmaceutical education, offered by approved providers, be submitted at intervals of 3 years. No carry-over of credit is allowed.

**OKLAHOMA**

Relicensure or licensure by reciprocity requires satisfactory proof of not less than 15 clock hours of participation in accredited continuing education programs per year. Carry-over credit is not allowed.

**OREGON**

Requires that each year pharmacists must satisfactorily complete 1.5 CEUs (15 hours) in approved continuing education programs OR must pass with a minimum score of 75% a challenge examination given by the Board of Pharmacy at least 10 months prior to July 1 of each year. No carry-over credit is allowed.

**PUERTO RICO**

As of July 1, 1983, pharmacists must complete 35 hours (3.5 C.Ph.E. Units) of continuing pharmaceutical education for recertification every three years, with a minimum of 10 hours per year. In the three year period, a minimum of 5 hours must be covered in each of the following areas: dispensing, pharmacology or drug interactions; pharmacy administration; and communication skills.

For additional information regarding specific requirements, contact the appropriate Board of Pharmacy.

**SOUTH DAKOTA**

Pharmacists must provide evidence of completion of 12 hours of continuing education in approved programs in order to be eligible for annual relicensure.

**TENNESSEE**

Continuing education as a prerequisite for relicensure will become effective on July 1, 1985, until which time it is voluntary. The Board is presently promulgating rules for implementation.

**WASHINGTON**

Pharmacists are required to complete 1.5 CEUs (16 hours) of professional continuing education as a prerequisite for annual license renewal. No carry-over of credit is allowed.

**WYOMING**

Each pharmacist must complete a minimum of 0.6 CEUs of accredited continuing pharmaceutical education each year. No carry-over of credit is allowed.

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**Boards of Pharmacy Which Have Been Granted Legislative Authority to Promulgate Regulations:**
**DISTRICT OF COLUMBIA**

Enabling legislation was passed by the City Council and the Board of Pharmacy is currently developing regulations.

**ILLINOIS**

Enabling legislation has been passed by the State Legislature.

**NORTH DAKOTA**

Enabling legislation has been passed by the State Legislature.

**VERMONT**

Enabling legislation has been passed by the State Legislature.

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**States Reporting Related Activities**
**CONNECTICUT**

Continuing pharmaceutical education as a prerequisite for relicensure is being considered by the Connecticut Pharmaceutical Association and the profession.

**GEORGIA**

Regulations have been implemented establishing a voluntary continuing education program. Proof of having obtained 3.0 CEUs is required for biennial continuing education certification at the time of license renewal.

**MARYLAND**

Continuing education is being considered by the Maryland Pharmaceutical Association.

**PENNSYLVANIA**

An act requiring continuing education for pharmacists is currently pending in the State Legislature.

**SOUTH CAROLINA**

The Board of Pharmacy is currently proposing continuing pharmaceutical education for relicensure.

**WEST VIRGINIA**

The West Virginia Pharmacists Association has passed a resolution in support of continuing education for pharmacists.

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For additional copies of this report or information about the ACPE Provider Approval Program, please contact:  
 W. Robert Kenny, Ph.D.  
 Associate Executive Director  
 American Council on Pharmaceutical Education  
 311 West Superior Street, Suite 512  
 Chicago, Illinois 60610  
 312/664-3576

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## LICENSING LAW

VII. REQUIREMENTS FOR RECIPROCAL LICENSURE  
(See Requirements for Examination and Registration)

State	Temporary Permit to Qualified Applicants	Fee for Reciprocity*	Special Requirements	Equivalent Requirements in Prior State	Former Requirements in Lieu of Present College and Experience Requirements
Alabama	No	\$200.00	A, E, H or F	A	Prior to 1927 four yrs. exper., two yrs. H.S. after 1919. Two yrs. exper. required of two-yr. graduates.
Alaska	Yes	\$ 25.00	E, H	B	Prior to 3-29-55 five yrs. exper.
Arizona	No	\$250.00	E, F	A	Prior to 8-20-35 four yrs. exper., credit allowed for actual time in college.
Arkansas	Yes	\$200.00	E, F	A	Prior to 7-1-36 four yrs. exper. Two yrs. H.S. after 1923.
California					No Reciprocity.
Colorado	No	\$300.00	E, F, H	A	Prior to 5-26-29 four yrs. exper., credit allowed for time in college. Legal exper. prior to 5-26-29 exempts from H.S. and college until 5-26-34.
Connecticut	No	\$ 50.00	A, E, F, H	A	Prior to 1-1-25 four yrs. exper. Two yr. grads must have two yrs. exper. Apprentices in 1921 exempt from college.
Delaware	No	\$ 75.00	E	A	Prior to 3-30-27 four yrs. exper., credit allowed for time in college up to two yrs.
Dist. of Columbia	No	\$ 80.00	C, F	A	Prior to 3-4-28 four yrs. exper. two-yr. grads. must have three yrs. exper.
Florida					No Reciprocity.
Georgia	No	\$300.00	C, E, F	A	Prior to 6-1-34 three yrs. exper. Credit allowed for time in college.
Hawaii					No Reciprocity.
Idaho	No	\$250.00	E, H	A	Prior to 4-14-30 four yrs. exper. Two yrs. college and two yrs. exper. thereafter. Four yrs. college and one yr. exper. after 5-1-39.
Illinois	No	\$100.00	H	A	Prior to 7-1-17 four yrs. exper. credit up to two yrs. allowed for time in college. Legal exper. prior to 7-1-17 exempts from college. No deadline date.
Indiana	No	\$150.00	E, F	A	Prior to 1-1-20 four yrs. exper. Credit up to two yrs. allowed for time in college. Exper. recorded prior to 7-1-23 exempts from college 1-1-41.
Iowa	No	\$150.00	E, P	B	Prior to 7-1-17 four yrs. exp. apprentices and assistants registered prior to 1-1-17 exempt from college to 7-1-24. After 7-1-17 two yrs. college and two yrs. exp. After 7-4-36 four yr. grad. recog. college.
Kansas	No	\$250.00	A, E, G	A	Prior to 5-28-29 four yrs. exper. Credit allowed for time in college.
Kentucky	Yes	\$150.00	C, E, F, H	A	Prior to 7-1-24 four yrs. exper. two yrs. H.S. credit allowed for time in college.
Louisiana	No	\$375.00	E, F	A	Prior to 1-1-28 four yrs. exper. Credit allowed for actual time in college up to three yrs. See Legend K.
Maine	No	\$150.00	C, E	A	Prior to 6-19-31 four yrs. exper. Credit allowed for time in college. Six months exper. prior to 6-19-31 exempt from college to 6-19-36.
Maryland	No	\$100.00	C, P	A	Prior to 6-1-20 four yrs. exper. Credit allowed for time in college. Four yr. course after 1936.

## LICENSING LAW

VII. REQUIREMENTS FOR RECIPROCAL LICENSURE -- (cont.)  
(See Requirements for Examination and Registration)

State	Temporary Permit to Qualified Applicants	Fee for Reciprocity*	Special Requirements	Equivalent Requirements in Prior State	Former Requirements in Lieu of Present College and Experience Requirements
Massachusetts	No	\$ 50.00	H, I	A	Prior to 1-1-48 four yrs. exper. Credit allowed for actual time in college.
Michigan	No	\$100.00	E, I	A	Four yrs. exper. prior to 1-1-29. Two yrs. col. thereafter. Four yrs. col. after 1-1-38. No exper. for 4-yr. grads prior to 7-1-55.
Minnesota	No	\$150.00	E, F, H	A	Prior to 4-23-19 four yrs exper. Credit allowed for time in college. Two yrs. college and two yrs. exper. required after 4-23-19. Graduation after 3-28-29. Exp. prior to 4-23-19 exempts to 3-28-67.
Mississippi	No	\$ 70.00	C, E	A	Prior to 1-1-21 4 yrs. exper. graduate thereafter.
Missouri	No	\$300.00	E	A	Prior to 9-1-37 four yrs. exper. Credit allowed for time in college. One yr. H.S. after 8-1-13, two yrs. after 8-1-20 four yrs. after 8-1-23.
Montana	No	\$225.00	E	A	Prior to 3-17-39 four yrs. exper. Credit allowed for time in college. Graduation thereafter.
Nebraska	No	\$125.00	E, F	A	Prior to 1-1-42 four yrs. exper. Credit up to two yrs. allowed for time in college. One yr. college required after 1-1-30.
Nevada	No	\$150.00	E	B	Five yrs. exper. prior to 1-1-48.
New Hampshire	No	\$150.00	E, H, K, L	A	Prior to 1-1-39 four yrs. exper. Credit allowed up to two yrs. for time in college.
New Jersey	No	\$125.00	E, F, H, L	A	Prior to 1920 four yrs. exper. Credit allowed up to two yrs. for college work. 4-yr. course compulsory for matriculants after 1-1-32.
New Mexico	No	\$150.00	A, E, F, M	A	Prior to 5-20-35 three yrs. exper. Credit allowed for time in college. Recognized apprenticeship exper. prior to 1-1-20-34 exempt from college to 5-20-40.
New York	No	\$155.00	E, F	A	Prior to 1-1-04 four yrs. exper. Credit allowed for time in college. Two yrs. college, 4 yrs. exp. after 1-1-04. Three yrs. college after 1-1-28. Four yrs. college, 1 yr. exper. after 6-1-41.
North Carolina	No	\$200.00	E, F	A*	Prior to 1-1-18 four yrs. exper. Credit allowed for time in college. One yr. college after 1-1-18. Graduation after 1-1-22.
North Dakota	Yes	\$150.00	E, P	A	Prior to 1-1-30 two yrs. college and two yrs. exper. Prior to 1-1-15 four yrs. exp. Credit allowed for time in college.
Ohio	No	\$225.00	B	A	Prior to 8-20-16 four yrs. exper. Credit if a graduate allowed for actual time in college. Four yrs. apprenticeship prior to 7-1-17 exempts from college. No exper. for 4-yr. grads 1932-45.
Oklahoma	No	\$200.00	F	A	Prior to 7-15-23, four yrs. exper. Credit allowed up to two yrs. for time in college. One yr. of college required after 7-15-21. Assistants prior to 1-1-22 exempt.
Oregon	No	\$200.00	E, F, M	A	Prior to 1921 four yrs. exper. Credit allowed for time in college. One yr. college required 1-1-21, two yrs. 1-1-22, three yrs. 7-1-25, four yrs. for matriculants after 7-1-30.

## LICENSING LAW

VII. REQUIREMENTS FOR RECIPROCAL LICENSURE - (cont.)  
(See Requirements for Examination and Registration)

State	Temporary Permit to Qualified Applicants	Fee for Reciprocity*	Special Requirements	Equivalent Requirements in Prior State	Former Requirements in Lieu of Present College and Experience Requirements
Pennsylvania	No	\$ 75.00	E, H	A	Prior to 1-1-06 four yrs. exper. Matriculants after 1906, two yrs. college and four yrs. exper.; after 1926, three yrs. college and two yrs. exper.; after 1932, four yrs. college and one yr. exper. Two yrs. H.S. after 1920, 3 yrs. H.S. after 1923.
Puerto Rico	No	\$100.00	E	B	Prior to 3-12-27 four yrs. exper.
Rhode Island	No	\$100.00	E, H	A	Prior to 1-10-10 three yrs. exper.
South Carolina	No	\$200.00	E	A	Prior to 7-1-18 three yrs. exper. Credit allowed for time in college. Ten yrs. exp. exempts from college 3-1-25 to 1-1-33.
South Dakota	Yes	\$150.00	F, G (waived for ND & IA)	A	Prior to 7-1-31 three yrs. exper. Credit allowed for time in college, or graduated and one yr. exper. Four yrs. college after 7-1-33.
Tennessee	No	\$200.00	E, G	B	Prior to 1-1-41 four yrs. exper. Credit allowed up to two yrs. for time in college.
Texas	No	\$250.00	E, H, J, K, L	A	
Utah	No	\$ 80.00	E	A	Prior to 7-1-27 four yrs. exper. Credit allowed up to two yrs. for time in college. Two-yr. course compulsory for all after 1-1-27.
Vermont	No	\$100.00	E	B	Four yrs. exper. prior to 6-30-56.
Virginia	No	\$300.00	E, H	A	Prior to 4-1-22 four yrs. exper. Credit allowed up to two yrs. for time in college; after 4-1-22 graduation, no exper.; after 7-1-43 graduation and one yr. exp.
Washington	No	\$200.00	E, H	A	Prior to 6-13-63, 2 yr. graduate and 2 yrs. exper. or 3-yr. graduate and 1 yr. exper.
West Virginia	No	\$130.00	E	A	Prior to 1-1-23 four yrs. exper. Credit allowed for time in college.
Wisconsin	No	\$ 50.00	E, H, R	A	Prior to 8-1-27 five yrs. exper. Credit allowed for time in college. Two yrs. H.S. after 1920.
Wyoming	No	\$ 50.00	C, E	A	Prior to 7-1-36 four yrs. exper. One yr. credit allowed for time in college.

## LEGEND:

Basic rule for reciprocity: An applicant must have had the legal qualifications at the time of examination and registration in the state from which he applies which would at that time have enabled him to qualify for examination and registration in the state to which he applies for reciprocal registration.

Personal appearance before board or some member general requirement in all states.

Failure in examination usually a bar to reciprocal registration in the same state later.

A - Qualifications at time of original registration must be equivalent to requirements for examination and registration at that time. (N.C. qualifications at time of application must be equivalent to requirements for registration at that time.)

B - Standards at discretion of the board.

C - Examination discretionary—usually none other than oral.

D - Practical examination given when "E" is waived.

E - Examination in jurisprudence. (Ks. also pharmacy practice test).

F - Pharmacists who have not been licensed one year are not eligible to be licensed by reciprocity.

G - "E" requirement applicable to licensees from states that impose that qualification for reciprocal licensure.

H - Photographs, identification and special forms furnished by state in addition to official NABP application.

I - Residence or employment in state to which application is made, required of applicants.

J - Reciprocal state must grant reciprocal licensing to Texas Pharmacists, under like circumstances and conditions.

K - Reciprocity applicant originally licensed after January 1, 1978, must show proof of having passed NABPLEX or equivalent examination based on criteria no less stringent than the criteria in force in Texas or licensed and in good standing for a period of two years immediately prior to the application for reciprocal licensure. \*NH-Date is 7-1-78.

L - Reciprocity applicant must have graduated and received a baccalaureate in pharmacy or Pharm.D. from an accredited college of pharmacy that has been approved by the board.

M - "E" may be waived if internship is comparable to internship requirements of state.

N - Board may only issue a temporary license for first year for a place of practice. Must complete 85 hr./mo. practice requirement for one year.

O - Pharmacists must be licensed six months in state of original license.

P - "E" is waived if licensed by NABPLEX.

R - Wet lab required if inactive R.Ph. or if licensed less than 1 year, plus jurisprudence and practice of pharmacy.

## \*Fees for Grade Certification

\$10.00-CO

\$20.00-DC, NY

\$15.00-NH

\$19.00-AZ, AR, GA, IL, IA, KS, LA, MN, MO, MT, NV, NM, NC,

\$ 6.75-OH

\$ 5.00-AL, ID, IN, MD, MA, MI, MS, NE, NJ, OR, SD, TN

\$ 3.00-DE, KY, RI

\$ 1.00-All other states (no fee-PR)

## LICENSING LAW

## VIII. INTERNAL BOARD RECIPROCITY REQUIREMENTS

State	Hearings Per Year	Hearing Location	Jurisdiction Exam Required?	Are Retakes Allowed if Failed	Length of Wait for License	Temporary Licenses	Forms Required Beyond NABIP's	Policy on Exam Failures	Does the Board offer Inactive RPh Licenses?
Alabama	6	Bd. Mgts.	Yes	Yes	Immed.	No	No	Retake	Varies
Alaska	Upon request	Varies	Yes	Yes	Next, Bd. meeting	Yes	Yes	Retake	No
Arizona	4	Varies	Yes	Yes	1 Wk.	No	Yes	Must pass NABPLEX	Yes
Arkansas	4	Bd. Off.	Yes	Yes	2 Wks.	Yes	No	Retake	Yes
California (2)	NON-RECIPROCAL		--	--	--	--	--	--	--
Colorado	3	Bd. Off.	Yes	Yes	2 Wks.	No	No	Retake	No
Connecticut	12 or PRN	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	No
Delaware	6	Bd. Off.	Yes	Yes	1 Wk.	No	No	Retake	Practical
Dist. of Columbia	3	Bd. Off.	No	--	2 Wks.	No.	No.	Not recipro.	No policy
Florida	NON-RECIPROCAL		--	--	--	--	--	--	--
Georgia	7	Exam sites	Yes	Yes	2 Wks.	No	No	No	No
Hawaii	NON-RECIPROCAL		--	--	--	--	--	--	No
Idaho	CBO	Varies	Yes	Yes*	1 Wk.	No	No	Retake	No
Illinois	6	Springfield + Chicago	Yes	N/A	4-6 Wks.	Work letter	No	N/A	Yes
Indiana	6	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	Yes
Iowa	12	Reg. Mgts.	Yes	Yes	Immed.	No	No	2 Retakes	No
Kansas	Upon request	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	Yes
Kentucky	4	Varies	Yes	Yes	Immed.	Yes	Yes	Retake	Yes
Louisiana (2)	4	Varies	Yes	Yes	Immed.	No	No	Retake	No
Maine	6	Varies	Yes	Yes	Immed.	No	No	Retake	Yes
Maryland	12	Bd. Off.	No	N/A	Immed.	No	No	--	No
Massachusetts	20	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	No
Michigan	12	Bd. Off.	Yes	Yes	4-6 Wks.	No	Yes	Yes	No
Minnesota	4	Bd. Off.	Yes	Yes	2 Wks.	No	No	Not recipro.	No
Mississippi	Any sched- uled meeting	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	No

\*not sooner than 30 days nor longer than 1 year from fall date.

## LICENSING LAW

## VIII. INTERNAL BOARD RECIPROcity REQUIREMENTS--(Cont)

State	Exams Per Year	Exam Location	Jurisprudence Exam Required?	Are Retakes Allowed if Failed	Length of Wait for License	Temporary Licenses	Exams Required Beyond NABP's	Policy on Exam Failure	Does the Board Administer Rth License?
Missouri	5	Bd. Mgts.	Yes	Yes	1 Wk.	No	No	Retake	No
Montana	2	Bd. Mgts.	Yes	Yes	1 Wk.	No	No	Retake	No
Nebraska	5	Bd. Off.	Yes	Yes	1 Wk.	No	No	Retake	No
Nevada	12	Varies	Yes	Yes	Immed.	No	Yes	Retake	No
New Hampshire	12	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	No
New Jersey	26	Bd. Off.	Yes	Yes	2 Wks.	No	Yes	Retake	No
New Mexico	4+	Varies	Yes	Yes	Immed.	No	No	Retake	Yes
New York	4	Varies	Yes	Yes	1 Month	No	No	Not recipro.	Yes
North Carolina	6	Varies	Yes	Yes	1 Day	No	CBO	5 Yr. wait	Yes
North Dakota	4	Varies	Yes	Yes	Immed.	Yes	No	Retake	No
Ohio	7	Varies	No	-	Immed.	No	No	Retake	No
Oklahoma	9	Bd. Off.	Yes	Yes	2 Wks.	No	No	Retake	Yes
Oregon	4	Bd. Mgts.	Yes	Yes	Immed.	No	No	Retake	No
Pennsylvania	12	Varies	Yes	-	10 Days	No	Yes	Retake	No
Puerto Rico (2)	CBO	-	-	-	-	-	-	-	-
Rhode Island	12	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	Yes
South Carolina	5	Varies	Yes	Yes	2 Wks.	No	No	Retake	No
South Dakota	4	Bd. Off.	Yes	Yes	2 Days	Yes	No	Retake	No
Tennessee	9-12	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	No
Texas	6	Bd. Off.	Yes	Yes	4 Wks.	No	Yes	Retake	No
Utah	12	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	No
Vermont	Varies	Capitol	Yes	Yes	Immed.	No	Yes	No policy	No
Virginia	12	Bd. Off.	Yes	Yes	Immed.	No	No	Retake	Yes
Washington	6	Bd. Off.	Yes	Yes	1 Wk.	No	Yes	Retake	Yes
West Virginia	3	Varies	Yes	Yes	10 Days	No	No	Retake	No
Wisconsin (1)	3	Bd. Off.	Yes	Yes	2 Wks.	No	Yes	Retake	Practical exam
Wyoming	3	Exam sites	Yes	Yes	10 Days	No	No	Retake	Varies

## LEGEND:

CBO - Contact Board Office for Information.

(1) - Reciprocity Examinations.

(2) - As of September 1, 1980, these states did not administer NABP's or an equivalent examination. Candidates initially licensed by these states who have not been licensed in any other state by examination may not be eligible for reciprocity.



## LICENSING LAW

## IX. REVOCATION PROCEEDINGS

State	Specified in Statute	Written Notice Required	Statement of Charges Furnished	Hearing Required	Issuance of Subpoenas	Court Review or Retrial
Alabama	A	A	A	A	B	C
Alaska	A	A	A	A	C	C
Arizona	A	A	A	A	B	C
Arkansas	A	A	A	A	B	C
California	A	A	A	A	A	B
Colorado	A	A	A	A	B	B
Connecticut	A	A	A	A	B	B
Delaware	A	A	A	A	A	C
Dist. of Columbia	A	A	A	A	A	C
Florida	A	A	A	A	A	A
Georgia	A	A	A	A	A	A
Hawaii	A	A	A	A	A	A
Idaho	A	A	A	A	A	A
Illinois	A	A	A	A	B	C
Indiana	A	A	A	A	A	C
Iowa	A	A	A	A	A	A
Kansas	A	A	A	A	B	C
Kentucky	A	A	A	A	A	A
Louisiana	A	A	A	A	A	C
Maine	A	A	A	A	B	E
Maryland	A	A	A	A	A	C
Massachusetts	A	A	A	A	B	C
Michigan	A	A	A	A	B	C
Minnesota	A	A	A	A	B	C
Mississippi	A	A	A	A	C	B
Missouri	A	A	A	A	A	B
Montana	A	A	A	A	B	C
Nebraska	A	A	A	A	B	B
Nevada	A	A	A	A	B	B
New Hampshire	A	A	A	A	B	C
New Jersey	A	A	A	A	B	C
New Mexico	A	A	A	A	B	C
New York	A	A	A	A	B	C
North Carolina	A	A	A	A	B	C
North Dakota	A	A	A	A	A	C
Ohio	A	A	A	A	B	C
Oklahoma	A	A	A	A	C	C
Oregon	A	A	A	A	B	C
Pennsylvania	A	A	A	A	C	B
Puerto Rico	A	B	A	A	A	A
Rhode Island	A	A	A	A	A	F
South Carolina	A	A	A	A	A	C
South Dakota	A	A	A	A	A	C
Tennessee	A	A	A	A	A	C
Texas	A	A	A	A	A	C
Utah	A	A	A	A	A	C
Vermont	A	A	A	A	B	C
Virginia	A	A	A	A	A	C
Washington	A	A	A	A	A	C
West Virginia	A	A	A	A	A	C
Wisconsin	A	A	A	A	B	C
Wyoming	A	A	A	A	C	C

## LEGEND:

A - Yes

B - May do so.

C - Provided for.

D - Appeals to Governor or Attorney General.

E - Original proceedings in court only.

F - Appeal to Adjudication Officer.

## LICENSING LAW

## X. ISSUANCE AND RENEWAL OF LICENSES

State	Examination	Issuance of Licenses			License Suspension	License Revocation	License Renewal Annual Unless Otherwise Specified	
		Initial and Renewal	Temporary*	To Foreign Educated			Expiration Date**	Mailing Date
Alabama	Yes	Yes	None	None	Yes	Yes	Dec. 31	Dec.
Alaska	Yes	Yes	Yes 10	None	Yes	Yes	June 30	May 1
Arizona	Yes	Yes	None	Yes 7,9	Yes	Yes	Cyclical (2)	1 mo. prior
Arkansas	Yes	Yes	Yes	None	Yes	Yes	Dec. 31	Dec.
California	Yes	Yes	None	Yes 7	Yes	Yes	Cyclical (2)	2 mos. prior
Colorado	Yes	Yes	None	None	Yes	Yes	Nov. 1	Sept.
Connecticut	Yes	Yes	None	None	Yes	Yes	Mar. 31	Feb.
Delaware	Yes	Yes	None	Yes 7,9	Yes	Yes	Dec. 31	Oct. (4)
Dist. of Columbia	Yes	Yes	None	None	Yes	Yes	Feb. 28	Dec.
Florida	Yes	Yes	Yes 1	Yes 7,9	Yes	Yes	June 20 (6)	April
Georgia	Yes	Yes	None	Yes 7	Yes	Yes	Dec. 31 (4)	Oct.
Hawaii	Yes	Yes	Yes	None	Yes	Yes	Dec. 31	Nov.
Idaho	Yes	Yes	None	Yes 7	Yes	Yes	June 30	May
Illinois	Yes	Yes 4	None	Yes 7,9	Yes 3	Yes 3	Mar. 31	Jan.
Indiana	Yes	Yes	None	None	Yes	Yes	June 30 (4)	April
Iowa	Yes	Yes	None	Yes 7	Yes	Yes	June 30 (2)	May
Kansas	Yes	Yes	None	Yes 7,9	Yes	Yes	June 30	May
Kentucky	Yes	Yes	Yes	None	Yes	Yes	Dec. 31	Nov.
Louisiana	Yes	Yes	None	None	Yes	Yes	Jan. 15	Nov.
Maine	Yes	Yes	None	None	Yes	Yes	June 30	June
Maryland	Yes	Yes	None	Yes 7	Yes	Yes	Sept. 30 (6)	Aug.
Massachusetts	Yes	Yes	None	None	Yes	Yes	Dec. 31 (4)	Oct.
Michigan	Yes	Yes	None	Yes 7	Yes	Yes	June 30	Mar.
Minnesota	Yes	Yes	None	Yes 7,9	Yes	Yes	Mar. 1	Jan.
Mississippi	Yes	Yes	Yes	None	Yes	Yes	Dec. 31 (4)	Oct.
Missouri	Yes	Yes	None	None	Yes	Yes	Oct. 31	Sept.
Montana	Yes	Yes	None	None	Yes	Yes	June 30	May
Nebraska	Yes	Yes 3	None	Yes 7	Yes 3	Yes 3	Jan. 1 (4)	Nov.
Nevada	Yes	Yes	None	Yes 7	Yes	Yes	Oct. 31 (2)	Aug.
New Hampshire	Yes	Yes	None	None	Yes	Yes	Dec. 31	Nov.
New Jersey	Yes	Yes	None	Yes 7	Yes	Yes	April 30 (2)	Mar. (2)
New Mexico	Yes	Yes	None	None	Yes	Yes	Last day of birth month	Month prior to birth month
New York	Yes	Yes 3	None	Yes 7	Yes 3	Yes 3	Dec. 31 (5)	Oct.
North Carolina	Yes	Yes	None	Yes 8	Yes	Yes	Dec. 31	Nov.
North Dakota	Yes	Yes	Yes	Yes 7,9	Yes	Yes	March 1	Jan.
Ohio	Yes	Yes	None	Yes 7,9,11	Yes	Yes	Sept. 15	June
Oklahoma	Yes	Yes	None	None	Yes	Yes	June 30	May
Oregon	Yes	Yes	None	None	Yes	Yes	June 30	May
Pennsylvania	Yes	Yes	None	Yes 7	Yes	Yes	Sept. 30 (4)	July
Puerto Rico	Yes	Yes	None	None	Yes	Yes	July 1	June
Rhode Island	Yes	Yes	None	None	Yes	Yes	June 30	June
South Carolina	Yes	Yes	Yes	Yes 7,9	Yes	Yes	June 30	May
South Dakota	Yes	Yes	Yes	Yes 7	Yes	Yes	Sept. 30	Sept.
Tennessee	Yes	Yes	None	None	Yes	Yes	Dec. 31	Nov.
Texas	Yes	Yes	None	None	Yes	Yes	Staggered	45 days prior
Utah	Yes	Yes 3	None	None	Yes 3	Yes 3	Dec. 31 (4)	Oct.
Vermont	Yes	Yes	None	Yes 7	Yes	Yes	Sept. 30	Sept. 1
Virginia	Yes	Yes	None	Yes 7	Yes	Yes	Dec. 31	Nov.
Washington	Yes	Yes	None	Yes 7	Yes	Yes	Feb. 1	Jan. 1
West Virginia	Yes	Yes	None	None	Yes	Yes	June 30	May
Wisconsin	Yes	Yes	None	None	Yes	Yes	May 31 (4)	Mar.
Wyoming	Yes	Yes	None	None	Yes	Yes	Dec. 31	Nov.

\* Temporary licenses or permits are issued to qualified applicants pending examination or completion of reciprocity procedures.

\*\* Excludes grace period.

## LEGEND:

1- Temporary permits are issued to interns.

2- Biennial (CA, NV, NJ-odd years).

3- The board or committee recommends to the department which has the function. (In NY suspension or revocation is voted by the Board of Regents.)

4- Biennial, even years.

5- Triennial registration periods.

6- Biennial, odd and even license numbers in odd/even years.

7- FPGEC certified applicants who successfully pass state board examination may be licensed. (NY-comply with foreign graduate rule.) (MI, OH-after adoption of rule.)

8- Must be graduate of ACPE accredited school.

9- Practical experience requirements must be met.

10- Temporary permits are issued to qualified reciprocity applicants.

11- Test of spoken English required.

## LICENSING LAW

## XI. FINANCIAL PRACTICES OF STATE BOARDS

State	Fees Charged by Board			Method of Financing the Board		
	Examination	Reciprocity	Renewal*	State Board Account	Special Fund in State Treasury	State General Revenue Fund
Alabama	\$100.00	\$200.00	\$ 45.00 9	Yes		Yes
Alaska	\$ 50.00	\$ 25.00	\$200.00 11			
Arizona	\$100.00	\$250.00	\$ 60.00 2	Yes	Yes	
Arkansas	\$ 25.00 5	\$200.00	\$ 25.00			
California	\$110.00		\$100.00 2		Yes	
Colorado	\$185.00	\$298.00	\$125.00 2		Yes	
Connecticut	\$ 50.00	\$ 50.00	\$ 15.00			Yes
Delaware	\$100.00	\$ 75.00	\$ 30.00 2			Yes
Dist. of Columbia	\$ 60.00	\$ 80.00	\$ 95.00 2			Yes
Florida	\$250.00		\$ 60.00 2		Yes	
Georgia	\$150.00	\$300.00	\$ 60.00 2			Yes
Hawaii	\$100.00		\$ 70.00 2			Yes
Idaho	\$100.00	\$250.00	\$ 75.00 10		Yes	
Illinois	\$ 25.00 14	\$100.00	\$ 60.00 2			Yes
Indiana	\$125.00	\$150.00	\$ 60.00 2			Yes
Iowa	\$100.00	\$150.00	\$ 60.00 2			Yes
Kansas	\$125.00	\$250.00	\$ 50.00		Yes	
Kentucky	\$100.00	\$150.00	\$ 50.00	Yes	Yes	
Louisiana	\$ 50.00 14	\$375.00	\$ 50.00			
Maine	\$100.00	\$150.00	\$ 30.00		Yes	
Maryland	\$ 85.00	\$100.00	\$ 50.00 2			Yes
Massachusetts	\$ 75.00	\$ 60.00	\$ 50.00 2			Yes
Michigan	\$ 80.00	\$100.00	\$ 20.00 2			Yes
Minnesota	\$ 30.00	\$150.00	\$ 50.00	Yes	Yes	Yes
Mississippi	\$100.00	\$ 70.00	\$ 70.00 2			
Missouri	\$150.00	\$300.00	\$ 35.00		Yes	
Montana	\$100.00	\$225.00	\$ 40.00		Yes	
Nebraska	\$150.00	\$125.00	\$ 70.00 2	Yes	Yes	
Nevada	\$ 85.00	\$150.00	\$ 50.00 2			
New Hampshire	\$ 70.00 14	\$150.00	\$ 40.00			Yes
New Jersey	\$ 50.00 14	\$125.00	\$ 80.00 2			Yes
New Mexico	\$ 75.00	\$150.00	\$ 35.00 6			Yes
New York	\$150.00 1	\$155.00 1	\$ 90.00 3	Yes	Yes	Yes
North Carolina	\$ 75.00	\$200.00	\$ 40.00			
North Dakota	\$110.00	\$150.00	\$ 50.00 7	Yes		
Ohio	\$110.00 14	\$225.00	\$ 30.00			Yes
Oklahoma	\$150.00	\$200.00	\$ 40.00	Yes	Yes	Yes
Oregon	\$100.00 5	\$200.00 5	\$ 55.00			
Pennsylvania	\$ 50.00	\$ 75.00	\$ 25.00 2			Yes
Puerto Rico	\$ 10.00	\$100.00	\$ 2.00			Yes
Rhode Island	\$100.00	\$100.00	\$ 25.00			Yes
South Carolina	\$110.00 5	\$200.00	\$ 25.00			Yes
South Dakota	\$100.00	\$150.00	\$ 25.00	Yes		Yes
Tennessee	\$100.00	\$200.00	\$ 30.00 8			
Texas	\$100.00 5,15	\$250.00 5	\$ 48.00	Yes 12		Yes
Utah	\$ 25.00 15	\$ 80.00	\$ 25.00 2,15,16			
Vermont	\$100.00	\$125.00	\$ 32.00 2	Yes		
Virginia	\$200.00	\$300.00	\$ 20.00		Yes	Yes
Washington	\$175.00 1	\$200.00	\$ 50.00			Yes
West Virginia	\$125.00	\$130.00	\$ 30.00		Yes	
Wisconsin	\$ 50.00	\$ 50.00	\$ 35.00 2		Yes	Yes
Wyoming	\$ 70.00	\$ 50.00	\$ 25.00		Yes	

\*Average renewal fee \$49.46.

## LEGEND:

- |  |   |
|--|---|
| 1— Includes fees for application and initial license where such fees are applicable. | 9— Controlled substance fee \$35.                                   |
| 2— Biennial renewal.   | 10— Controlled substance fee \$15. Wholesale-\$25.                  |
| 3— Triennial renewal.  | 11— Four-year renewal.  |
| 4— Includes a \$1 identification fee.  | 12— Except for fines collected under Pharmacy Act.                  |
| 5— Additional license fee.   | 13— CS fee \$30.  |
| 6— New Mexico renewal inactive fee \$25; Non-resident active fee \$25.               | 14— Plus cost of exam materials.                                    |
| 7— Non-resident fee \$25.  | 15— Proposed changes. (Utah—subject to review and change annually.) |
| 8— Controlled substance fee \$10.  | 16— Controlled substance fee \$40.                                  |

**INTERNSHIP LAW**
**XII. REQUIREMENTS FOR INTERNSHIP REGISTRATION AND CERTIFICATION**

State	Fee	Annual Renewal Fee	Maximum Period of Registration
Alabama	No		
Alaska	\$10.00	\$10.00	1 Year
Arizona	\$ 5.00	\$10.00 3	6 Years 2
Arkansas	\$20.00		Intern duration
California	\$25.00		5 Years
Colorado	\$27.00		1 year (May-April)
Connecticut	\$10.00	None	Intern duration
Delaware	\$ 5.00	\$ 5.00 3	2.5 Years
District of Columbia	No		
Florida	No		Intern duration
Georgia	\$25.00		5 Years 4
Hawaii	No		1 Year
Idaho	\$ 5.00	\$ 5.00	1 Year
Illinois	\$20.00	\$40.00 3	2 Years
Indiana	\$10.00		6 Years + one 5-yr. renewal
Iowa	\$10.00		Intern duration
Kansas	\$25.00		Intern duration
Kentucky	\$25.00		4 Years
Louisiana	\$ 5.00	\$ 5.00	1 Year
Maine	No		
Maryland	No		
Massachusetts	No		
Michigan	\$ 3.00		1 Year post grad
Minnesota	\$20.00		Duration
Mississippi	No		
Missouri	No		5 Years
Montana	\$40.00		2 Years post grad
Nebraska	\$40.00		Intern duration
Nevada	\$10.00 3		4 Years
New Hampshire	No		
New Jersey	No		6 months post grad
New Mexico	\$10.00	\$ 5.00	Intern duration
New York	\$40.00		5 Years 1
North Carolina	No		
North Dakota	\$10.00		Intern duration
Ohio	\$10.00	\$10.00	1 Year 4
Oklahoma	\$20.00		4 Years
Oregon	\$ 7.50	\$ 7.50	1 Year
Pennsylvania	\$10.00		6 Years
Puerto Rico	No		
Rhode Island	No		
South Carolina	\$10.00		4 Years 4
South Dakota	\$10.00		Each work experience
Tennessee	No		
Texas	No		Intern duration
Utah	\$20.00	\$15.00 3	Intern duration
Vermont	No		Intern duration
Virginia	No		
Washington	\$10.00	\$10.00	1 Year
West Virginia	\$10.00		3 Years
Wisconsin	\$10.00	\$10.00	7-19 mo, expire 7/31 the next year
Wyoming	\$ 2.00	\$ 2.00	Intern duration

**LEGEND:**

- 1 - One 2-year renewal permitted.  
 2 - After 6 years must be reevaluated.  
 3 - Biennial.  
 4 - May be renewed.

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**INTERNSHIP LAW**


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**XIII. STATE INTERNSHIP REQUIREMENTS FOR LICENSURE**

Table XIII responds to the following questions:

1. Amount of practical experience required by the board?
2. Amount of total time required after graduation?
3. Amount of college supervised experience allowed by board:
  - A. Internship time while enrolled in school but not in classes (i.e., vacation, breaks);
  - B. Internship time gained while attending classes but not in academic structured program;
  - C. Internship gained in conjunction with academic credit (i.e., externship, clerkship, clinical rotation);
  - D. Total amount of college experience allowed by board (add A, B, and C).
4. When does college supervised experience credit begin with the board (i.e., 4th year)?
5. Time allowed in the National Pharmaceutical Council summer industrial internship program or similar industry program (i.e., industrial, home health, institutional, nuclear, mental health)?
6. Does the board require licensure/registration of: interns, preceptors and sites?

State	1.	2.	3.				4.	5.	6.
			A.	B.	C.	D.			
ALABAMA	1500 R	400 R	---	---	400 R	400	3rd yr.	none	yes
ALASKA	1500 S	160 S	1 sem. or quarter	---	---	---	3rd yr.	---	yes
ARIZONA	1500	none	1100	none	400	1500	3rd yr.	500	yes
ARKANSAS	2000	1000	up to 400	none	600	up to 400	2nd yr.	yes, under certain conditions	interns and preceptors
CALIFORNIA	1500 S	none R	min. of 900 hrs.	min. of 900 hrs.	max. of 600 hrs.	600	1st prof. yr. max. of 250 hrs.	yes	interns
COLORADO	1800 hrs.	200	40 hr. week	40 hr. week	600	1200	on admission	none	Interns and preceptors
CONNECTICUT	1500	none	varies	varies	varies	1500	3rd yr.	varies	interns
DELAWARE	1500	0	1000-1500	500	all hours	1500	3rd yr.	500	interns
DIST. of COLUMBIA	1500/1000R	---	none	none	none	none	3rd yr.	---	yes
FLORIDA	2080 varies	n/a	varies	varies	varies	varies	varies	none	Interns and preceptors
GEORGIA	1500 R	---	R	---	480	---	4th/5th yr.	0	interns only
HAWAII	2000	none	varies	varies	varies	varies	2nd yr.	yes, RPH supervised	yes
IDAHO	1500 R	none	allowed	allowed	allowed	640	3rd yr.	1/2 credit R	yes R
ILLINOIS	400 S	none	none	none	400 S	400	n/a	n/a	yes
INDIANA	1040	520	varies	n/a	n/a	520	n/a	n/a	interns
IOWA	1500 R	none	---	---	1000	1000	n/a	board decision	yes
KANSAS	1500 S&R	none	none	none	1000 prog. accepted by board	1000	3rd yr.	Individual evaluation	yes
KENTUCKY	1600	none	no limit	200	640	1600	3rd yr.	400	interns
LOUISIANA	1 yr. S 1500 R	500	---	min. of 600 before externship	400	1000	3rd yr.	none	yes
MAINE	1500	none	400	no restrict.	400	800	1st yr.	bd's decision	no
MARYLAND	1500 R	none	all R	none	all R	---	n/a	all R	no
MASSACHUSETTS	1500	none	breaks only	special program	externship	clinical to 400 hrs. extern; all	5th yr.	up to 400 hrs. includes clinical	no
MICHIGAN	1000	none	16 hr/week	16 hr/week	up to 400	400	5th yr.	up to 400	yes
MINNESOTA	1500	0	0	400	varies	varies	3rd yr.	varies	Interns only
MISSISSIPPI	1500	n/a	up to 900	none	600	up to 1500	4th yr.	300	no

## INTERNSHIP LAW

## XIII. STATE INTERNSHIP REQUIREMENTS FOR LICENSURE--(Cont)

State	1.	2.	3.				4.	5.	6.
			A.	B.	C.	D.			
MISSOURI	1500	none	620	40 hr/week	620	1500	5th yr.	200 hrs.	yes
MONTANA	1500 R	none	varies	none	700	700	4th yr.	bd, approved	Interns and preceptors
NEBRASKA	1500 R	none	--	--	--	varies	4th yr.	none	Interns and preceptors
NEVADA	1500 S	none	none	none	1000	500	1st yr.	none	yes
NEW HAMPSHIRE	1500 R&S	none	no limitations -- at discretion of board				4 months prior to 3rd yr	bd, decision	no
NEW JERSEY	1000 R	varies	varies	none	varies	1000 R	3rd yr.	none	yes
NEW MEXICO	1 yr. S	none	varies	1000	500	--	30 sem. hrs.	yes	yes
NEW YORK	6 mo. R	none	none	none	none	none	none	none	yes
NORTH CAROLINA	1500	0	0	0	up to 800	up to 800	not specified	up to 500	no
NORTH DAKOTA	1500	none	none	none	800	800	5th yr.	400	Interns only
OHIO	1500 R	none	no limit	no limit	hrs. board approved must be full-time program		bd, approved	300 hrs.	yes
OKLAHOMA	2000	none	40 hr/week	up to 1000	1000	1000	3rd yr.	no limit	yes
OREGON	1500	400	none	none	500	500	3rd yr.	none	yes
PENNSYLVANIA	1500	none	50 hr/week	50 hr/week	50 hr/week	--	5th yr.	350	yes
PUERTO RICO	1000	none	--	--	400	--	3rd yr.	300	--
RHODE ISLAND	1500	none	0	96 hrs.	654 hrs.	750 hrs.	3rd yr.	1/2 credit	yes
SOUTH CAROLINA	1500 R	none	2 wk. min.	none	500 max.	--	1st yr.	1000 max.	Interns
SOUTH DAKOTA	1500	0	0	0	640	640	3rd yr.	400	Interns
TENNESSEE	1500	none	no limit	none	500	500+	1st yr.	up to 500	no
TEXAS	1500 R	none	varies	varies	varies	1500 R	4th yr.	varies	yes
UTAH	1500	none	900	--	800	--	5th yr.	varies	yes
VERMONT	1500 R	none	--	up to 750	--	up to 750	3rd yr.	up to 750	yes
VIRGINIA	6 mo.	none	none	none	4 mo.	4 mo.	4th yr.	all	Interns
WASHINGTON	1500	none	no limit	500	700	1500	3rd yr.	300	yes
WEST VIRGINIA	1500	none	yes	500	yes	640	4th yr.	520	yes
WISCONSIN	2000 R	6 mo. R	none	none	500 max. R	500 max. R	3rd yr.	600 max. R	yes
WYOMING	1500 R	none	1000 hours either (A) or (B)		500 R	1500 R	3rd yr.	up to 500	yes-all three S&R

## LEGEND:

R — Required by Regulation  
S — Required by Statute

## NABP Internship Committee's definition of "concurrent time":

"We define concurrent time as experience gained while a person is a full-time student. Further, a full-time student is defined as one carrying, in any given school term, at least seventy-five percent of the average number of credit hours per term needed to graduate within five years.

"The 400 concurrent hours may be in any of three areas or combinations of them:

1. traditions: Internship supervised by the college;
2. clinical pharmacy programs;
3. demonstration projects.

"In the event that the student is registered in a college-administered practicum which involves the student in a 40-hour work week, he is not to be considered as acquiring concurrent time in this situation, he could be carrying three semester hours or less of didactic, academic work."

## DRUG LAW

## XIV. LICENSURE REQUIREMENTS FOR DRUG DISTRIBUTION

State	Pharmacy Permit Required	New Permit Fee	Annual Fee Renewal	Minimum Standards of Equipment Required	Pharmacy Inspected Annually	Outlets Other than Pharmacies Licensed to Sell Packaged Drugs	
						Saleable Drugs	Annual Fee
Alabama	Yes	\$ 50.00 A,T	\$ 25.00 T	K	Yes	G	No
2 Alaska	Yes	\$100.00 V	\$200.00 V	K	Yes	No	No
1,2 Arizona	Yes	\$300.00	\$300.00 P	K	Yes	G,H	\$100.00
Arkansas	Yes	\$100.00 A	\$ 50.00	K	Yes	G	No
1,2,3 California	Yes	\$200.00	\$130.00	K	Yes		
Colorado	Yes	\$304.00	\$192.00	K	Yes R		
1,2,3 Connecticut	Yes	\$200.00 C	\$ 50.00	K	Yes	G,H	\$35.00
1,2,3 Delaware	Yes	\$ 50.00	\$ 50.00 P	K	Yes	G	\$100.00 P
Dist. of Columbia	Yes	\$ 85.00 A	\$ 85.00	K	Yes		\$ 52.00
Florida	Yes	\$100.00	\$ 50.00 E	K	Yes		No
1 Georgia	Yes	\$100.00 A	\$ 60.00 P	K	Yes		No
1 Hawaii	Yes	\$ 50.00	\$150.00 P	K	Yes P		\$150.00 P
1,2,3 Idaho	Yes	\$100.00 A	\$100.00 A	K	Yes	H	25/\$15/\$40
Illinois	Yes	\$ 50.00	\$100.00 P	K	Yes		No
Indiana	Yes	\$ 25.00 B	\$ 25.00	K	Yes	G	No
1,2 Iowa	Yes	\$ 50.00	\$ 50.00 O	K	Yes		\$ 50.00
1,2 Kansas	Yes	\$250.00 Q	\$200.00 Q	K	Yes	N	\$ 12.00
1,2 Kentucky	Yes	\$ 50.00 A	\$ 50.00	K	Yes		No
Louisiana	Yes	\$ 75.00 A,F,S	\$ 75.00 A,S	K	Yes	J	No
Maine	Yes	\$100.00	\$100.00	K	Yes	G	\$100.00
1,2 Maryland	Yes	\$ 40.00 B	\$ 25.00	K	Yes		No
1,2 Massachusetts	Yes	\$200.00 B,S	\$200.00 B,S	K	Yes		No
1,2,3 Michigan	Yes	\$ 35.00 B,O,P	\$ 50.00 P	K	Yes		No
1,2,3 Minnesota	Yes	\$ 80.00 A	\$ 90.00	K	Yes		No
Mississippi	Yes	\$150.00 A	\$150.00 P	K	Yes		No
Missouri	Yes	\$150.00 A	\$ 65.00	K	Yes		No
Montana	Yes	\$100.00 A	\$ 75.00 O	K	Yes		No
Nebraska	Yes	\$100.00 E,O	\$ 50.00 Q	K	Yes		No
1,2 Nevada	Yes	\$150.00 B	\$200.00 P	K	Yes	U	\$200.00 P
New Hampshire	Yes	\$150.00 A	\$100.00 A	K	Yes		No
1,2 New Jersey	Yes	\$200.00 B,O	\$ 85.00	K	Yes	G	No
1,2,3 New Mexico	Yes	\$150.00 A,O	\$150.00 O	K	Yes	G	Yes
1,2 New York	Yes	\$200.00 D	\$150.00 M	K	Yes	H	\$ 45.00 M
North Carolina	Yes	\$200.00 B	\$100.00	K	Yes		No
North Dakota	Yes	\$100.00 A	\$160.00	K	Yes	G,H	\$ 3.00
1,2,3 Ohio	Yes	\$ 50.00	\$ 50.00	K	Yes P		No
1,2 Oklahoma	Yes	\$ 80.00 A	\$ 90.00	K	Yes	G	No
1,2,3 Oregon	Yes	\$ 70.00	\$ 70.00	K	Yes	H	\$15-\$25
1,2 Pennsylvania	Yes	\$ 50.00 B	\$ 50.00 P	K	Yes	G	No
Puerto Rico	Yes	\$ 3.00 A	\$ 3.00	K	Yes	G	No
1,2 Rhode Island	Yes	\$ 50.00 A,S	\$ 25.00	K	Yes	G	No
South Carolina	Yes	\$100.00 A,O	\$ 30.00 O	K	Yes	G	No
South Dakota	Yes	\$100.00	\$100.00	K	Yes	G,H	\$ 6.00
1,2,3 Tennessee	Yes	\$ 30.00 A,O	\$ 30.00 A,O	K	Yes		No
1,2 Texas	Yes	\$100.00 A	\$100.00 A	K	Yes P		
1,2 Utah	Yes	\$100.00	\$ 40.00 P	K	Yes	G	No
Vermont	Yes	\$ 30.00 P	\$ 30.00 P	K	Yes	U	\$ 30.00 P
1,2 Virginia	Yes	\$ 75.00 A	\$ 75.00	K	Yes		No
1,2 Washington	Yes	\$125.00 A,L,O	\$ 65.00 L,O	K	Yes		\$ 10.00
1,2 West Virginia	Yes	\$150.00 D,O	\$ 75.00 O	K	Yes		No
1,2 Wisconsin	Yes	\$ 50.00 A	\$ 50.00 P	K	Yes		No
Wyoming	Yes	\$ 50.00	\$ 50.00	K	Yes R		No

## LEGEND:

1 - License required to manufacture.  
 2 - License required to wholesale.  
 3 - License required to ship into state.  
 A - Not transferable.  
 B - Transfer fee same.  
 C - Transfer fee \$15.00.  
 D - Transfer fee \$25.00. (IN-Y-\$200.)  
 E - Transfer fee \$50.00.  
 F - Administrative fee \$50.00.  
 G - Dangerous drugs saleable designated by law, including vet clinics, clinics, public health & outpatient hospitals.

H - Drugs saleable designated by Board, Arizona §10 Illinois general dealer permit.  
 J - Louisiana Board Health License products of Manufacturer.  
 K - Minimum standards designated by Board.  
 L - Pharmacy Asst. Utilization fee (§30-WA).  
 M - Triennial.  
 N - Only "retail dealers" selling more than 12 different non-prescription drug products are licensed; those selling 12 or less are exempt from licensure.

O - Additional fee. Controlled Substances Act.  
 P - Biennial.  
 Q - Registration under Controlled Substances Act included.  
 R - Twice a year.  
 S - Controlled Substances permit \$25.  
 T - Controlled Substances permit \$75.  
 U - Manufacturing, wholesale and research outlets.  
 V - Quadrennial.

## DRUG LAW

## XV. STATE DRUG RESTRICTIONS

State	Model Food and Drug Act Enacted	Dangerous Drug Law	Controlled Substances Act	Method of Rescheduling: Legislation, Regulation or other
Alabama		Yes H	Yes H	Yes
Alaska		Yes	Yes	Yes
Arizona	Yes	Yes	Yes H	Yes
Arkansas		Yes	Yes L	Yes
California	Yes	Yes	Yes	Yes
Colorado	Yes L		Yes	Legis.
Connecticut	Yes M	Yes M	Yes M	Yes M
Delaware	Yes A, F	Yes	Yes L	Yes
Dist. of Columbia	Yes A	Yes	Yes A, J	Yes
Florida	Yes F	Yes A	Yes A, F	Yes
Georgia		Yes H	Yes	Yes
Hawaii	Yes L	Yes L	Yes L	Yes L
Idaho	Yes		Yes K	Legis./Reg.
Illinois	Yes H	Yes H	Yes H	Yes R
Indiana	Yes	Yes	Yes K	Legis.
Iowa	Yes		Yes K	Legis.
Kansas		Yes H	Yes H	Yes K
Kentucky	Yes	Yes	Yes	Yes T
Louisiana	Yes L, T	Yes H	Yes K, T	Yes T
Maine		Yes	Yes	Yes L
Maryland	Yes	Yes H	Yes M	Yes
Massachusetts			Yes	Yes
Michigan	Yes F		Yes K	Yes
Minnesota	Yes F	Yes	Yes K	Legis./Reg.
Mississippi		Yes	Yes K	Legis.
Missouri	Yes	Yes J	Yes L	Reg. Q
Montana	Yes	Yes	Yes	Yes
Nebraska		Yes	Yes N	Yes G
Nevada	Yes	Yes K	Yes K	Legis./Reg.
New Hampshire			Yes K	Reg.
New Jersey	Yes F	Yes H	Yes L	Yes
New Mexico	Yes K	Yes K	Yes K	Reg.
New York	Yes		Yes	Legis.
North Carolina	Yes		Yes O	Yes
North Dakota	Yes K, P	Yes K, P	Yes B	Yes P
Ohio	Yes K	Yes K	Yes K	Reg.
Oklahoma	Yes F	Yes H	Yes C	Yes
Oregon	Yes D	Yes	Yes	Yes
Pennsylvania	Yes L	Yes J	Yes L	Yes L
Puerto Rico		Yes	Yes	
Rhode Island	Yes		Yes H	Yes
South Carolina		Yes H	Yes L	Legis.
South Dakota		Yes H	Yes L	Yes
Tennessee	Yes	Yes	Yes K	Yes G
Texas	Yes L	Yes	Yes E	Legis./Reg.
Utah			Yes S	Yes
Vermont	Yes	Yes	Yes L	No
Virginia	Yes		Yes K	Yes
Washington	Yes	Yes	Yes K	Yes
West Virginia			Yes K	Yes
Wisconsin		Yes	Yes K, L	Yes
Wyoming			Yes K, C	Yes

## LEGEND:

A - Same as federal regulations permit.  
 E - Controlled Substances Board.  
 C - Commissioner of Drugs and Substances Control.  
 C - Applicable to foods only.  
 H - State enabling act permits enforcement of federal act.  
 G - Exception: Cocaine containing cough syrup.

H - Uniform.  
 J - Dangerous Drug Law including stimulants and hallucinogenics.  
 K - Board of Pharmacy.  
 L - State Board of Health.  
 M - Department of Consumer Protection.  
 N - Bureau of Examining Boards.  
 O - Commission on Mental Health, Mental Retardation, and Substance Abuse.

P - State Laboratories Department.  
 Q - Commissioner of Narcotics and Dangerous Drugs Control.  
 R - Department of Alcoholism and Substance Abuse.  
 S - Attorney General.  
 T - Department of Human Resources.



## DRUG LAW

## XVI. MISCELLANEOUS STATE PHARMACY LAWS

Does the Board Have Regulations Requiring:	Time Requirement on PRN Refill Instructions	Patient Profile Records	Pharmacy Security in Absence of Pharmacist	Computerized Storage of Prescription Records	Brand/ Generic Name & Strength on Label
Alabama	No	No	Yes	Yes	Yes
Alaska	No	No	Yes	No	Yes
Arizona	Yes	No	Yes	Yes	Yes
Arkansas	No	No	Yes	Yes	Yes-not strength
California	No	No	Yes	No	Yes
Colorado	Yes	No	Yes	Yes	Yes-not strength
Connecticut	No	No	Yes 4	Yes	Yes
Delaware	Yes	Yes	Yes 3,5	Yes	Yes**
Dist. of Columbia	Yes	No	Yes	No	Yes
Florida	No 2	No	Yes	Yes	Yes
Georgia	No	No	Yes	Yes	No
Hawaii	No	No	Yes	No	Yes
Idaho	Yes	Yes	Yes	Yes	Yes
Illinois	No	No	Yes	Yes	Yes
Indiana	Yes	No	Yes	Yes	Yes*
Iowa	Yes	Yes 1	Yes	Yes	Yes
Kansas	No	No	Yes	Yes	Yes**
Kentucky	Yes	No	Yes	Yes	Yes-not strength
Louisiana	No	No	Yes	Yes	Yes
Maine	No	Yes	Yes	No	Yes
Maryland	No	No	Yes	Yes	Yes
Massachusetts	Yes	No	Yes	Yes	Yes-not strength
Michigan	No	No	Yes	No	Yes
Minnesota	No	No	Yes 4	Yes	Yes
Mississippi			Yes	Yes	Yes
Missouri	No	No	Yes	Yes	Yes
Montana	Yes	No	Yes	No	Yes
Nebraska	No	No	Yes 3,5	No	Yes
Nevada	No	No	Yes	Yes	Yes
New Hampshire	Yes	No	Yes 3,4,5	Yes	Yes
New Jersey	Yes	Yes	Yes	Yes	Yes
New Mexico	Yes	No	Yes	Yes	Yes-not strength
New York	No 6	No	Yes	Yes	Yes
North Carolina	Yes	No	Yes	No	Yes
North Dakota	Yes	Yes	Yes 5	Yes	Yes
Ohio	Yes 2	No	Yes	Under consid.	Yes
Oklahoma	No	No	Yes	No	No
Oregon	Yes	No	Yes	Yes	Yes
Pennsylvania	Yes	No	Yes	Yes	Yes
Rhode Island	No	No	No	No	No
South Carolina	No	No	No 3	No	Yes
South Dakota	No	No	Yes	Yes	No
Tennessee	No	No	Yes 3	No	Yes
Texas	Yes	No	Yes	Yes	Yes**
Utah	No	Yes	Yes	Yes	Yes
Vermont	Yes	No	Yes	No	Yes
Virginia	Yes	No	Yes	Yes	Yes
Washington	Yes	Yes	Yes	Yes	Yes
West Virginia	No	No	Yes	No	Yes
Wisconsin	Yes	Yes CSII	Yes	Yes	Yes
Wyoming	Yes	No	Yes	No	Yes

\* If substituted for brand (effective 8/1/84).

\*\* Manufacturer or distributor's name also required on label when using generics.

## LEGEND:

- 1 - If interns on premises.  
 2 - PRN not recognized as valid refill authorization.  
 3 - Sign must be posted.  
 4 - Pharmacy must be closed.  
 5 - ND - Pharmacy must be secured (alarmed), DE, NE, ND - Prescription Department secured and locked.  
 6 - PRN for one refill only (no for all CS).

## DRUG LAW

## XVI. MISCELLANEOUS STATE PHARMACY LAWS—(Cont)

State	Require Pharmacist-Patient Consultation For Dispensed Medicine?	Is State Contemplating Such a Requirement?	Is Prescription Needed to Buy Syringes/Needles?	Are Syringes/Needles Restricted to Sale Only in Pharmacy?	Sell Schedule V Preparations O-T-C*
Alabama		No	No	Yes	Yes
Alaska		No	No	No	Yes
Arizona		No	No	No	Yes
Arkansas		Yes	No	No	Yes
California		No	Yes	Yes	No
Colorado	Yes-if needed	No	No	No	No
Connecticut	Encouraged	No	Yes	No	Varies
Delaware	Yes		Yes	No	Cough syrups 1
Dist. of Columbia	Yes	No	Yes	Yes	Yes
Florida	Yes		No	No	Yes
Georgia			No	and Physicians	
Hawaii					
Idaho		No	No	No	Yes
Illinois		No	Yes	No	Yes
Indiana		No	No	No	Yes
Iowa		No	No	No	Yes
Kansas	Yes		No	No	Yes
Kentucky		No	No	No	Yes-some
Louisiana		No	No	No	Only Antidiarrheals
Maine	Yes		Yes	No	Yes
Maryland			No	No	Yes
Massachusetts	Yes		Yes	Yes	Varies
Michigan		No	No	No	Yes
Minnesota		No	No	Yes	Only Antidiarrheals
Mississippi		No	No	No	Yes
Missouri		No	No	No	Varies
Montana		No	No	No	No
Nebraska		No	No	No	No
Nevada		No	No	No	Yes
New Hampshire		No	Yes	Yes	Yes 1
New Jersey	Yes		Yes	Yes	Yes
New Mexico		No	No	No	Yes
New York		No	Yes	Yes	No
North Carolina		No	No	No	Yes
North Dakota	Yes		No	No	No
Ohio		No	No	No	Yes
Oklahoma		No	No	No	Yes
Oregon	Yes 2		No 3	No	No
Pennsylvania		No	Yes	No	Varies
Rhode Island		Yes	Yes	Yes	No
South Carolina		No	No	No	Yes
South Dakota		No	No	No	No
Tennessee		Yes	No	No	Varies-All codeine containing products restricted
Texas		No	No	No	
Utah					
Vermont	Yes	No	No	No	No Only Antidiarrheals
Virginia		No	No	Yes	Yes
Washington	Yes		No	No	Yes
West Virginia	Yes		No	No	Yes
Wisconsin	Yes		No	No	Yes
Wyoming		No	No	No	Yes

\*Check state requirements.

## LEGEND:

1 - Cough syrups containing codeine shall not be dispensed without a prescription.

2 - Where alcohol is contraindicated.

3 - Cannot sell to minors.

## DRUG LAW

## XVI. MISCELLANEOUS STATE PHARMACY LAWS--(Cont.)

Does the State Have Statutes/Regulations Requiring?	Duplicate or Triplicate (CSA) Prescription Forms	Imprints on Solid Dosage Medications	Penalties for Sale of OTC Look-Alikes	Penalties for Sale of Drug Paraphernalia
Alabama	No	Yes	Yes	Yes
Alaska	No	No	No	No
Arizona	No	Yes	Yes	Yes
Arkansas	No	No	Yes	Yes
California	Triplicate-Sched. II	No	Yes	Yes
Colorado	No	No	Yes	Yes
Connecticut	No	No	Yes	Yes
Delaware	No	No	Yes	Yes
Dist. of Columbia	No	No	No	Yes
Florida	No	Yes	Yes	Yes
Georgia	No	No	If promoted as C.S.	Yes
Hawaii				
Idaho	Triplicate-Sched. II	Yes	Yes	Yes
Illinois	Triplicate	No	Yes	No 1
Indiana	No	No	Only if promoted as C.S.	Yes
Iowa	No	No	Yes	Yes 1
Kansas	No	No	Yes	Yes
Kentucky	No	Yes (7-1-83)	Yes	Yes
Louisiana	No	Yes	Yes	Yes
Maine	No	No	No	Yes
Maryland	No	No	Yes	Yes
Massachusetts	Duplicate pending	No	Yes	Yes
Michigan	No	No	No	No
Minnesota	No	Yes	Yes	Yes 1
Mississippi	No	No	No	Yes
Missouri	No	No	Yes	Yes
Montana	No	Yes	Yes	Yes
Nebraska	No	Yes	No	Yes
Nevada	No	Yes	Yes, if promoted as C.S.	No
New Hampshire	No	No	Yes	Yes
New Jersey	No	No	Yes	Yes
New Mexico	No	No	Yes 2	No
New York	Sched. II only	Yes	Yes	Yes
North Carolina	No	Yes	Yes, if promoted as C.S.	Yes
North Dakota	No	Yes	Yes 2	Yes
Ohio	No	Yes	Yes	Yes
Oklahoma	No	No	If promoted as C.S.	No
Oregon	No	Yes	Yes	No
Pennsylvania				
Puerto Rico				
Rhode Island	Yes	No	No	Yes
South Carolina	No	No	Yes	Yes
South Dakota	No	Yes	Yes	Yes
Tennessee	No	No	Yes, if promoted as C.S.	No
Texas	Yes - CII	No	Yes	Yes
Utah	No	Yes	Yes	Yes
Vermont	No	No	Yes	Yes
Virginia	No	No	Yes	Yes
Virgin Islands				
Washington	No	Yes	Yes 2,3	Yes
West Virginia	No	Yes	Yes C.S.	Yes
Wisconsin			Yes	Yes
Wyoming	No	Yes	No	Yes

## LEGEND:

1 - Local laws/statutes only.

2 - Includes term "imitation" controlled substances.

3 - Ephedrine is considered a legend drug.

## DRUG LAW

## XVI. MISCELLANEOUS STATE PHARMACY LAWS—(Cont.)

Does the Board's State Act Provide for:	Separate Institutional Pharmacy Regulations	Separate Nuclear Pharmacy Regulations	Prescribing Authority for Optometrist's Diagnostics	Prescribing Authority for Nurse Practitioners or PAs	Prescribing Authority for Pharmacists
Alabama	No	No	No	No	No
Alaska	No	No	No	Yes - limited	No
Arizona	Yes	Yes	No	Yes	No
Arkansas	Yes	Yes	No	Yes	No
California	No	No	No	No	Yes
Colorado	No	Yes	No	Yes	No
Connecticut	Yes	Yes	No	No	No
Delaware	Nursing homes	No	No	No	No
Dist. of Columbia	Yes	Yes	No	No	No
Florida	Yes	Yes	Yes	No	Yes
Georgia	Yes	Yes	Yes	No	No
Hawaii					
Idaho	Yes	No	No	Nurse under protocol	No
Illinois	In process	In process	No	No	No
Indiana	Yes	No	No	No	No
Iowa	No	Yes	Pending	No	No
Kansas	Yes	Pending	No	No	No
Kentucky			No	No	No
Louisiana	Yes	Yes	No	No	No
Maine	Yes	No	No	Yes	No
Maryland	No	No	No	No	No
Massachusetts	Yes	Yes	No	No	No
Michigan	Yes	Yes	No	Under restrictions	No
Minnesota	Yes	Yes	Yes	No	No
Mississippi	Yes	Yes	No	Yes	No
Missouri	No	No	Yes	No	No
Montana	Yes	No	Yes	No	No
Nebraska	No	No	No	No	No
Nevada	Considering	Considering	Yes	RN=yes PA-no	No
New Hampshire	Yes	No	No	Nurses under protocol	No
New Jersey	Yes	Pending	No	No	No
New Mexico	Yes	Yes	Limited	PA restr. nurse-protocol	No
New York	No	No	No	No	No
North Carolina	Yes	No	Yes	Yes	No
North Dakota	No	Yes	Yes	No	No
Ohio	Yes	Yes	No	No	No
Oklahoma	No	No	Yes	No	No
Oregon	Yes	Considering	No	Limited	No
Pennsylvania	Yes	No	No	No	No
Puerto Rico					
Rhode Island	No	No	No	No	No
South Carolina	No	No	Yes	No	No
South Dakota	Yes	No	Yes	Yes	No
Tennessee	Yes	Pending	No	Nurses under protocol	No
Texas	Yes	Yes	No	No	No
Utah	No	No	Yes	Restr. nurse protocol	No
Vermont	Yes	No	No	Yes	No
Virginia	Yes	Yes	Yes	No	No
Virgin Islands					
Washington	Yes	Yes	Yes	Limited	Under protocols
West Virginia	No	No	Limited	No	No
Wisconsin	Yes	No	Yes	PA under protocol	No
Wyoming	No	No	Yes	No	No

## DRUG LAW

## XVII. PRODUCT SELECTION LAWS

## NPC Compilation: Key Provisions of State Drug Product Selection Laws

State	Formulary	2-line Rx Format	Permissive or Mandatory*	How to Prevent Substitution	Pharmacy Record Required	Cost Savings Pass-on	Patient Consent**	Label Specifications	Liability Disclaimer
Alabama	None	Yes	P	A	Yes	(8)	No	Yes	No
Alaska	None	No	P	B (5)	No	(8)	Yes	No	No
Arizona	None	Yes	P	A	Yes	(9)	Yes	Yes	No
Arkansas	Negative	No	P	B (5)	No	(8)	Yes	Yes	Yes
California	Negative	No	P	B (5)	No	(8)	Yes	Yes	Yes
Colorado	None	No	P	B	Yes	(7)	Yes	Yes	Yes
Connecticut	None	No	P	B	Yes	(7)	Yes	Yes	Yes
Dalaware	Positive (1)	Yes	P	A	Yes	(7)	Yes	Yes	No
Dist. of Columbia	Positive	No	P	B	Yes	(8)	Yes	Yes	Yes
Florida	Negative (2)	No	M	B	Yes	(7)	Yes	No	Yes
Georgia	None	Yes	P	A	Yes	(9)	Yes	No	No
Hawaii	Positive (1)	No	M	B	Yes	(8)	Yes	Yes	Yes
Idaho	None	Yes	P	A	Yes	(7)	Yes	Yes	No
Illinois	Positive	No	P	B (5)	Yes	(8)	Yes	No	Yes
Indiana	None	Yes	P	A	Yes	(8)	Yes	Yes	No
Iowa	None	No	P	B	Yes	(7)	Yes	No	No
Kansas	None	Yes (optional)	P	A/B	No	(8)	No	No	No
Kentucky	Negative (1)	No	M	B	Yes	(8)	No	Yes	Yes
Louisiana	None	No	P	B	Yes	(7)	Yes	No	No
Maine	None	No	P	B (5)	No	(10)	Yes	Yes	No
Maryland	Positive	No	P	B	Yes	(8)	Yes	Yes	Yes
Massachusetts	Positive	Yes	M	A	No	(8)	No	Yes	No
Michigan	None	No	P	B	Yes	(7)	Yes	Yes	No
Minnesota	None	No	P	B	No	(7)	Yes	Yes	No
Mississippi	None	Yes	M	A	No	(8)	Yes	Yes	Yes
Missouri	Negative	Yes	P	A	Yes	(8)	Yes	Yes	Yes
Montana	None	No	P	B	No	(7)	Yes	Yes	Yes
Nebraska	Negative	No	P	B	No	(7)	Yes	Yes	Yes
Nevada	Positive (1)	Yes	P	A	Yes	(8)	Yes	No	Yes
New Hampshire	Positive (1)	No	P	B	Yes	(8)	Yes	Yes	Yes
New Jersey	Positive	Yes	M	A	No	(7)	Yes	No	No
New Mexico	Positive (1)	No	P	B	No	(7)	No	Yes	No
New York	Positive	Yes	M	A	Yes	(8)	Yes	Yes	No
North Carolina	None	Yes (optional)	P	A/B	Yes	(8)	No	Yes	Yes
North Dakota	None	Yes	P	A	Yes	(8)	Yes	Yes	Yes
Ohio	Positive (2)	No	P	B	No	(7)	Yes	Yes	Yes
Oklahoma	(11)						(11)		
Oregon	None	No	P	B	Yes	(8)	Yes	Yes	Yes
Pennsylvania	Positive (3)	Yes	M	A	Yes	(8)	Yes	Yes	Yes
Puerto Rico	Positive	No	P	B	Yes	(8)	Yes	No	No
Rhode Island	Negative	Yes	M	A	Yes	(7)	No	No	Yes
South Carolina	None	Yes	P	A	Yes	(9)	Yes	Yes	No
South Dakota	None	Yes	P	A	No	(9)	No	No	No
Tennessee	Positive	Yes	P	A	Yes	(7)	No	No	Yes
Texas	None	Yes	P	A	Yes	(8)	Yes	Yes	Yes
Utah	Positive (1)	No	P	B (5)	Yes	(7)	Yes	Yes	Yes
Vermont	Positive	No	M	B	No	(10)	Yes	Yes	No

\* P = Permissive, M = Mandatory

\*\* (Yes) includes states where consent is required and those which required the patient to be notified/informed of substitution.

## DRUG LAW

## XVII. PRODUCT SELECTION LAWS--(Cont)

## NPC Compilation: Key Provisions of State Drug Product Selection Laws

State	Formulary	2-line Rx Format	Permissive or Mandatory*	How to Prevent Substitution	Pharmacy Record Required	Cost Savings Pass-on	Patient Consent**	Label Specifications	Liability Disclaimer
Virginia	Positive	Yes	P	A	Yes	(8)	Yes	Yes	Yes
Washington	Positive (1)	Yes	M	A	Yes	(8)	No	Yes	Yes
West Virginia	Negative	Yes (optional)	M (4)	A/B	Yes	(7)	Yes	Yes	Yes
Wisconsin	Positive (1)	No	P	B	No	(8)	Yes	Yes	Yes
Wyoming	None	Yes	P	A	Yes	(8)	No	Yes	Yes

\* P = Permissive, M = Mandatory

\*\* (Yes) Includes states where consent is required and those which required the patient to be notified/informed of substitution.

## LEGEND:

- (1) - Uses FDA Therapeutic Equivalency List.  
 (2) - Each pharmacy is to develop DPS List.  
 (3) - Each pharmacy is to list commonly used generics from state developed formulary.  
 (4) - Unless in the pharmacist's professional judgment.  
 (5) - Allows use of preprinted "do not sub" check-box.  
 (6) - Box must be checked to prevent DPS.  
 (7) - Full savings must be passed on to consumer.  
 (8) - Drug dispensed must be less expensive than drug prescribed.  
 (9) - No cost savings pass-on requirement mentioned.  
 (10) - No more than usual and customary charge for prescribed drug.  
 (11) - Oklahoma; O.S. (1981) simply states that it is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser.  
 (A) - Prescriber's signature on appropriate line of 2-line prescription.  
 (B) - Prescriber expressly indicates do not DPS in some manner.

Researched and compiled by the National Pharmaceutical Council in conjunction with Jesse E. Stewart, Ph.D., Associate Professor of Pharmacy Administration, College of Pharmacy, The University of Illinois at Chicago.

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**DRUG LAW**

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**XVIII. MINIMUM STANDARDS OF PRACTICE**

The United States Pharmacopoeia and National Formulary have been designated as the official compendia by the Congress of the United States through the Federal Food, Drug, and Cosmetic Act.

Articles listed in the USP or NF are official and the standards set forth in the monographs apply to them when the articles are intended or labeled for use as drugs or medical devices and when bought, sold, or dispensed for these purposes whether or not the articles are designated USP or NF.

- The designation USP or NF in conjunction with the official title on the label of an article is a reminder that the article purports to comply with USP or NF standards; it does not constitute assurances by the USP that the article is known to comply with USP or NF standards.

An article is recognized in the Pharmacopoeia when a monograph for the article is published in it, including its supplements, addenda, or interim revisions, and an official date is generally or specifically assigned to it.

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**ROSTER OF STATE BOARD EXECUTIVES**


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Below are the names and addresses of the board executives (chief administrative officers) of all NABP active member boards and U.S. associate members. Inquiries into state board laws, regulations and policies should be addressed to these individuals.

NABP Headquarters: O'Hare Corporate Center, 1300 Higgins Road, Suite 103, Park Ridge, IL 60068, 312/698-6227

AL... James W. McLane ..... 205/252-8976 2312 City Federal Bldg., Birmingham 35203	NE... Laura J. Partsch, Director ..... 402/471-2115 P.O. Box 95007, Lincoln 68509
AK... Harry D. Treagar, Director ..... 907/465-2534 Pouch D, Juneau 99811	NV... Elliott King ..... 702/322-0691 1201 Terminal Way, Suite 212, Reno 89502
AZ... John P. Street ..... 602/255-5125 6066 S. 19th Ave., Suite 101, Phoenix 85015	NH... Paul G. Boisseau ..... 603/271-2350 Health & Welfare Bldg., Hazen Dr., Concord 03301
AR... Lester Hosto ..... 501/681-2833 P.O. Box 55356, Little Rock 72225	NJ... Robert J. Terranova, Exec. Dir. .... 201/648-2433 1100 Raymond Blvd., Newark 07102
CA... Lorie Garris, Exec. Secy. .... 916/445-5014 1020 "N" St., Room 448, Sacramento 95814	NM... Charles A. Pineau, Exec. Director .... 505/841-6311 2340 Menaul N.E., Suite 220, Albuquerque 87107
CO... David L. Simmons ..... 303/866-2526 1525 Sherman St., Denver 80203	NY... Albert J. Sica ..... 518/474-3848 Cultural Education Center, Rm. 3035, Albany 12230
CT... Edward C. Liska ..... 203/566-3917 State Office Building, Hartford 06115	NC... David R. Work ..... 919/942-4454 P.O. Box H, 602H Jones Ferry Rd., Carrboro 27510
DE... Martin Golden ..... 302/736-4708 Robbins Bldg., Silver Lake Plaza, Dover 19501	ND... William J. Groz ..... 701/258-1635 P.O. Box 1354, Bismarck 58502-1354
DC... Carlyle McAdams ..... 202/727-7468 614 H Street N.W., Room 923, Washington 20001	OH... Frank Wickham ..... 614/466-4143 65 S. Front St., Room 504, Columbus 43215
FL... C. Rod Presnell, Exec. Director .... 904/488-7546 130 N. Monroe St., Tallahassee 32301	OK... Joe Schwemin ..... 405/521-3815 4545 Lincoln Blvd., Room 112, Oklahoma City 73105
GA... Donald C. Jackson, Exec. Director .... 404/656-3912 166 Pryor St., S.W., Atlanta 30303	OR... Ruth Vandever ..... 503/229-5849 P.O. Box 231, State Office Bldg., Room 904A 1400 S.W. 5th Ave., Portland 97207-0231
HI... Noe Noe Tom ..... 808/548-3086 P.O. Box 3469, Honolulu 96801	PA... R. Bruce Miller, Secretary ..... 717/783-7157 P.O. Box 2649, Transportation & Safety Bldg., 6th Fl. Harrisburg 17105-2649
ID... L. A. Lloyd ..... 208/334-2356 700 West State St., Boise 83720	PR... Carlos S. Rabell, MPA, Director, Div. of Exam. Boards Health Dept.-Pharmacy, Box 9342, Santurce 00908
IL... Gary L. Clayton, Director ..... 217/785-0800 Dept. of Registration & Education, Unit IV 320 W. Washington St., Springfield 62786	RI... Anthony F. DiSanto ..... 401/277-2837 304 Cannon Bldg., 75 Davis St., Providence 02908
IN... William S. Keown, Exec. Dir. .... 317/232-1120 Health Professions Service Bureau 964 N. Pennsylvania St., Indianapolis 46204	SC... C. Douglas Chaveus ..... 803/758-5447 P.O. Box 11927, Columbia 29211
IA... Norman Johnson ..... 515/281-5944 1209 East Court, Exec. Hills West, Des Moines 50319	SD... Harold Schuler ..... 605/224-2338 Box 518, Pierre 57501
KS... Everett L. Willoughby ..... 913/296-4056 503 Kansas Ave., P.O. Box 1007, Topeka 66601	TN... James Floyd Ferrell, Jr., Director .... 615/741-2718 404 Doctors Bldg., 706 Church St., Nashville 37219
KY... Richard L. Rcus ..... 502/564-3833 1228 U.S. 127 South, Frankfort 40601	TX... Fred S. Brinkley, Jr. .... 512/478-9827 211 E. 7th Street, Suite 1121, Austin 78701
LA... Howard B. Bolton ..... 504/925-6496 5615 Corporate Blvd., Suite 8E, Baton Rouge 70808	UT... Robert O. Bowen, Director ..... 801/530-6634 160 E. 300 So., P.O. Box 45802, Salt Lake City 84145
ME... Richard O. Campbell ..... 207/783-9769 1 Northwood Road, Lewiston 04240	VT... Wilfred Griffin ..... 802/828-2372 26 Terrace Street, Redstone Bldg., Montpelier 05602
MD... Roslyn Scheer, Exec. Director ..... 301/383-7245 201 West Preston St., Baltimore 21201	VA... J. B. Carson ..... 804/786-0239 517 1/2 Grace St., P.O. Box 27708, Richmond 23261
MA... Charles Monahan, Jr. .... 617/727-3076 100 Cambridge St., Boston 02202	VI... Angel LeBron, Chrmn. Pharm. Dept. .... 809/774-0117 Dept. of Health, P.O. Box 7309, St. Thomas 00801
MI... Herman Fishman, Licensing Exec. .... 517/373-0620 611 W. Ottawa, 4th Floor, Lansing 48909	WA... Donald H. Williams ..... 206/753-6834 WEA Bldg., 319 E. 7th Ave., Olympia 98504
MN... David E. Holmstrom ..... 612/623-6411 717 Delaware St., S.W., Rm. 351, Minneapolis 55414	WV... C. Herbert Traubert ..... 304/527-1270 150 Rockdale Road, Follansbee 26037
MS... H. W. Holloman ..... 601/354-6750 Suite 107-F, C&F Plaza, 2310 Hwy. 80 West Jackson 39204	WI... Sharon A. Russell, Program Asst. .... 608/266-8794 P.O. Box 8936, 1400 E. Washington, Madison 53708
MO... Kevin Kinkade ..... 314/751-2334 P.O. Box 625, Jefferson City 65102	WY... Marilyn H. Mitchell ..... 307/234-0294 1720 S. Poplar, Suite 5, Casper 82601
MT... Warren R. Amole, Jr. .... 406/761-5131 or 444-5436 510 1st Ave. N., Suite 100, Great Falls 59401	

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The NABP NEWSLETTER Roster of Chief Executive Officers is revised and published every January and July.



## NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.

Office Address:  
4110 CROMWELL STREET, ALEXANDRIA, VIRGINIA 22314  
Mailing Address:  
PO BOX 1417 049 ALEXANDRIA VIRGINIA 22313  
Telephone 703 549 3001

JAMES I. HARRISON, JR., CHAIRMAN OF THE BOARD  
ROBERT J. BOLGER, PRESIDENT

January 14, 1986

The Honorable Michael Bilirakis  
U. S. House of Representatives  
1130 Longworth House Office Building  
Washington, DC 20515

Dear Mr. Bilirakis:

I would like to take this opportunity to respond to your letter of December 17th. On behalf of NACDS, we appreciate your interest in the recent hearings before the Subcommittee on Oversight and Investigations concerning prescription drug diversion. As our testimony to the Subcommittee indicated, NACDS is deeply concerned with this issue and we hope our legislative recommendations contained in our statement will be given serious consideration.

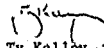
Regarding the specific questions in your letter, NACDS would like to make the following observations. First, on the issue of prescription drugs sold to the public through the mail, this practice is generally regulated by an individual state Board of Pharmacy or by State Business and Professional Codes. Mail-order prescriptions is one facet of the retail prescription drug distribution system. There currently exists certain business entities that are involved exclusively in mail-order pharmacy. This practice has expanded in recent years as insurance companies, unions, etc. Institute potential cost-saving options to control increasing health insurance rates.

Secondly, you ask whether NACDS is aware of the growing practice of doctors selling prescription drugs in their own office. NACDS is very concerned with this trend for a number of reasons. We object to physician dispensing because in many instances doctors are selling medications to patients without having to comply with labeling and record-keeping requirements that govern prescription drugs that are dispensed in retail pharmacies. Doctors are usually serviced by vendors and will dispense the medication to the patient in an envelope that does not identify the drug or provide basic instructions for proper use. On other occasions, it is not uncommon for doctors to dispense several different drugs in the same envelope. In brief, NACDS believes that this type of practice is wrong and should be stopped in the interest of patient care. It should be noted that the 98th Congress placed tighter controls on physician dispensing of controlled substances and we feel that adequate labeling and recordkeeping should also be applied to non-controlled drugs that are dispensed by doctors.

As to your last question, NACDS has no knowledge or information as to whether the mail order business or physician dispensing serves as channels for the distribution of diverted or counterfeit drugs.

In conclusion, we deeply appreciate your inquiry and hope that our responses will be useful. If we can be of further assistance, please let us know.

Sincerely,

  
Ty Kelley  
Vice President  
Government Affairs

TK/kar

Bruce J. Brennan  
SENIOR VICE PRESIDENT AND  
GENERAL COUNSEL

**Pharmaceutical  
Manufacturers  
Association**

January 24, 1986

The Honorable Michael Bilirakis  
U. S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Bilirakis:

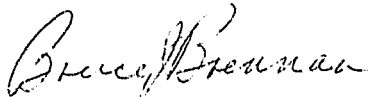
This responds to your December 17, 1985 inquiry regarding the sale of prescription drugs through the mails and physician dispensing of such drugs in their own offices. The PMA represents over 100 research-based manufacturers of prescription drugs but does not include within its membership mail order pharmacies or practicing physicians. However, to the best of our knowledge the practices referred to in your letter are regulated as follows.

Prescription drugs may legally be sent through the mails by a pharmacy to a patient who presents a valid prescription to the pharmacy. A mail order pharmacy is regulated in the same fashion as other pharmacists, that is the pharmacy and its pharmacists are licensed by the state, and their practices are regulated by the applicable State Board of Pharmacy. We would estimate the total mail order market to be less than 3% of the prescription drug volume in this country, including the approximately 20 million prescriptions filled through the mails each year by the Veterans Administration. We are not aware of the distribution of any counterfeit or diverted drugs by mail order pharmacies.

The practice of physician selling of prescription drugs to patients in their own offices in connection with office visits is also regulated by state law. In general this practice is permitted under state Medical Practice and Pharmacy Practice Acts; however, approximately 10 states limit such sales by physicians to a 24-hour supply. Typically the physician charges the patient for the medication which is given to the patient at the conclusion of the office visit. The physician in many instances will purchase the medication directly from the manufacturer; however a physician may also purchase the product from pharmaceutical services companies who in turn purchase from the manufacturer and repackage into unit of use packages for sale to the physician. Again, we do not know of any sales of diverted or counterfeit products by physicians who dispense from their own offices.

We appreciate the opportunity to submit these responses for the record in connection with the December 6, 1985 hearing before the Subcommittee on Oversight and Investigations concerning prescription drug diversion. If you have additional questions please contact me.

Sincerely,



Bruce J. Brennan

Bruce J. Brennan  
SENIOR VICE PRESIDENT AND  
GENERAL COUNSEL

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Subcommittee on Oversight  
and Investigations

January 30, 1986

Pharmaceutical  
Manufacturers  
Association

The Honorable Ron L. Wyden  
U. S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Hyden:

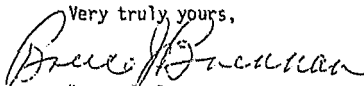
At the December 6, 1985 hearing conducted by the Subcommittee on Oversight and Investigations on drug diversion issues, you inquired as to company procedures for monitoring compliance with "own use" provisions included in company contracts with non-profit institutions.

PMA member companies regularly insist that non-profit hospitals sign a detailed declaration that pharmaceuticals being purchased by the institution at favorable prices are for the institution's "own use", as that term was defined by the U.S. Supreme Court in the Portland Retail Druggists Association decision. Companies also closely monitor volume and frequency of sales to non-profit institutions in order to identify any unusual purchases. If such purchases are discovered, they are subjected to additional scrutiny to insure that the pharmaceuticals are being utilized by the purchaser in accordance with the limitations in the hospital's certification of "own use".

PMA inquired of its major members active in the PMA Marketing Section of their enforcement policies regarding non-profit institution certification. No lawsuits brought by PMA member companies against non-profit institutions based on the certification process have been identified. However, individual companies regularly refuse to continue to supply their products at favorable prices to institutions that they have determined are purchasing in violation of own use limitations. When a company terminates a contract with a non-profit hospital, applicable wholesalers are also notified of the company's decision and are instructed not to continue to supply the terminated facility at the contract favorable price.

We appreciate the opportunity to include the PMA's response in the official record of the Subcommittee's hearing on drug diversion.

Very truly yours,



Bruce J. Brennan

✓ cc: The Honorable John Dingell  
Chairman  
Subcommittee on Oversight and Investigations

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**THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS**

205 DAINGERFIELD ROAD, ALEXANDRIA, VA 22314  
(703) 683-8200

January 3, 1986

U.S. House of Representatives  
Committee on Energy and Commerce  
Room B-334, Rayburn House Office Building  
Washington, D.C. 20515

Re: December 6, 1985 transcript of Dr. Charles M. West.

Dear Mr. Watt:

Attached is the original transcript which we received just prior to closing our office for the holidays. Corrections are indicated in red. Additionally, the material requested for the record with placement indicated by page and line are as follows:

Page 42, Line 952.

NARD's January 1985 proposed amendment to the 1938 Non-Profit Institutions Act; 1985 NARD Resolution and select state resolutions supporting same; and related materials.

Page 42, Line 959.

Text of H.R.2385 regarding FTC report on predatory pricing practices as approved by the House on 9/17/85; and the text of S.1078 addressing the same subject approved by the Senate on 7/25/85.

Page 43, Line 967.

Text of Office of Advocacy, SBA, recommendations for an amendment clarifying FTC authority and related IRS recommendations impacting commercial non-profits.

January 3, 1986  
Page two

Page 43, Line 981.

Text of H.R. 3839 and companion Senate bill S.1849 - Bills to protect consumers and automobile dealers from unfair price discrimination in the sale by manufacturers of new automobiles.

Page 44, Line 997.

Two articles regarding state legislative hearings focused on the need to obtain charitable drug prices for the Medicaid drug prescription program.

Page 81, Line 1855.

NARD will submit response for the record to 11/5/85 letter to the Honorable James T. Broyhill from Phillip Kirk, Secretary of North Carolina's Department of Human Resources in conjunction with additional material requested by Subcommittee member Bilirakis on or before January 14, 1986.

Page 99, Line 2275.

Acting Chairman Wyden expressed concern regarding the possible application of the proposed NARD legislation to the governmental entities. The Supreme Court has exempted the purchases by federal, state and local governments from price discrimination sanctions of the Robinson-Patman Act unless the government engages in non-traditional functions such as the establishment of a retail pharmacy which competes directly with retail pharmacies such as those NARD represents. Thus, the traditional governmental functions which Chairman Wyden mentioned would not be affected by the NARD proposed amendment to the 1938 exemption which protects charitable non-profits from the sanctions of the Robinson-Patman Act.

Two leading cases on the issue are: Jefferson County Pharmaceutical Assn Inc. v. Abbott Laboratories et al, 1983, and Abbott Laboratories et al v. Portland Retail Druggists Assn. Inc. 1976. We request that each opinion in its entirety to be included in the record in conjunction with Chairman Wyden's questions.

Page 99, Line 2297.

Partial text (page 3 - 6) of testimony by U.S. Attorney Larry D. Thompson presented to the Subcommittee on 10/31/85 regarding the cost shifts to the general public caused by discriminatory pricing practices and drug diversion (see especially, page 5),

January 3, 1986  
Page three

Page 100, Line 2313.

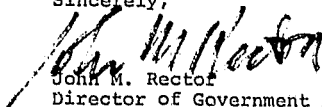
The chart presented to the Subcommittee on 7/10/85 by staff members Sims and Nelson.

Page 103, Line 2394.

Text of Table IX entitled Wholesale Price INcreases For The Top Twenty Prescription Drugs as of July 1985. From staff report on Price Increases for Prescription Drugs and Related Information, submitted 7/15/85 to the Subcommittee on Health and the Environment.

Please let us know if we can be of further assistance on this matter.

Sincerely,



John M. Rector  
Director of Government Affairs

JMR/eu

Enclosures

(Editor's note: The documents referred to above have been retained in subcommittee files.)

