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United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-248618

July 21, 1992

The Honorable Fortney H. (Pete) Stark
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

A major concern in the nation's battle against drug abuse is the illegal diversion of prescription drugs, such as morphine, codeine, and diazepam (known by the brand name Valium), that are subject to abuse because of their psychological or physical effects on the user. Drug diversion can involve the illegal sale of prescriptions by physicians, illegal dispensing by pharmacists, or "doctor shopping" by individuals who visit multiple physicians to obtain prescriptions. The Drug Enforcement Administration (DEA) estimates that several hundred million doses of these types of prescription drugs are diverted to illicit use from the more than 1.5 billion prescriptions dispensed annually.

Ten states use prescription drug monitoring programs that state program and Medicaid officials believe have been effective in detecting and deterring drug diversion. An additional state has recently established a drug monitoring program.[1] These programs use information from prescriptions for selected drugs to evaluate physician prescribing patterns, pharmacist dispensing patterns, and patient purchasing habits. Eight states collect this information from multiple-copy prescription forms, two others obtain the information electronically, and one collects information electronically, in addition to retaining a multiple-copy form requirement. The programs apply to all prescriptions written for selected drugs, regardless of whether the prescription is paid for in cash, through third-party reimbursement, or by the state's Medicaid program.[2]

At your request we examined the 10 established state programs to determine (1) whether the programs have benefited investigation efforts and have been effective in detecting and reducing drug diversion and (2) whether savings have resulted to state Medicaid programs through reduced Medicaid claims for prescription drugs. We also obtained descriptive information on the new program in Massachusetts. In addition, we examined concerns of program opponents who contend that these

[1]Massachusetts adopted its program in April 1992.

[2]Medicaid is a federally supported and state-administered assistance program that provides medical care for certain low-income individuals and families.

programs adversely affect medical practice and compromise patient care by causing physicians to change their prescribing habits, and compromise patient confidentiality by allowing the state to maintain information on the prescription drugs an individual takes.

Results in Brief

Prescription drug monitoring programs save investigators' time and improve their productivity by providing information that allows them to identify potential cases of drug diversion. Because the programs provide law enforcement and health care licensing and regulatory agencies with access to complete information on the prescribing, dispensing, and purchasing of selected prescription drugs in a state, investigators are able to utilize their time and resources more efficiently. Although one goal of the programs is to reduce the number of prescriptions for selected drugs by eliminating inappropriate or illegal prescriptions, only 5 of the 10 states reviewed actually showed declines in the number of prescriptions for these drugs since their programs were implemented. From the information available, it is not clear whether the decreases were due to reduced diversion, changes in physician prescribing practices, or both. Four of the remaining five states did not have information on their program's effect on covered prescription drugs, and one state reported no change.

Prescription drug monitoring programs were not designed to measure their effect on reducing health care costs, however, 2 of the 10 states have reduced state Medicaid prescription drug costs by an estimated $27 million over 2 years and $440,000 for 1 year, respectively. The other eight states were unable to estimate Medicaid savings because (1) the drug monitoring programs had been in effect for many years, thus data were not available to compare the before and after effects on Medicaid claims, or (2) changes in Medicaid coverage or prices paid for some drugs made calculating savings difficult.

Claims by medical, pharmaceutical, and patient organizations that prescription drug monitoring programs adversely affect a physician's ability to practice medicine or compromise patient care or confidentiality have not been substantiated. Program opponents contend that the programs adversely affect the practice of medicine, however, none of the state laws or regulations authorizing the programs restrict a physician from writing prescriptions for covered prescription drugs. Of the 10 states we reviewed, only 1 had a confirmed complaint that their drug monitoring program had affected patient care. All the state programs have controls

that protect patient confidentiality, and none has reported receiving complaints that their program had compromised patient confidentiality.

Background

Drugs categorized as controlled substances are subject to the guidelines of the Controlled Substances Act of 1970. The act places controlled substances into one of five schedules based on their potential for abuse, addiction, and medical use. Controlled substances on schedule I, such as heroin, and those on schedule II, such as morphine, have the highest potential for abuse. All but schedule I controlled substances have accepted medical use and are legally available to the public.

DEA reports that diversion of controlled substances that have a high potential for abuse or profit in illicit markets is both serious and pervasive. Diversion can occur in a number of ways, including

- illegal sales by physicians or pharmacists;
- illegal acquisition of prescriptions by individuals from multiple physicians under the pretense of legitimate medical need;
- indiscriminate, inappropriate, or careless prescribing by physicians or dispensing by pharmacists;
- prescription forgery; and
- drug theft from physicians and pharmacies.

While federal efforts to control diversion are concentrated at the wholesale and manufacturing levels, states' efforts have focused on detecting diversion where it is most likely to occur—at the retail level. One approach that some states use is to establish prescription drug monitoring programs that track the prescribing, dispensing, and purchasing of certain controlled substances.

As of May 1992, 11 states[3] —California, Hawaii, Idaho, Illinois, Indiana, Massachusetts, Michigan, New York, Oklahoma, Rhode Island, and Texas—operated prescription drug monitoring programs (see table 1). Many programs have been in place for more than 10 years, with California's the oldest (implemented in 1940) and Oklahoma's and Massachusetts' the newest (1991 and 1992, respectively). Each state collects and analyzes information on the prescribing, dispensing, and purchasing of selected controlled substances. They do not, however,

[3]Washington also has a prescription drug monitoring program, but it applies only to those physicians disciplined for poor prescribing practices.

collect information on whether the prescription is paid for in cash, by a third-party payer, or by Medicaid.

The programs typically cover schedule II controlled substances, such as morphine and codeine, though some programs also include other controlled substances, such as anabolic steroids, from schedule III. Over time, California, Illinois, Michigan, and New York expanded their programs to cover additional controlled substances. New York is the only state to cover tranquilizers and antidepressants known as benzodiazepines that are schedule IV controlled substances.

Table 1: Prescription Drug Monitoring Programs

State	Year started	Covered controlled substances
California	1940	Schedule II[a]
Hawaii	1943	Schedule II[b]
Idaho	1967	Schedule II
Illinois	1961	Schedule II, glutethimide, pentazocine[c]
Indiana	1989	Schedule II
Michigan	1989	Schedule II, anabolic steroids[d]
Massachusetts	1992	Schedule II
New York	1977	Schedule II, anabolic steroids, benzodiazepines[e]
Oklahoma	1991	Schedule II
Rhode Island	1979	Schedule II, syringes
Texas	1982	Schedule II

[a]The program initially included only selected narcotics. In 1972, the program became mandatory for all schedule II narcotic controlled substances and, in 1981, it was extended to schedule II nonnarcotic controlled substances.

[b]Initially, the program covered selected narcotics. In 1972, it was revised to include all schedule II controlled substances.

[c]The program includes only selected schedule II controlled substances, such as narcotics and amphetamines. Pentazocine and glutethimide were added in 1978 and 1984, respectively.

[d]Anabolic steroids were added to the program in 1990.

[e]The program for schedule II controlled substances became fully implemented in 1977. In 1989, the program was expanded to include schedule IV benzodiazepines, and in 1990, anabolic steroids.

Except for Oklahoma and Massachusetts, the states require physicians to write prescriptions for covered controlled substances on multiple-copy

prescription forms.[4] Generally, physicians keep one copy, the pharmacist keeps another, and the remaining copy is sent to the state program agency. Oklahoma does not use multiple-copy prescription forms, but has the pharmacist transmit prescription information electronically[5] to the state program agency. Massachusetts has also adopted this electronic transmission system. In April 1992, Hawaii modified its program by implementing an electronic transmission system similar to Oklahoma's. This system will operate in tandem with the requirement for a multiple-copy prescription form until the effectiveness of the new system is evaluated.

Eight of the 11 states maintain a computerized data base that provides comprehensive information on the prescribing, dispensing, and purchasing of all covered controlled substance prescriptions by physicians, pharmacists, and patients regardless of method of payment. Both Hawaii's and Massachusetts' new electronic transmission systems will provide a computerized data base of prescription information. In California, staff enter prescription information into the computer only on the drugs that the state considers most abused because the program lacks sufficient resources for full implementation.

States use the computerized data bases to generate reports on prescribing practices of physicians, dispensing activities of pharmacies, or purchasing practices of individuals. Potential cases of diversion or inappropriate prescribing are identified by using established criteria for the number of prescriptions written, controlled substances dispensed, or the number of prescriptions an individual obtains from different physicians. Reports can also be prepared for individual or multiple controlled substances or for controlled substance activity within a particular geographic area of the state or statewide.

Information generated by the prescription drug monitoring programs is used by law enforcement, licensing and regulatory agencies, and some Medicaid fraud control units for investigative purposes. Program information is also used by state agencies for physician education purposes. One state, New York, provides reports to county medical societies for peer review counseling.

[4]Eight of the nine states require the use of a state-issued multiple-copy prescription form. Hawaii does not have such a form, but requires physicians to write controlled substance prescriptions in duplicate.

[5]Pharmacies and dispensing physicians may submit prescription information to the state by computer or on diskette or tape. Pharmacies that are not computerized may submit information on a universal claim form.

Prescription drug monitoring programs, particularly those with multiple-copy prescription requirements, have been opposed by a number of medical, pharmaceutical, and patient organizations. They contend that the fear of a state investigation results in some physicians prescribing alternative, less effective drugs that are not covered by a state's monitoring program for patients, and that other physicians have stopped prescribing certain controlled substances altogether. Opponents are also concerned that these programs compromise patient confidentiality because they provide the state with information on the controlled substances a patient is taking. Programs that require multiple-copy prescription forms are also opposed by physicians and pharmacists because they impose additional paperwork and record-keeping requirements.

Scope and Methodology

To assess how the 11 state programs control diversion, we visited three states—Illinois, Michigan, and New York. In these states, we interviewed state program, Medicaid, and law enforcement officials; members of state and county medical associations; and pharmacy association representatives to obtain their views and studies relating to the programs. For seven other states, we contacted program officials and obtained information on program goals, operations, benefits, and costs. Because the program in Massachusetts is new, we could only include descriptive information about it in our review. We also met with officials from DEA, the Department of Health and Human Services' Office of the Inspector General, the National Institute on Drug Abuse (NIDA), and pharmaceutical manufacturers.

To determine whether the programs have resulted in Medicaid savings, we evaluated available state Medicaid information to determine whether there were changes in the number of claims for covered controlled substances following implementation of the program. If claims information was not available, we determined why. Additionally, we asked state Medicaid officials to estimate Medicaid savings, if any, resulting from their state's prescription drug monitoring program. We reviewed their savings estimate methodologies and determined that they were based on reasonable assumptions and data collection strategies, but did not verify the accuracy of the information used.

To determine if the programs adversely affected medical practice, patient care, or patient confidentiality, we reviewed available studies on these subjects. After determining that the programs had controls to protect

patient confidentiality, we determined whether states had received complaints that the controls have been violated. We also asked program officials in 10 states to provide us with the number and the types of complaints they received from physicians and patients. At a 1991 NIDA technical conference, we obtained information on prescription drug control systems' impact on medical practice and patients. We also discussed this issue with representatives of physician and pharmacy groups and several pharmaceutical company representatives and reviewed information they provided us to support their views.

We provided sections of a draft of this report to three of the states with drug monitoring programs and incorporated their comments where appropriate. We performed our work between March 1991 and May 1992 in accordance with generally accepted government auditing standards.

States Claim Programs Improve Investigations and Reduce Diversion

Prescription drug monitoring programs increase the efficiency of law enforcement operations and result in greater numbers of licensing and disciplinary actions against health care providers and prescription drug users, program officials report. Programs with multiple-copy requirements also allow for identifying forgeries and thefts through the use of special prenumbered forms that deter tampering and allow prescriptions to be traced. In addition, 5 of the 10 states with established programs experienced reductions in the number of prescriptions for covered controlled substances following program implementation or expansion. It is unclear, however, whether the reductions were due to reduced diversion, changes in physician prescribing practices, or both.

Program officials in the 10 states with established programs reported more effective and efficient law enforcement and licensing investigations as an important program benefit. The programs provide law enforcement and health care licensing and regulatory agencies information on the prescribing, dispensing, and consuming patterns for controlled substances that is otherwise unavailable. Without such a program, investigators must spend extensive time in pharmacies and physicians' offices collecting and analyzing information just to establish prescribing, dispensing, and consuming patterns. With the programs' centralized data base, information can easily be generated regarding high-volume prescribers and dispensers, prescribing patterns and changes, and patients that receive prescriptions for the same drugs during the same time period from multiple doctors.

In Michigan, for example, access to comprehensive data enabled state officials to identify and arrest an individual who had acquired prescriptions for schedule II controlled substances from 69 physicians. In another case, Michigan officials were able to identify an individual who obtained 41 schedule II prescriptions from 24 physicians that were filled by 27 pharmacies in 14 different cities.

In Indiana, the drug monitoring program identified a general practice physician who was writing very large quantities of schedule II prescriptions for patients from four states who were traveling many miles to obtain these drugs. Upon investigation, the physician was found to be writing prescriptions for these drugs without examining patients, and was found to be supplying many patients who had criminal records in drug-related offenses. The physician pleaded guilty to violating the Controlled Substances Act and surrendered his license to practice medicine.

In Texas, officials estimated cost savings as a result of increased efficiencies in investigations. Texas investigators conducted 289 investigations for criminal as well as licensing and regulatory board actions during the 2-1/2 year period following the program's implementation. The state reports that to achieve the same results in the same time without the program would have required an extra $2.6 million to fund additional staff to collect, analyze, and follow-up on controlled substance prescription information.

Declines in the total number of prescriptions for controlled substances, ranging from about 10 to 60 percent, were reported by California, Michigan, New York, Rhode Island, and Texas following the first 2 years that their programs were implemented or expanded. None of these states, however, could tell us whether the declines were due to (1) physicians, pharmacists, or patients reducing prescription drug diversion; (2) physicians cutting back on unnecessary or necessary controlled substance prescriptions; or (3) both.

Program officials from Indiana and Oklahoma told us that they had not evaluated their program's effect on controlled substance prescriptions or diversion because the programs were relatively new. They plan to perform a program evaluation during 1992. The Massachusetts program is also too new to evaluate its impact.

Officials in Illinois and Idaho stated that due to program age, they did not have historical data to determine whether decreases in controlled substance prescriptions occurred following their program's implementation in 1961 and 1967, respectively. Hawaii reported no change in the number of controlled substance prescriptions following implementation of its current program in 1972.

Medicaid Savings Are Difficult to Quantify

Medicaid is a federal/state program, authorized by title XIX of the Social Security Act, under which the federal government assists the states in paying for health services needed by low-income individuals. States design and operate their Medicaid programs within broad federal requirements, and the federal government pays a percentage of state costs for health services. States must cover a number of health services, while others are optional. Coverage of outpatient prescription drugs is an optional Medicaid benefit offered by all 50 states and the District of Columbia.

As stated earlier, states with drug monitoring programs gather prescription information for covered drugs regardless of whether the prescription is paid for in cash, by a third-party payer, or by the state Medicaid program. To the extent that the drug monitoring programs deter illegal diversion and reduce the number of prescriptions for covered controlled substances, prescription drug costs for third-party payers and Medicaid would decline.

In the 10 states with established programs, Medicaid officials believe that their state's drug monitoring program provides a deterrent and reduces the illegal diversion of controlled substances paid for by Medicaid. However, prescription drug monitoring programs are not designed to track health care costs and cannot separately identify Medicaid claims. Although Medicaid claims for covered controlled substances declined in five states following implementation or expansion of the monitoring programs, the Medicaid programs in only two of three states—New York and Michigan—had the information to estimate Medicaid cost savings. Of the remaining five states, four did not have the information necessary to determine whether there were declines in Medicaid prescription claims for covered controlled substances, and one reported no change in Medicaid claims.

Two States Estimated Medicaid Cost Savings

New York's Medicaid program realized an estimated $27 million savings from January 1989 through December 1990 caused by an approximate 55-percent decrease in benzodiazepine prescriptions after they were added

to New York's drug monitoring program in 1989. This savings estimate takes into account an offsetting 20-percent increase in the cost for noncovered substances that physicians may have prescribed as substitutes for benzodiazepines to avoid the state monitoring program.

Michigan's Medicaid program had an estimated savings of about $440,000 for certain controlled substances in the year following implementation of the prescription drug monitoring program. This is based on a 47-percent decrease in controlled substance prescription claims. Unlike in New York, however, Medicaid officials in Michigan did not find physicians substituting noncovered controlled substances for covered controlled substances.

Lack of Data Hampers Estimating Medicaid Savings and Tracking Program Results

Prescription drug monitoring programs were not designed to track changes in Medicaid controlled substance prescription claims and costs. As a result, information is not generally available to estimate Medicaid cost savings. Several other factors also affect states' ability to estimate whether their drug monitoring programs resulted in Medicaid savings.

Medicaid controlled substance prescription claims in Oklahoma declined by 10 percent in the first quarter following program implementation; in Indiana claims declined by 27 percent in the first year after implementation; and in Texas, claims declined by 60 percent after 2 years of implementation. However, Medicaid officials did not have the data to estimate savings for several reasons. Some of the states expanded Medicaid's coverage of controlled substances at the same time Medicaid implemented its prescription drug monitoring program. Also, the number of Medicaid recipients increased significantly over the 2-year period following program implementation, or the prices Medicaid paid for controlled substances increased after program implementation.

Medicaid officials in California, Idaho, Illinois, and Rhode Island told us that they could not determine whether the prescription drug monitoring programs produced Medicaid savings because they did not have the historical data from when the monitoring programs started over a decade ago. Medicaid programs usually do not retain data of this age that could be used to determine whether Medicaid controlled substance prescription claims decreased and resulted in savings following program implementation.

Program Effect on Medical Practice, Patient Care, and Confidentiality

Medical, pharmaceutical, and patient organizations oppose drug monitoring programs that use multiple-copy prescription forms because they believe that the programs alter physician prescribing practices in a way that adversely affects patient care and compromises patient confidentiality. Although it appears that some physicians in New York changed their prescribing habits after the program was expanded in 1989, there is little additional evidence to support these contentions.

Program opponents contend that physicians fear multiple-copy prescription programs because such programs provide the state information that may be used to investigate their prescribing practices. In their view, physicians may write prescriptions for drugs that do not require use of the multiple-copy form. Program opponents thus believe that patients suffer from such physician behavior because they receive drugs that are less effective. In support of their contention, opponents cite a November 1991 study[6] that concluded that New York's multiple-copy prescription program had, in some cases, caused physicians to substitute less effective noncovered controlled substances for benzodiazepines that would have required them to use a multiple-copy form.

New York program officials acknowledge that some physicians changed their prescribing patterns after the program was expanded. They disagree, however, that substitution of alternative controlled substances has negatively affected patients or that physicians prescribe inappropriate medications for their patients. Further, New York officials report that prescribing of alternative controlled substances dropped off after the first year that benzodiazepines were added to the program.

Although opponents contend that multiple-copy programs cause physicians to change their prescribing habits, none of the state laws or regulations authorizing the 11 programs restricts a physician from writing prescriptions for covered prescription drugs. Also, DEA is not aware of any documented evidence that supports these allegations or shows that physicians deny their patients proper medical care because they are afraid of being held accountable for their prescriptions.

Except for New York, none of the states reported substantiating any complaints that the programs interfere with a physician's practice, hinder a physician's ability to provide appropriate patient care, or compromise patient confidentiality. Where complaints had been received, they typically

[6]"Consequences of the 1989 New York State Triplicate Benzodiazepine Prescription Regulations," Weintraub, and others, Journal of the American Medical Association, Nov. 6, 1991, vol. 266, no. 17, p. 2392-97.

reflected a physician's or patient's misunderstanding of program requirements. For example, physicians in Michigan wrote to the program complaining that the multiple-copy prescription form took much longer to complete than a standard prescription form used for noncovered controlled substances. However, the only additional information required on the multiple-copy prescription form compared to the standard form was the patient's age.

New York program officials reported receiving about 40 inquiries from patients who were concerned that the program restricted their physician from prescribing benzodiazepines following the addition of these controlled substances to the program. The state contacted these patients to explain that the program did not require physicians to change their prescribing practices and provided them information about the program. New York identified one case where a physician stopped prescribing a benzodiazepine for a patient following the addition of these drugs to the state's program. A program official told us that this patient was referred to another physician.

Another fear expressed by opponents is that drug monitoring programs compromise patient confidentiality by providing the state information on the prescription drugs a patient is receiving. Such information, they believe, should be kept confidential between the physician and the patient, and the state has no need for, or right to, this information. However, states usually have access to patient names and information when conducting pharmacy audits and investigations. Also, all 11 state programs have controls designed to protect patient confidentiality. Further, none of the 10 states with established programs has substantiated any complaints that their drug monitoring program has compromised patient confidentiality.

States Adopt Electronic Transmission Systems

The most recent trend in drug monitoring programs is toward using electronic point-of-sale transmission systems to collect prescription information. Both Oklahoma and Massachusetts have established electronic programs, and Hawaii has added this feature to its existing multiple-copy program. Programs that rely on electronic submission of data have met with less opposition than multiple-copy prescription programs because physician and pharmacy groups view electronic programs as less burdensome and less intrusive.

Oklahoma officials had tried for several years to obtain legislative approval for a multiple-copy prescription program to address concerns

about prescription drug diversion. However, they met with strong opposition from pharmaceutical manufacturers and physicians. State officials studied other systems that could provide them with the prescription information they needed, but would appear less invasive to physicians and pharmacists. The decision to pursue an electronic transmission system received support from the law enforcement and health community, as well as medical and pharmacy associations and pharmaceutical manufacturers that had opposed the multiple-copy approach.

Oklahoma's electronic transmission system is limited, however, in its ability to prevent forgeries and alterations and to detect and deter the theft of prescriptions. This is due to the absence of a requirement that prescriptions be written on special preprinted forms with assigned serial numbers. Preprinted prescription forms that use special paper and a unique numbering system, such as those required by most multiple-copy programs, make tampering with the forms difficult and allow stolen forms to be traced.

Oklahoma's electronic prescription drug monitoring program began on January 1, 1991. The program received about 75 percent of the funds needed for the first year of operation from a Department of Justice block grant. The program collects prescription drug information on schedule II controlled substances from the dispensing pharmacies that are responsible for entering the information that is sent to the program through computers, disks, tapes, or universal claims forms. Oklahoma's program collects information similar to a multiple-copy program, such as the name of the physician who wrote the prescription, the pharmacy that dispensed the drug, and the individual who received the prescription. Physicians write the prescriptions on ordinary prescription pads and are not required to submit multiple copies.

As of April 1992, the Oklahoma program had not received any complaints that it adversely affected a physician's medical practice or patient care or confidentiality. Access to the on-line computer is limited, and records are kept of all requests. Information is divulged only in criminal cases. Information is maintained by individual patient number (drivers license and state suffix), pharmacy name or number, and physician name or DEA number. Program officials believe that support for the program has increased as physicians and pharmacists become more knowledgeable about its ability to identify and provide them with feedback on individuals who may be seeking to divert schedule II controlled substances.

Two other states, Hawaii and Massachusetts, implemented electronic systems like Oklahoma's in April 1992. Hawaii has had a multiple-copy program in place since 1943. Massachusetts, like Oklahoma, adopted the electronic system after unsuccessful attempts to receive legislative approval for a multiple-copy program. Both Hawaii and Massachusetts also received funding from a Department of Justice block grant.

Unless you publicly announce its contents earlier, we plan no further distribution of this report for 10 days after its issue date. At that time, we will send copies to the House Committee on Ways and Means, House Energy and Commerce Committee, and the Senate Finance Committee, as well as the Secretary of Health and Human Se ices. We will also make copies available to others upon request. If you nave any questions concerning the information presented, please call me at (202) 512-7119. Other major contributors are listed in appendix I.

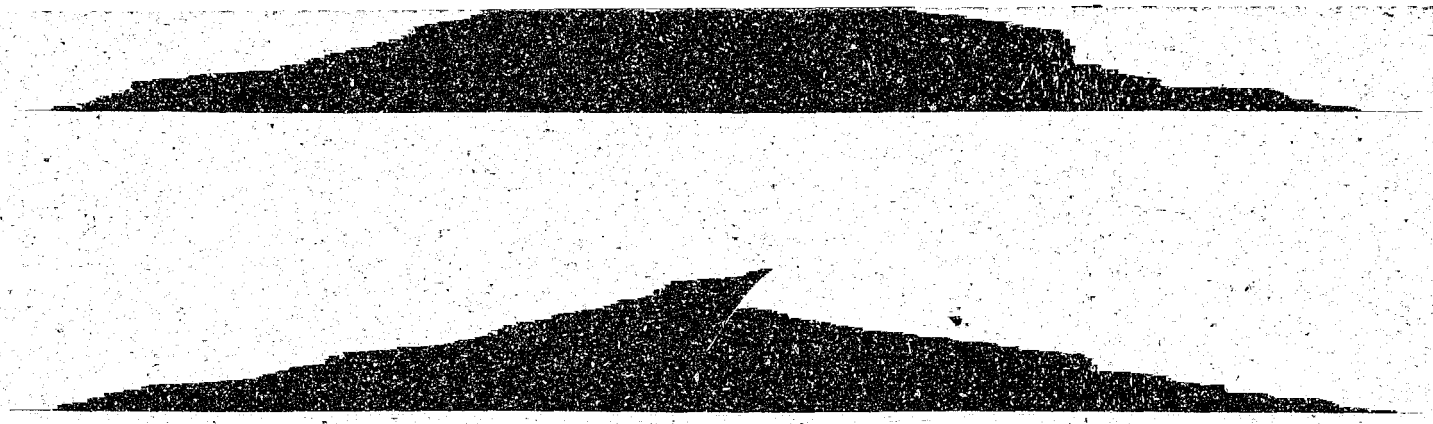
Sincerely yours,

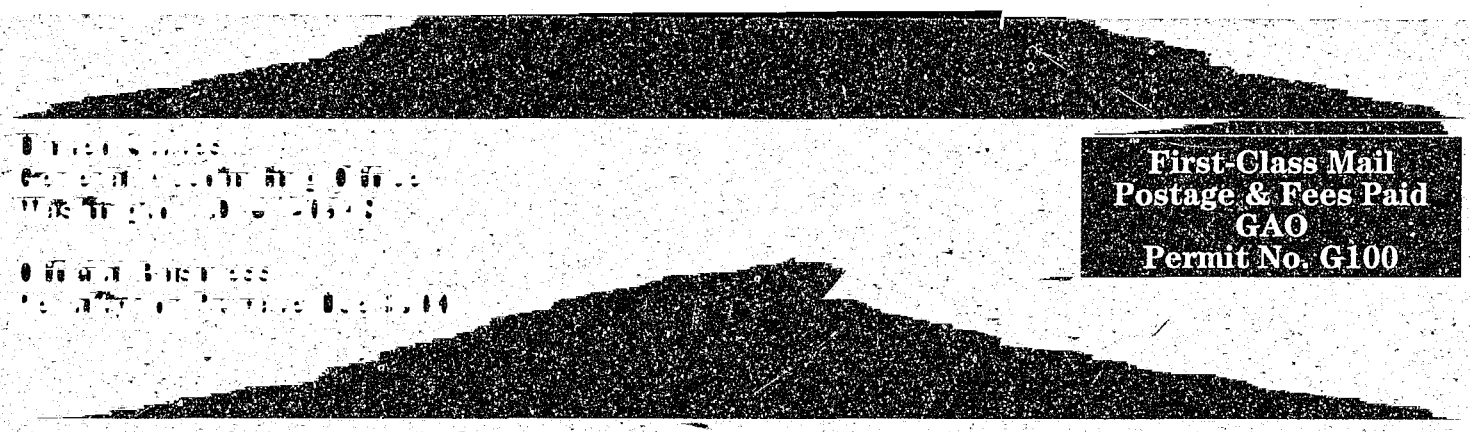
Janet L. Shikles

Janet L. Shikles
Director, Health Financing
and Policy Issues

Major Contributors to This Report

Human Resources Division, Washington, D.C.	John C. Hansen, Assistant Director, (202) 512-7114 Sibyl Tilson, Assignment Manager Christina Carpenter, Evaluator
Boston Regional Office	Robert Dee, Regional Management Representative Maureen Driscoll, Evaluator-in-Charge





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