NATIONAL SYNTHETIC DRUGS ACTION PLAN

The Federal Government Response to the Production, Trafficking, and Abuse of Synthetic Drugs and Diverted Pharmaceutical Products





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OFFICE OF NATIONAL DRUG CONTROL POLICY

Washington, D.C. 20503



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The United States faces an array of drugs of abuse. Many, such as cocaine, heroin, and marijuana have confronted us for decades. We have developed programs and initiatives to combat these drugs—to prevent use, treat the addicted, and disrupt production and the marketplace for drugs. The significant threat to the nation posed by synthetic drugs, especially methamphetamine and MDMA, or "Ecstasy," is a more recent phenomenon. Initial efforts to confront synthetic drugs are already showing results. As demonstrated by the findings of the most recent National Survey on Drug Use and Health (formerly known as the National Household Survey on Drug Abuse) and the 2003 Monitoring the Future study, when we collectively push back, the synthetic drugs threat also will decline.

A related threat is the growth in nonmedical use of pharmaceutical controlled substances. Diversion of these legitimate drugs is fueled in part by easy access over the Internet. The most recent NSDUH and other data indicate that we continue to confront increased use of such drugs, notably pain relievers and tranquilizers. This document recommends some new approaches to address this challenge.

This Action Plan is designed both to convey the seriousness of the challenges posed by synthetic drugs and diverted pharmaceuticals and to outline specific steps the federal government will take in the future to capitalize on recent successes and accelerate our national efforts against these harmful substances. Through the recommendations in this Action Plan and with the active engagement of our partners in state and local government, we intend to move aggressively in the coming years. To facilitate follow-up, this Action Plan creates a high-level interagency working group to ensure that these recommendations are implemented as effectively and rapidly as possible.

This document is a product of the hard work of the Department of Justice Criminal Division's Narcotic and Dangerous Drug Section, in cooperation with the Drug Enforcement Administration and several other agencies, and in consultation with various components of the Department of Health and Human Services. We are grateful for their efforts. The Action Plan represents an important step forward in our nation's effort to control dangerous synthetic drugs and pharmaceutical products and, moreover, in the continued achievement of the objectives set forth in the President's National Drug Control Strategy.

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I. Overview

A. Introduction

The illicit production of synthetic drugs is hardly a new problem in this country. For years, community leaders and law enforcement officials have understood the threat and expressed concern for the future based on the potential dangers of these drugs.

That uncertain future is now a disturbing reality. In the past five years, the use of synthetic drugs has climbed dramatically, a fact that lends urgency to the effort to control them. Recent drug-consumption studies indicate that substantial numbers of Americans are using these harmful substances. While the use of MDMA has fallen off significantly among young people in the last two years, its use remains at unacceptable levels. The gradual expansion in the use of methamphetamine may be continuing as well. These two drugs pose the most significant synthetic drug threats to the nation.

The expansion in the demand for these drugs is not limited to the United States. Several countries in Europe and Asia are similarly challenged by the spread of the synthetic drug trade. Encouraged and emboldened by the growing global demand for these drugs, traffickers are exploiting every available opportunity to produce, export, and market a wide variety of synthetic drugs. A large volume of precursor chemicals and synthetic drugs produced overseas is now smuggled into the United States to support domestic production and distribution as well.

The purpose of this document is to provide a blueprint for action under the President's National Drug Control Strategy that brings together the various strands of domestic and international efforts into a coherent plan for attacking and disrupting the trade in these dangerous drugs. This Action Plan focuses on illicitly manufactured synthetic drugs, including methamphetamine, amphetamine, MDMA, GHB, PCP, and LSD, which are not of primarily organic origin. It also discusses selected pharmaceutical products which are sometimes diverted from legitimate commerce, such as ketamine and oxycodone (particularly in the form of OxyContin), and the illegally imported depressant flunitrazepam (trade name Rohypnol). Regardless of the venues in which they are used, the problems posed by licitly produced pharmaceutical products are distinct from those pertaining to clandestinely produced drugs, and the approaches to prevent their illegal trafficking likewise vary.

Methamphetamine is the most widely used and clandestinely produced synthetic drug in the United States and, thus, receives the most attention in this Action Plan. Although methamphetamine is manufactured licitly for medical purposes, the vast majority of illegally trafficked methamphetamine is produced illegally in laboratories both here and abroad. The related synthetic stimulant amphetamine is typically trafficked interchangeably with methamphetamine and produced clandestinely by a similar process, and it has a similar effect on users.

While all of the drugs discussed in this paper are significant drugs of abuse, some of these substances—namely MDMA ("Ecstasy"), GHB, Rohypnol, and ketamine—are distinguished as "club drugs" because they are commonly encountered at nightclubs and late-night dance parties called "raves" or "circuit parties." MDMA (3,4-methylenedioxymeth-amphetamine) is a stimulant with

hallucinogenic properties that has surged in use in recent years. Gamma hydroxybutyric acid (GHB) and Rohypnol are depressants which are often used to incapacitate victims in sexual assaults; the instances of GHB use are increasing, while trafficking in Rohypnol appears to be decreasing. Ketamine is a dissociative anesthetic which has also become popular among rave and circuit party attendees. Furthermore, there is a virtual alphabet soup of "designer drugs" that are not frequently encountered by law enforcement, but which may proliferate at raves and other youth-oriented settings at any time.

Additionally, the use of synthetic opiates, especially oxycodone, is growing, and the dissociative anesthetic phencyclidine (PCP) is still being used. The hallucinogen lysergic acid diethylamide (LSD) has seen major declines in youth use—to the lowest levels since surveys began in 1975. None of these drugs, however, is commonly associated with raves and circuit parties.

Synthetic drugs not only harm the bodies and minds of those who use them, they also threaten human health through the damage they inflict on the environment. For example, the process of making methamphetamine requires the use of hazardous chemicals, many of them flammable, corrosive, or explosive. Moreover, methamphetamine is made primarily by unscrupulous chemists, often operating in makeshift labs, with little regard for public safety or environmental health.

Methamphetamine labs produce toxic byproducts that commonly end up in fields, public parks, and waterways. Some of these chemicals can cause disfigurement, illness, or even death on contact.

As discussed in the National Drug Control Strategy, synthetic drugs by their very nature present special challenges to the agencies and organizations working to stop them. Because the drugs are made in laboratories and not harvested from fields, there are no crops to eradicate as in the cases of marijuana, heroin, and cocaine. Instead, supply reduction efforts must focus on limiting access to precursor chemicals, shutting down illegal labs, and breaking up organized criminal groups that manufacture and distribute the drugs. We need to strengthen international and domestic law enforcement mechanisms, emphasizing informal, flexible, and rapid communications at the operational level. Like the traffickers who fuel the market, we must ourselves become more nimble, developing policies and methods that allow us to adapt quickly and seize every opportunity to disrupt the trade.

This Action Plan begins with a general outline of demand and trafficking trends with respect to the drugs highlighted above. Next, it discusses the status of prevention, treatment, regulatory and law enforcement efforts, and provides recommendations for future actions in each of these areas. The Action Plan also includes six appendices. Appendix A is a proposed outline for an early warning and response system to identify and address the impact of emerging drugs of abuse. Appendix B provides an overview of the new Drug Abuse Warning Network (DAWN) system design and implementation plans. Appendix C is a Drug Enforcement Administration (DEA) Action Plan to Prevent the Diversion and Abuse of OxyContin. Appendix D outlines the schedules and regulatory measures that apply to the subject controlled substances and their chemical precursors. Appendix E summarizes the applicable sentencing guidelines. Appendix F summarizes precursor chemical control laws in Missouri and Oklahoma.

B. Plan for Implementation of Recommendations

Overarching responsibility for implementing the recommendations in this Action Plan will reside in a new Synthetic Drugs Interagency Working Group (SD-IWG), to be co-chaired by the Office of National Drug Control Policy and the Department of Justice. The SD-IWG can, at the discretion of

the co-chairs, refer recommendations to other pre-existing government working groups. The SD-IWG will meet within 30 days of the publication of this report, and thereafter on an as-needed basis. The group will submit a written implementation update to the Director of the Office of National Drug Control Policy and the Attorney General six months after publication of this Action Plan.

C. List of Recommendations

1. Prevention

Develop an Early Warning and Response System - (NDIC, DOJ, HHS, ONDCP)

Establish a comprehensive, interagency, early warning and response system to detect the emergence of new drugs and trends. Appendix A lays out the possible parameters of such a system in detail, but it should include increased research efforts to develop and disseminate accurate, reliable, and cost-effective tests for identifying new synthetic drug use trends. Particular focus should be given to earlier identification and routine detection of licitly produced drugs with high illicit use potential.

Enhance Public Outreach Efforts Focusing on Synthetic Drugs - (SAMSHA, DOJ, ONDCP)

Develop a multimedia education campaign on the consumption of synthetic drugs, focusing initially on methamphetamine. The program should, as appropriate, incorporate messages about the environmental threat and risks to children from clandestine labs. Ensure adequate dissemination of all pertinent materials and information on synthetic drugs through the Department of Education's Office of Safe and Drug-Free Schools.

Improve Education and Training on Pharmaceuticals - (**DEA**, FDA, SAMHSA, ONDCP)

Ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances, including full disclosure of safety issues associated with pharmaceuticals. Develop a mechanism for the wider dissemination and completion of approved Continuing Medical Education courses for physicians who prescribe controlled substances. Develop Internet public service announcements regarding the potential dangers and illegality of online direct purchase of controlled substances.

Develop Best Practices to Assist Drug-Endangered Children - (HHS, EPA, DOJ, DEA, ONDCP)

Develop protocols for assisting drug-endangered children that generally address staff training; roles and responsibilities of intervening agencies; appropriate reporting, cross reporting, information sharing, and confidentiality; safety procedures for children, families, and responding personnel; interviewing procedures; evidence collection and preservation procedures; medical care procedures; and community resource development.

Research and Develop Targeted Prevention Programs - (NIDA, ONDCP)

Support research on the initiation of methamphetamine use and the progression of use leading to addiction. Programs should be developed to target high-risk groups or communities and to increase community involvement in prevention efforts.

Improve Data on Afflicted Geographic Areas - (NDIC, SAMHSA, DOJ, ONDCP)

Build on existing Geographical Information System (GIS) resources and databases to integrate federally mandated drug test results, crime laboratory evidence analysis, population demographics, and

other meaningful data pertaining to synthetic drugs and diverted pharmaceuticals in a manner that supports geographically based prevention and intervention efforts.

Examine the Use of Prescription Narcotics - (NIDA, SAMHSA, FDA, NIJ, DEA)

Assess the scope and magnitude of the licit and illicit use of prescription narcotic analgesics, in particular OxyContin, including the pursuit of additional data sources in cooperation with the Food and Drug Administration (FDA), the National Institute for Justice (NIJ), private entities, and others.

2. Treatment

Increase Treatment Capacity - (HHS)

Assess treatment needs for synthetic and diverted pharmaceutical drug addiction and, if necessary, expand that capacity in the community and in correctional facilities. Particular emphasis should be given to the development of additional treatment capacity for methamphetamine users, to include follow-up services that address the protracted recovery period associated with methamphetamine dependency.

Research Treatment for Synthetic Drug Abuse - (HHS, NIDA, SAMHSA, ONDCP)

Increase research on the physical and psychological effects of methamphetamine and other synthetic drugs, as well as on the development of effective treatment protocols for synthetic drugs.

Develop Guidelines for Juvenile Drug Treatment - (NIDA, SAMHSA)

Fund research on and pursue the development of guidelines with respect to the treatment of juveniles, who often are not adequately served in existing drug treatment programs designed for adults.

Develop Early Response Treatment Protocols - (NIDA, SAMHSA)

Develop and disseminate early-response protocols addressing requests for treatment of dependency on emerging synthetic drugs and diverted pharmaceuticals.

Study Options for Criminal Justice System Treatment - (NIDA, SAMHSA, NIJ)

Invest in additional studies on the efficacy of various comprehensive treatment programs for synthetic drug abuse and on their adaptability to diverse individual and community needs, especially those unique to the criminal justice system.

Expand Dissemination of Treatment Best Practices - (NIDA, SAMHSA, ONDCP, DEA)

Expand capabilities to disseminate pertinent research results and best-practices training techniques as part of the overall effort to increase access to effective treatments for dependencies on synthetic and diverted pharmaceutical drugs.

3. Regulation of Chemicals and Drugs

Support Stronger State Controls on Precursor Chemicals - (DOJ, ONDCP, DEA)

States that face significant levels of clandestine lab activity and chemical diversion are urged to consider the imposition of more stringent controls than those currently in place at the federal level. Several states, notably Oklahoma, have recently enacted strict retail-level controls. (See Appendix F). Additional state-level controls could include, for example: allowing only licensed pharmacists and pharmacy technicians to sell products containing precursor chemicals; placing such products behind the sales counter and/or in a locked display case; purchase limits imposed on a transaction

and/or monthly basis (with an appropriate tracking mechanism); and requirements of customer identification sales record keeping.

Remove the Blister Pack Exemption - (DEA, DOJ)

Support legislation that removes the blister pack exemption and eliminates distinctions based on the form of packaging, as recommended in DEA's November 2001 report to Congress.

Regulate Chemical Spot Market - (DEA, DOJ)

As an extension of existing authority over imports, law enforcement should seek the legislative authority to regulate sales of bulk chemicals on the domestic spot market by notification and approval of any deviations in quantity or customer from the import declaration.

Determine Licit Chemical Needs - (DEA, DOJ, ONDCP)

In cooperation with industry, commission a statistical analysis to estimate the legitimate needs for pseudoephedrine and ephedrine products—including combination products such as ephedrine with guaifenesin—both nationwide and regionally.

Enable Import Controls on Bulk Ephedrine and Pseudoephedrine - (DEA, DOJ, ONDCP)

Seek legislation that would treat the post-importation handling of bulk ephedrine and bulk pseudoephedrine in a similar manner, for regulatory purposes, as federal laws now treat the post-importation processing of Schedule I and II controlled substances. Impose such controls on these critical precursors as are needed to limit imports to those necessary for legitimate commercial needs and for maintenance of effective control over chemical diversion.

Limit Online Chemical Sales - (DEA, DOJ)

Continue ongoing efforts to advise the owners and operators of major on-line auction websites of the use of precursor chemicals in clandestine labs, and urge them to consider banning the sale of precursor chemicals over their websites.

Strengthen Cooperation with Mexico - (DEA, DOJ, State, ONDCP)

Solidify significant recent advancements by Mexico to increase the effectiveness of bilateral chemical control with the United States through continued partnership and meetings with the pertinent Mexican components, including their drug intelligence center (CENAPI), the Federal Investigative Agency (AFI), the chemical regulatory entity in the Ministry of Health (COFEPRIS), and the Health Commission.

Enhance Coordination and Information Exchange with Canada - (DHS, ICE, CPB, DEA)

Enhance ongoing coordination with Canada Customs and Revenue Agency on border detection, targeting, and interdiction efforts, and ensure appropriate focus by Canada-U.S. joint Integrated Border Enforcement Teams on the precursor chemical and synthetic drug threats. Further expand the ongoing exchange of information concerning Canadian businesses involved in the importation, production, and distribution of pseudoephedrine—particularly those firms whose products have frequently been diverted or smuggled into the United States.

Strengthen the Multilateral Chemical Control System - (DEA, DOJ, State, ONDCP)

Garner international support for making existing multilateral chemical controls more universal, formal, and well-supported by international institutions, including UN bodies such as the International

Narcotics Control Board and regional bodies such as the Organization of American States' Inter-American Drug Abuse Control Commission (CICAD). Work to realize the full potential of Project PRISM, and build support for the application of the 1988 UN Convention to pharmaceutical preparations containing precursor chemicals that can be easily recovered for use in illicit drug production.

Exchange Information with Chemical Producing Countries - (DEA, DHS, State, USTR)

Continue ongoing information-sharing efforts with the countries that produce precursor chemicals used to make amphetamine-type stimulants, particularly China, India, Germany, and the Czech Republic.

Educate Store Employees - (DEA, DOJ)

Building on efforts begun in a number of states, work to develop a model training program for pharmacists, retail management, and store employees concerning suspicious pseudoephedrine purchases, as well as suspicious sales of chemicals and items used in the manufacture of methamphetamine.

Encourage Voluntary Controls by Retail Pharmacies and Stores - (DEA, DOJ, ONDCP)

Seek the voluntary participation of major retail chains in programs to control pseudoephedrine products through restrictions on the quantity that can be purchased at a single time. Also support the voluntary movement of pseudoephedrine products from stores' open shelves to behind pharmacy counters or other manned counters in retail settings where pharmacies are not on site.

Work with Manufacturers to Reformulate Abused Pharmaceutical Products - (DEA, FDA)

Continue to support the efforts of firms that manufacture frequently diverted pharmaceutical products to reformulate their products so as to reduce diversion and abuse. Encourage manufacturers to explore methods to render products containing key precursors such as pseudoephedrine ineffective in the clandestine production of methamphetamine and pain control products such as OxyContin less suitable for snorting or injection.

Support State Prescription Monitoring Programs - (DEA, ONDCP)

Support states' creation of prescription monitoring programs designed to detect inappropriate prescribing patterns and prescription fraud. Law enforcement and regulatory entities should have access to information in case of apparent diversion or inappropriate prescribing of controlled substances, and some provision for state-to-state communication of adverse information should be examined. Supporting legislation should be explored.

4. <u>Law Enforcement</u>

Target Pseudoephedrine and Iodine Smuggling to and from Mexico - (DEA, ICE, CBP)

Focus law enforcement resources on stopping the recently-noted flow of suspicious shipments of precursor chemicals, notably pseudoephedrine, from Asia to Mexico, apparently destined for clandestine methamphetamine labs in Mexico and the United States. Also focus on the smuggling of iodine from Mexico. In all such cases, law enforcement should identify and aggressively pursue the persons and firms responsible.

Focus on Canadian Synthetics and Chemical Smugglers - (DEA, ICE, DOJ)

Expand joint U.S.-Canadian investigations into the smuggling of chemicals, methamphetamine, MDMA, and other club drugs and diverted pharmaceuticals. Assign high priority to investigations of

large seizures of pseudoephedrine and ephedrine from Canada, and develop prosecutable cases against rogue Canadian companies and their principals.

Investigate Ties between Canadian and Mexican Criminals - (DOJ, DEA, ICE, NDIC)

Analyze law enforcement reporting and intelligence with respect to Canadian pseudoephedrine and ties between Canadian sellers and Mexican lab operators in California. Analysis of the flow of funds generated from sales of pseudoephedrine in Canada and the United States should be coordinated by the appropriate agencies within the concerned Departments.

Investigate Asian and European Sources of Synthetic Drugs - (DEA, ICE, State)

Work with international law enforcement partners and regional groups to investigate Asian criminal groups in North America and in Asia that increasingly may be engaged in producing and trafficking synthetic drugs and their precursor chemicals. Enhance bilateral efforts with the Netherlands and other MDMA-producing countries in Europe to build investigations, share information, and extradite criminals where appropriate.

Enhance Methamphetamine Profiling Efforts - (DEA, DOJ, ONDCP)

Increase the number of samples available for analysis in DEA's methamphetamine profiling program by incorporating samples of the drug seized by state and local law enforcement at super labs, or from shipments strongly suspected of originating from such large-scale operations. Also leverage information on chemicals, adulterants, cutting agents, and equipment found at the site.

Review Lab Cleanup Resources - (DEA, DOJ, EPA)

Ensure adequate funding sources for clandestine laboratory and dumpsite cleanups, including funding for sufficient personnel to support laboratory cleanups and hazardous waste disposal, so that cleanup costs are not a disincentive to laboratory investigations or takedowns. Federal officials, in collaboration with state agencies, should conduct a needs assessment to identify potential program improvements and make recommendations on the specific support needed and the funds required.

Apply Updated Clandestine Lab Cleanup Guidelines - (DEA, EPA)

Disseminate and apply the latest guidelines for the cleanup of clandestine methamphetamine labs and, where necessary, coordinate environmental remediation by appropriate entities. These protocols for adulteration and destruction of precursor and essential chemicals, glassware, and methamphetamine waste should be part of clandestine laboratory certification training.

Increase Prosecutor and LEA Training - (DOJ, DEA, CBP)

Recognizing the unique issues presented by chemical and methamphetamine cases, the Federal Government should, as resources permit, offer training for criminal and civil prosecutors and federal, state, and local law enforcement agents more frequently and in different regions of the country.

Make Full Use of Charging and Sentencing Options - (DOJ, DEA)

Prosecutors should make full use of federal Sentencing Guidelines provisions, which set a sentencing floor (of 70-87 months) for any case involving methamphetamine manufacture that creates a substantial risk of harm to human life. Federal prosecutors should also make greater use of the environmental enhancement for clandestine drug manufacturing involving "unlawful discharge, emission, or release into the environment of a hazardous or toxic substance or for the unlawful transportation, treatment, storage, or disposal of a hazardous waste."

Increase Access to Civil Penalty Case Experts - (DOJ)

The Department of Justice should develop and disseminate a list of attorneys who have experience in civil penalty cases under the Controlled Substances Act and who are available to assist U.S. Attorney's Offices in districts where such cases have never or rarely been referred or pursued.

Prevent Exploitation of Mail Services - (DEA, CBP, ICE, State, NDIC)

Work with the U.S. Postal Service and private express mail delivery services to target illegal mail-order sales of chemical precursors, synthetic drugs, and pharmaceuticals, both domestically and internationally.

Improve Intelligence Efforts Related to Synthetic Drugs - (NDIC, DEA, CIA, CBP, ICE, State) Intensify intelligence components' focus on gathering and sharing information regarding the nature and scope of synthetic drugs trafficking. Make full use of NDIC's real-time analytical database for both pre- and post-operation link analysis and document exploitation. Strengthen mechanisms for sharing actionable intelligence, trend analysis, and information on criminal organizations among the United States and concerned Western European countries.

Target Raves Where Drug Use is Facilitated - (DEA, DOJ)

Focus attention on the promoters and operators of rave events that facilitate the trafficking and abuse of MDMA and other club drugs, making innovative and effective use of the federal "crack house" statute, including amendments in the Rave Act.

Consider New Legislation on Club Drugs - (DOJ, DEA)

Federal officials should continue efforts to develop additional legislation to address legal issues that often arise with respect to club drugs and rave-type events. For example, the distribution of imitation controlled substances could be explicitly criminalized at the federal level, and the provisions governing controlled substance analogues and counterfeits could be clarified.

Strengthen Controls on Internet Sales - (DOJ, DEA)

Support legislation that regulates the burgeoning business of Internet sales of drugs, particularly controlled substances, by prohibiting the dispensing of controlled substances online without a valid prescription. The new law would define a valid prescription as one issued for a legitimate medical purpose in the usual course of professional practice, and would require at least one in-person medical evaluation by the prescribing doctor.

Increase Internet Investigations - (DEA, DOJ, NDIC, ICE, FDA, State)

Expand investigations and prosecutions of Internet-based synthetic and pharmaceutical drug diversion and sales, to include the establishment of task forces and coordination mechanisms dedicated to this purpose. Agencies should work with Internet Service Providers to assist them in limiting children's access to illegal drug sites.

Target OxyContin and Vicodin Diversion - (DEA, DOJ)

Support efforts to target individuals and organizations involved in the diversion, illegal sale, pharmacy theft, fraud, and abuse of OxyContin and other drug products containing oxycodone, hydrocodone, or hydromorphine, such as Vicodin and Lorcet.

Seek Updated Sentencing Guidelines for Club Drugs - (DEA, DOJ)

Work with the U.S. Sentencing Commission to review data on the impact and effectiveness of current sentences for trafficking in ketamine, GHB and its precursors and analogues, and other club drugs, and, if advisable, propose enhanced guidelines sentences.

Share Law Enforcement Best Practices - (DEA, DOJ)

Based on the successes achieved by local law enforcement in Southern California using reverse-buy investigations and by communities in the Midwest that have set more strenuous penalties and regulations regarding synthetic drugs, establish a mechanism for sharing best practices among federal, state, and local law enforcement as well as with international partners who are confronting synthetic drug threats.

II. Nature of the Problem

A. Consumption Trends

National indicators have shown a general increase over the last decade in the use of certain synthetic drugs, particularly among youth and young adults. However, recent data indicate that this trend may be changing for the better as part of broad reductions in teen drug use. Hospital statistics reflecting the adverse consequences of drug use as measured by the number of medical emergency mentions were statistically unchanged for all synthetic drugs except PCP from 2000 to 2002, yet long-term data reflect significant increases in emergencies involving a number of synthetic drugs. Furthermore, in 2001 individuals age 25 and younger were involved in a disproportionate number of such emergencies involving MDMA, GHB, and LSD, and nearly three out of four emergency room episodes involving these three drugs also involved alcohol or another major substance of abuse. More encouraging news is found in the 2003 Monitoring the Future (MTF) study, which reported a decline in the use of illicit drugs by teenagers, including the second consecutive year of major reductions in the use of MDMA, along with substantial decreases in the use of LSD.

1. Methamphetamine



Figure 1: The appearance of methamphetamine varies with the production process. Scientific and chemical journals list more than 150 processes for methamphetamine production, along with an undetermined number of processes developed by clandestine chemists. Shown here are some of the most common forms of illicit methamphetamine.

Source: ©Drug Identification Bible



The level of methamphetamine use in the United States has been rising among adults and declining among adolescents over the last several years. Over 12 million Americans have used methamphetamine in their lifetimes, according to the 2003 National Survey on Drug Use and Health, including an estimated 1.3 million past-year users. The mean age of the approximately 326,000 new methamphetamine users in 2001 was 18.7, and about 50 percent of the users were under the age of 18.

PERCENTAGE REPORTING METHAMPHETAMINE USE 2003 NATIONAL SURVEY ON DRUG USE AND HEALTH			
Age	Lifetime	Annual	Past 30 Days
12–17	1.3%	0.7%	0.3%
18–25	5.2	1.6	0.6
26+	5.7	0.4	0.2
12+ (Total)	5.2	0.6	0.3

Figure 2: 2003 NSDUH Survey Results for Methamphetamine Use

According to the 2003 Monitoring the Future study, there has been significant progress against methamphetamine use in the critical teenage segment of the population. The overall decline in use since questions regarding methamphetamine were first added to the study in 1999 is unmistakable—the rate of past-year methamphetamine use (also known as the "annual rate") dropped between 1999 and 2003 from 3.2 percent to 2.5 among 8th graders, from 4.6 percent to 3.3 percent among 10th graders, and from 4.7 percent to 3.2 percent among 12th graders.

PERCENTAGE REPORTING METHAMPHETAMINE USE 2003 MONITORING THE FUTURE STUDY			
Grade	Lifetime	Annual	Past 30 Days
8th Grade	3.9%	2.5%	1.2%
10th Grade	5.2	3.3	1.4
12th Grade	6.2	3.2	1.7

Figure 3: 2003 Monitoring the Future Results for Methamphetamine Use

The number of emergency room drug episodes involving methamphetamine increased from 13,505 in 2000 to 17,696 in 2002. Methamphetamine mentions occurred in approximately 3 percent of all emergency room drug episodes in 2002. Previously, medical examiners participating in the 1999 Drug Abuse Warning Network (DAWN) survey mentioned methamphetamine in connection with 6 percent of all drug-related deaths and 8 percent of such deaths involving 18-25 year olds, and between 1994 and 1998 participating medical examiners associated a total of 2,601 deaths with methamphetamine use.

EME	RGENCY DEPART	MENT SYNTHET (DAWN)	TC DRUG MENTI	ONS
Year	Methamphetamine	MDMA	GHB	Ketamine
1994	17,537	253	56	19
1995	15,933	421	145	
1996	11,002	319	638	81
1997	17,154	637	762	
1998	11,486	1,143	1,282	209
1999	10,447	2,850	3,178	396
2000	13,505	4,511	4,969	263
2001	14,923	5,542	3,340	679
2002	17,696	4,026	3,330	260

Figure 4: DAWN Synthetic Drug Mentions, 1994-2002

Preliminary findings from urinalysis tests show high rates of recent methamphetamine use among adult arrestees in many urban areas in the West and Midwest in 2002. Positive test rates for methamphetamine use ranged between 20-31 percent for male arrestees and between 12-42 percent for female arrestees in Des Moines, Omaha, Phoenix, Portland, Salt Lake City, San Diego, and San Jose. In major cities in the eastern United States, positive test rates for adult arrestees were much lower.

ADULT ARRESTEES TESTING POSITIVE FOR METHAMPHETAMINE (%) (ADAM)						
Primary City	20	00	21	001	2002	
	Male	Female	Male	Female	Male	Female
Des Moines, IA	18.6	20.5	22.0	27.5	20.2	24.0
Honolulu, HI	35.9	47.2	37.4	36.1	44.8	50.0
Omaha, NE	11.0	13.2	15.6	10.3	21.0	12.0
Phoenix, AZ	19.1	24.1	25.3	32.3	31.2	41.7
Portland, OR	21.4	23.5	20.4	20.4	21.9	22.7
Salt Lake City, UT	17.1	28.9	17.2	18.8	21.9	37.7
San Diego, CA	26.3	28.7	27.9	37.4	31.7	36.8
San Jose, CA	21.5	40.0	30.2	38.2	29.9	42.8

Figure 5: ADAM Testing Results for Methamphetamine, 2000-2002

Although methamphetamine use is spreading eastward, it is still somewhat regionally concentrated in the West, Midwest, and parts of the South. In some states, such as Hawaii, local trends outstrip the wider regional and national norms. Methamphetamine currently stands out as the greatest drug threat to society in Hawaii. There are growing concerns in Hawaii regarding crystallized methamphetamine (called "ice") addiction rates in particular. Drug treatment facility admissions for methamphetamine use climbed by more than 300 percent in Hawaii from 1993 to 2000. Methamphetamine use also shows a high correspondence to the commission of crime in Hawaii; more than 44 percent of adult males and 50 percent of adult females arrested in Honolulu in 2002 tested positive for the drug. Moreover, there were 62 methamphetamine-related deaths in Honolulu in 2002, up from 27 in 1998.

2. MDMA/Ecstasy









Figure 6: A close-up of the imprints on four MDMA tablets seized in 2001. Ecstasy manufacturers often stamp their products with familiar logos or other images designed to entice young people.

Source: Wyoming Highway Patrol

MDMA use, which increased sharply between 1995 and 2000, is declining. The 2003 National Survey on Drug Use and Health estimated that 10.9 million individuals age 12 and over had tried MDMA during their lifetime. The Survey estimated that 1 million individuals tried MDMA for the first time in 2002, a significant decline from the 1.7 million new users in 2001 and 2000.

PERCENTAGE REPORTING MDMA USE 2003 National Survey on Drug USE and Health			
Age	Lifetime	Annual	Past 30 Days
12–17	2.4	1.3	0.4
18–25	14.8	3.7	0.7
26+	3.1	0.3	0.1
12+ (Total)	4.6	.9	0.2

Figure 7: 2003 NSDUH Survey Results for MDMA Use

MDMA use by high school students declined for the second year in a row, according to the 2003 Monitoring the Future study. The Monitoring the Future high school survey indicated increased annual MDMA use between 1999 and 2001: from 1.7 percent to 3.5 percent among 8th graders, from 4.4 percent to 6.2 percent among 10th graders, and from 5.6 percent to 9.2 percent among 12th graders. In contrast, annual MDMA use rates for high school students in 2003 were 2.1 percent among 8th graders, 3.0 percent among 10th graders, and 4.5 percent among 12th graders. These reductions were accompanied by significant declines in the rates of past-month MDMA use across all three grades in 2003 as well, and the lifetime use of MDMA dropped 32 percent, from 8.0 percent to 5.5 percent.

PERCENTAGE REPORTING MDMA USE 2003 MONITORING THE FUTURE STUDY			
Grade	Lifetime	Annual	Past 30 Days
8th Grade	3.2%	2.1%	.7%
10th Grade	5.4	3.0	1.1
12th Grade	8.3	4.5	1.3

2003 Monitoring the Future Results for MDMA Use

According to DAWN statistics, the number of emergency room drug episodes involving MDMA remained relatively stable between 2001 and 2002, with 5,542 mentions in 2001 and 4,026 mentions in 2002. However, the number of mentions in 2001 represents a 95 percent increase in the number of mentions since 1999 and almost a 22-fold increase over the estimated 253 MDMA mentions in 1994. Although less than one-third of all emergency room drug episodes in 2002 involved persons age 25 or younger, approximately 75 percent of emergency room MDMA episodes involved such individuals. The 2002 DAWN statistics also indicate that marijuana was mentioned in nearly 40 percent of emer-

gency department visits involving MDMA, ¹⁰ and the Community Epidemiology Work Group (CEWG) report from June 2002 noted that the annual number of deaths associated with MDMA may be increasing as well, although the mortality numbers remain low. ¹¹

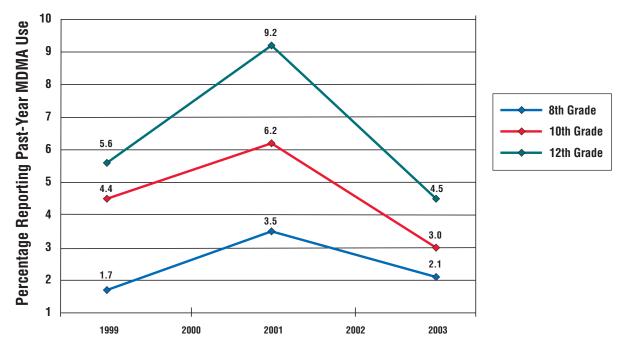


Figure 8: 2003 Monitoring the Future Results and Trends for MDMA Use

3. Other Club Drugs

GHB is the club drug which is most often associated with date rape. A capful can be slipped undetected into a beverage to incapacitate a victim. There were 3,330 GHB mentions in emergency room drug episodes in 2002, a figure that remained stable in comparison with the 3,340 GHB mentions in 2001. However the number of emergency room episodes associated with GHB in 2002 represents a one-third decrease from the 4,969 mentions in 2000. Like other club drugs, GHB is mostly used by young people, as reflected in DAWN statistics for 2002 showing that although less than one-third of all emergency room drug episodes that year involved individuals age 25 or younger, approximately 56 percent of emergency room GHB episodes involved such individuals. Nonetheless, GHB use among high school students has shown little change since it was first measured in the Monitoring the Future survey in 2000. Annual prevalence rates in 2003 for students in grades 8, 10, and 12 are estimated at 0.9 percent, 1.4 percent, and 1.4 percent, respectively.

The use of flunitrazepam (Rohypnol), which is associated with drug-facilitated sexual assault, appears to be on the decline. The Monitoring the Future survey estimates past-year Rohypnol use among 8th, 10th, and 12th graders in 2003 to be 0.5 percent, 0.6 percent, and 1.3 percent respectively. Rohypnol use among 8th, 10th, and 12th graders in 2002 was 0.3 percent, 0.7 percent, and 1.6 percent respectively.

Ketamine retains a small but persistent hold as a club drug used by young people. The Monitoring the Future study estimates the annual prevalence of ketamine use in 2003 for 8th, 10th, and 12th

graders at 1.1 percent, 1.9 percent, and 2.1 percent, respectively. There has been little change in these figures since 2000, when questions regarding ketamine use were first included in the survey. According to DAWN statistics, there were 260 ketamine mentions in emergency room drug episodes in 2002. Although less than one-third of all emergency room drug episodes in 2002 involved persons 25 and younger, approximately 68 percent of emergency room ketamine episodes involved such persons. ¹⁴







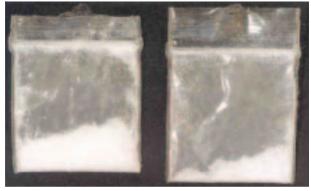


Figure 9: **Rohypnol:** Although Rohypnol is illegal in the U.S., the drug is legally prescribed in some foreign countries. **GHB:** GHB is found in both powder and liquid form. **Ketamine:** Ketamine is available as a powder and in liquid injectible form. The drug is commonly stolen from veterinary clinics.

Source: DEA Museum

4. Other Synthetic Drugs and Diverted Pharmaceuticals

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. Emergency room visits associated with narcotic pain relievers have increased 163 percent since 1995. The Administration already engages Federal, state, and local officials; the medical community; and businesses working in the area of Internet commerce to prevent and stop the illegal sale, diversion, and abuse of prescription pshychotherapeutic drugs. However, increased efforts are required in this area.

Oxycodone, particularly in the controlled release form of OxyContin, is a growing drug problem throughout the nation. Although the rate of non-medical use of oxycodone is still considered relatively low compared to major drugs of abuse on a national basis, there is evidence of an emerging problem in

many communities, particularly rural locales with limited public health and law enforcement resources. The estimated number of persons over age 12 who have illicitly used oxycodone rose from 221,000 to 399,000 between 1999 and 2000. DAWN statistics for emergency room drug episodes involving prescription drugs containing oxycodone increased 22 percent from 18,409 mentions in 2001 to 22,397 mentions in 2002. This 2002 figure also represents a 107 percent increase over the 10,825 emergency room mentions in 2000 and a 450 percent increase over the roughly 4,000 mentions in 1994. Monitoring the Future surveyed OxyContin use in 2003 and found annual prevalence rates for grades 8, 10, and 12 of 1.7 percent, 3.6 percent, and 4.5 percent, respectively.

The hallucinogen PCP continues to be used, often mixed with marijuana, and is reported at elevated levels in the emergency department data for certain cities in the DAWN network, including Chicago, Los Angeles, Philadelphia, and Washington, D.C. The Community Epidemiology Working Group has also found indications of increased PCP use in Phoenix and Texas as well. The estimated 7,648 PCP mentions in emergency room drug episodes in 2002 represent an increase of approximately 109 percent in the number of mentions since 1999. Of the persons age 12 or over who first used PCP each year between 1994 and 1999 (estimated at 82,000 in 1994 and 151,000 in 1999), at least 60 percent were age 12-17. During that period the mean age of initiation dropped from 16.8 to 15.8 as well. The 2003 Monitoring the Future study estimated an annual prevalence rate for PCP use among 12th graders of 1.3 percent.

Following a decline in use in the 1970s, LSD use was level in the late 1980s but began to increase between 1991 and 1996. Over the last two years, however, LSD use has fallen steeply to the lowest levels since Monitoring the Future data collection began. For example, the annual prevalence rate for 12th graders, which peaked at 8.8 percent in 1996, was down to 1.9 percent in 2003; prevalence rates declined for 8th and 10th graders as well. Lifetime use of LSD fell 43 percent, from 6.6 percent to 3.7 percent. Moreover, the number of LSD mentions in emergency room drug episodes in 2002 dropped to 891 from 5,126 mentions in 1999. DAWN statistics indicate that although less than one-third of all emergency room drug episodes in 2002 involved persons age 25 or younger, approximately 76 percent of the emergency room LSD episodes involved such individuals.



Figure 10: Pure PCP, as pictured here, is a white, odorless crystal with a metallic or bitter taste. Because of impurities resulting from makeshift manufacturing procedures, the color of much of the crystal PCP on the street will vary from tan to brown.

Source: ©Drug Identification Bible

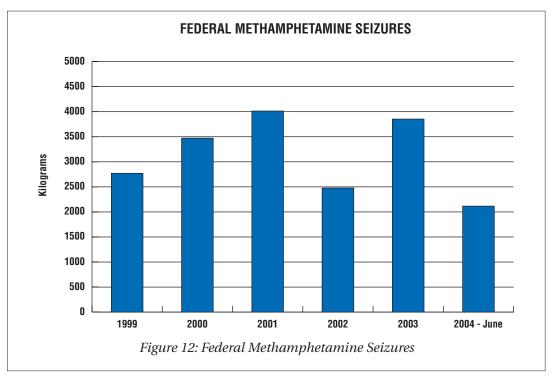


Figure 11: LSD crystals next to the point of a needle. When exposed to air, light, or heat, LSD will degrade and darken, eventually turning black. Purer forms of LSD are white or semi-clear in color.

Source: ©Drug Identification Bible

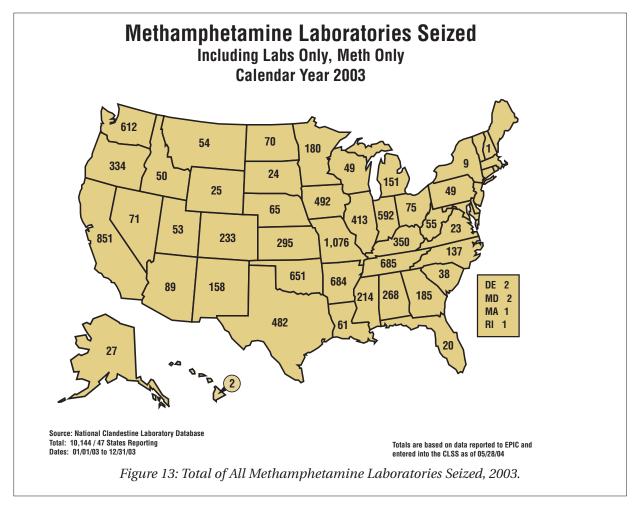
B. Trafficking Trends²¹

1. Methamphetamine



Although both domestic and U.S.-Mexico border seizures have increased in three of the last four years and are a continuing concern, the surge in domestic lab seizures is particularly troubling (see Figure 13, next page). Methamphetamine accounts for about 96 percent of all clandestine drug laboratory seizures in the United States. The number of reports of domestic methamphetamine lab seizures continued to rise in 2003, with the Drug Enforcement Administration's (DEA) El Paso Intelligence Center (EPIC) receiving reports of more than 10,000 lab seizures, compared to the 9,193 seizures reported for 2002. EPIC reported almost 5,000 labs seized in the first six months of 2004. The great majority of methamphetamine labs—over 95 percent in 2002—are seized and investigated by state and local law enforcement. California remains the state with the highest methamphetamine production levels. Hundreds of clandestine methamphetamine labs are seized in California each vear.23 Moreover, the large "super labs" in California, capable of producing more than ten pounds of methamphetamine per cycle, are responsible for the production of most of the methamphetamine trafficked illegally in the United States, despite a dramatic increase in the number of smaller, independent clandestine methamphetamine laboratories operating in the Midwest. Missouri leads the nation with over one thousand seizures of these smaller labs in 2003, and the number of labs seized in Arkansas, Oklahoma, and Tennessee tripled between 2000 and 2003.

The methamphetamine trade is controlled largely by well-organized Mexican crime groups that operate within a system of flexible alliances. Indeed, most of the large super labs in California are run by organizations with ties to Mexico. However, outlaw motorcycle gangs are gaining a larger share of domestic methamphetamine trafficking. Prices for methamphetamine vary greatly by locality, ranging between \$20-\$300 per gram across the 48 contiguous states.



High-purity, crystallized "ice" methamphetamine remains prevalent in Hawaii, but law enforcement has noted an increased market preference for ice methamphetamine on the U.S. mainland as well, and more is being produced to meet this demand. There are indications that ice methamphetamine may also be flowing into the United States directly from Asia and Mexico. In Honolulu, ice

methamphetamine sells for \$200-\$400 per gram.

The trafficking of methamphetamine creates numerous hazards for the communities where it is produced. Officials estimate that for every pound of methamphetamine produced in a clandestine laboratory, approximately 5-6 pounds of toxic by-products are generally left over, with as much as ten pounds of toxic waste remaining in some cases.

> Methamphetamine cooks bury the leftover chemical waste in the soil or dump it into septic systems or streams in rural areas, or into the plumbing when staying at hotels or rental homes. The toxic waste dumped into the soil or streams can then make



Figure 14: "Ice" is a purified form of methamphetamine that is ingested by smoking. Frequently described as resembling broken glass or shattered ice, the drug is essentially odorless and has a hard texture. Its purity is generally very high, often exceeding 90 percent.

Source: ©Drug Identification Bible

its way into the water table. Law enforcement officials discovered over 3,600 methamphetamine lab dumpsites in 2003 alone.24

The cleanup operation following the discovery of a dump or clandestine laboratory site is typically an extremely expensive endeavor. The initial cleanup of a site includes removing the chemicals and any leftover cooking equipment. These costs are typically covered by state, local, or federal government and average almost \$2,700 per cleanup operation in California; DEA-funded cleanups average roughly \$1,900 nationwide. Secondary cleanup entails removing contaminated soil and razing contaminated buildings, and funding the job is often left to the landowner. In some states liens are also placed on the property until the contamination is remediated. When combined with the opportunity cost of an affected property being legally condemned or deemed commercially or agriculturally unusable, the cost incurred by the property owner can run into the millions of dollars.



Figure 15: These five-gallon buckets from a meth lab contain a redcolored reaction liquid and "lye water," a strong alkali solution that will be added to the reaction liquid.

Source: Riverside County, CA, Sheriff's Department

The average cost of cleaning up a dump or lab site appears to be escalating as well. California authorities reported performing 2,088 initial cleanups of clandestine lab sites during 2000 at a cost of \$4.3 million. While the number of clean-up sites in 2002 was smaller (1,846 sites), the total cost of performing the cleaning rose to \$4.7 million. These shifts are explained by methamphetamine cooks' increasing sophistication, which enables the production of higher amounts of drugs at a single site. Some labs are now able to produce 100 pounds or more of methamphetamine per production

cycle. This increased productivity leaves behind increased amounts of toxic waste, which can pol-

lute the water supply and manifest itself in as-yet-unknown health and environmental consequences.²⁵

Small, independent operators (sometimes called "mom and pop labs" or "small toxic labs") that produce ouncesize quantities of methamphetamine for local use and distribution account for the majority of the clandestine laboratory seizures in the United States. These labs initially emerged as a problem in the Midwest in the 1990s, using the relatively simple "Birch" method or the pseudoephedrine/iodine/red phosphorus methods of manufacturing methamphetamine. The proliferation of these small labs—which can be located in



Figure 16: Makeshift laboratory equipment and chemicals used in a small meth lab. Some of the more common chemicals found at meth labs include sodium hydroxide, methanol, acetone, isopropyl alcohol, ether (starting fluid), and charcoal lighting fluid.

Source: ©Drug Identification Bible



Figure 16a: A homemade punch used by a large-volume meth lab for removing over-the-counter tablets containing ephedrine or pseudoephedrine from blister packs.

Source: Riverside County, CA, Sheriff's Department trailers, hotel rooms, or ordinary homes—has created many problems, including a dramatic increase in hazardous waste cleanups. The operational, financial, and manpower resources needed to combat the thousands of small clandestine drug labs in many parts of the country severely tax the resources of local police and sheriff's departments in smaller communities.

Thus, while the larger laboratories are of concern due to the amount of methamphetamine that can be produced and the concentration of toxic waste, the smaller toxic labs are of concern because they are so widespread. Furthermore, the potential

for the public to be exposed to the toxic chemicals from these smaller laboratories is also much greater, since they are commonly found in either transient housing facilities or homes in residential neighborhoods. This fact also highlights what is probably the darkest side of the entire methamphetamine problem: drug-endangered children. In 2003, more than 3,000 children were found on site during law enforcement actions related to clandestine methamphetamine laboratories nationwide. Forty-one of these children were reported injured and one child was killed by explosions or fires at clandestine methamphetamine labs. ²⁶

Year	Methamphetamine Lab Related Incidents	Children Affected
2000	9,311	1,239
2001	13,839	2,345
2002	16,238	3,643
2003	16,506	3,625

Figure 17: Children Affected in Methamphetamine Laboratory Related Incidents, 2000-2003

2. MDMA/Ecstasy

Most of the MDMA consumed worldwide is produced in the Netherlands and, to a lesser extent, Belgium. The United Nations Office on Drugs and Crime (UNODC) report *Ecstasy and Amphetamines: Global Survey 2003* states that 75 percent of responding countries indicated that the source of the MDMA seized in their country was the Netherlands. Belgium was the next most frequently mentioned country, appearing in the responses of 31 percent of the countries surveyed. Interpol reports that in 2001, 37 million MDMA tablets were seized worldwide. Of these, the Dutch reported that over 25 million, or approximately 68 percent, originated in the Netherlands. UNODC reports that total Ecstasy produced worldwide in 2002 was approximately 113 metric tons a year or 1.4 billion tablets. According to laboratory seizure data submitted to EPIC, there have never been more than 13 MDMA labs seized in the United States in a single year.

Manufacturers in the Netherlands and Belgium have associated with organized crime syndicates from other European countries and Israel for distribution, with smugglers using methods such as express mail service, commercial air couriers, and air/sea freight.²⁹ Groups with ties to Southeast Asia

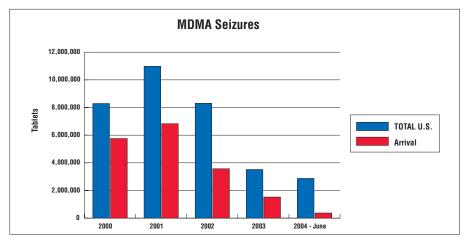


Figure 18: Total U.S. & Arrival Zone MDMA Seizures, 2000-2004

have also become heavily involved in the MDMA trade. Shipments to the United States typically contain 10,000 tablets or more, but, consistent with the patterns of declining use among young people, the total amount of MDMA entering the United States appears to be falling. As shown in Figure 18, annual aggregate seizures, both in the "arrival zone" (border area) and the rest of the country, have decreased in the past few years, reflecting the decline in usage.³⁰

The ever-shifting routes used by MDMA traffickers require improved measures to monitor changes in the MDMA market. In 2000, 63 percent of MDMA tablets seized were smuggled into the

United States by airline, 27 percent by express mail, and 10 percent by shipping. The departure points for these seized MDMA shipments were the Netherlands (77 percent), France (9 percent), Belgium (8 percent), Germany (3 percent), and Spain (3 percent). In contrast, in 2003 26 percent of MDMA tablet were smuggled into the United States by airline, 19 percent by mail, 7 percent by express mail, 8 percent by shipping, and the remaining 40 percent by other means. The departure points for MDMA smuggled into the United States were the Netherlands (21 percent), Canada (18 percent), the United Kingdom (11 percent), France (6 percent), Germany (3 percent) and Belgium (2 percent).

The chemicals and equipment necessary to manufacture a kilogram of MDMA can cost as little as \$500, but the process requires significantly more skill than the manufacture of methamphetamine. ³² It costs as little as 25 cents to produce a single MDMA pill that typically retails for \$20-30, although prices vary widely. Retail prices per dosage unit in 2001 ranged from \$10 to \$60, and wholesale prices ranged from \$5 to \$17.

Quality and purity also vary, as MDMA is often cut with other substances such as caffeine, ephedrine, and dextromethorphan (DXM). Paramethoxymethamphetamine (PMA), a synthetic hallucinogen with potent stimulant effects, is also packaged and distributed as counterfeit or imitation MDMA. The DEA Source Determination Program's analysis



Figure 19: Equipment for mixing glacial acetic acid, safrole, toluene, and other chemicals in a high-volume clandestine MDMA lab.

Source: Texas Department of Public Safety

of MDMA samples in 2000 revealed that 12 percent of the samples contained amphetamine or methamphetamine, but not MDMA; 5 percent contained no controlled substances; and 3 percent were determined to be other substances but were sold as ecstasy.³³

According to DEA's System to Retrieve Information on Drug Evidence (STRIDE) data, Florida, New York, and California are the highest MDMA trafficking areas in the United States. Other states that have significant MDMA trafficking include New Jersey, Illinois, Georgia, Texas, Massachusetts, Virginia, and Washington, D.C. 34

One region that appears to have a substantial connection to MDMA trafficking is Denver, Colorado. While most MDMA in Colorado comes from Europe (Belgium and the Netherlands), three MDMA labs were seized in Colorado in 2001. Law enforcement officials have found that drug trafficking organizations are using Denver as a hub to reach several MDMA markets across the country, in cities such as Chicago, San Francisco, Detroit, and New York. The organizations involved have connections to the Middle East as well as Europe. In 2001, interagency task forces from the High Intensity Drug Trafficking Area (HIDTA) program took down an Israeli-run operation in the Denver region that was believed to be responsible for peddling more than 100,000 MDMA tablets each month. The Area of the Middle East as well as Europe.

A dangerous new trend identified by the European Union's Police Organization, Europol, is the production of "super Ecstasy" pills with higher MDMA content than normal. These pills carry the normal logos and can be fatal to people used to normal doses. The extra heavy pills have been discovered in the Netherlands, Belgium, Denmark, and the United States.

3. Other Club Drugs

GHB is often manufactured clandestinely using recipes and ingredients obtained over the Internet. Most often the drug is consumed orally in liquid form (and rarely in powder, tablet, or capsule form). Individuals and organizations operating via the Internet commonly sell GHB analogues such as gamma butyrolactone (GBL) and 1,4-butanediol as "cleaning agents" in an attempt to mask their illicit activities. In 2001, a retail dose of GHB (by the capful, drops, etc.) sold for \$5-\$30.

Flunitrazepam (Rohypnol), which has never been approved for medical use in the United States, is smuggled from countries such as Mexico where it is legal and widely available. Reports of use, however, rapidly declined after 1996 legislation that increased penalties for trafficking in the substance.

Ketamine powder is not manufactured domestically, but is imported by U.S. firms from Germany—by far the largest source country—as well as from Colombia, China, and Belgium. U.S. firms process and package the powder into 10 mg/ml, 50 mg/ml, and 100 mg/ml injectable dosage forms. Ketamine reaches the illicit market by diversion from legitimate pharmaceutical sources or is obtained through burglaries of veterinary clinics (the most frequently reported source). Law enforcement officials have not encountered clandestinely manufactured ketamine, but ketamine smuggled from Mexico has been another significant source of supply to the illicit market.³⁷ However, thanks to coordinated law enforcement action in the United States and Mexico, key individuals within the ketamine-smuggling organization have been arrested, and the trafficking of ketamine from Mexico appears to be decreasing.

Licit ketamine is usually prepared in liquid formulations, and liquid is the primary form of illicit ketamine seized. Less frequently, street doses appear in crystal, powder, and, increasingly, tablet forms. Powder ketamine is obtained from pharmaceutical ketamine by evaporating off the liquid, and is snorted in 100 mg doses. A typical street package of ketamine powder (100 - 200 mg) sells for about \$20. According to data collected from state and local forensic laboratories by the National Forensic Laboratory Information System (NFLIS), there were 2,126 cases associated with, and 1,387

drug items identified as, ketamine during 2002 (compared to 1,802 items in 2001 and 581 items in 2000). In 2002, this constituted roughly 12 percent of all club drug exhibits entered in the NFLIS database.

4. Other Synthetic Drugs and Diverted Pharmaceuticals

The illegal diversion, theft, and medical mismanagement of prescription drugs (particularly opioid pain medications) have increased and, in some areas, present a larger public health and law enforcement challenge than cocaine or heroin. According to the most recent National Survey of Drug Use and Health, the misuse of psychotherapeutic drugs—pain relievers, tranquilizers, stimulants, and sedatives—was the second leading category of illicit drug use in 2002, following marijuana. An estimated 6.2 million Americans (approximately 2.6 percent of the population age 12 and older) had used a psychotherapeutic drug for nonmedical reasons in the month prior to the survey. The bulk of this abuse involves narcotic analgesics—an estimated 4.4 million Americans are pastmonth (so-called current) nonmedical users of pain relievers.

Reports of the diversion and abuse of oxycodone in the brand pharmaceutical OxyContin have spread from the rural areas of the East to all regions of the United States, based on recent emergency room and law enforcement data. Common means of obtaining oxycodone include unscrupulous physicians and pharmacists, "doctor-shopping," and fraudulent and altered prescriptions. The number of pharmacies that have been robbed by criminals seeking OxyContin has increased dramatically as well.

Illicit PCP is primarily manufactured clandestinely in Southern California, with limited clandestine production occurring in Indiana and, more recently, in Maryland. Most of the PCP produced in Southern California is destined for distribution to other U.S. locations, primarily along the East Coast. New York is one of the largest mid-level distribution hubs for PCP. The availability of PCP appears to be sporadic, with high levels of availability recently in Philadelphia, Chicago, New York, Los Angeles, Texas, and Washington, D.C. Packaging, purity, and pricing vary greatly; PCP is typically sold for use in combination with marijuana, alcohol, and other licit and illicit products. According to data collected by DEA near the end of 2002, PCP-laced cigarettes sell for about \$5-30 apiece; powder and liquid forms sell for about \$20-30 per gram, and liquid ounces sell for \$125-1,000. Wholesale prices for one gallon of liquid PCP are \$6,500-8,000 in Los Angeles and \$12,000-20,000 in New York.

Historically, LSD has been manufactured by a small number of chemists operating clandestine laboratories in California, but a very large lab was discovered and seized recently in the Midwest. LSD is available in almost every state, and the cost of a single dose, commonly referred to as a "hit," typically ranges from \$1 to \$10.

5. Internet Sales of Pharmaceuticals

In recent years, pharmacy websites have proliferated on the Internet; offering both controlled and non-controlled substances. While inappropriate online sales and misuse of non-controlled substances raise significant concerns, this Action Plan focuses on the sale and abuse of products containing controlled substances, notably the highly addictive narcotics hydrocodone (including Vicodin, on Schedule III) and Oxycodone (including OxyContin, on Schedule II). Obtaining controlled substances online is convenient—too convenient: The majority of online pharmacies offer to dispense drugs without valid prescriptions, making the Internet a haven for illicit drug-seekers.



Figure 20: A small glass vial containing about 3 cc's of liquid PCP. Smoking a cigarette that has been dipped in liquid PCP is the most common way of ingesting the drug.

Source: ©Drug Identification Bible



Figure 21: Most LSD seen on the street is in the form of blotter paper. The sheets of absorbent blotter paper are perforated into small squares and dipped into LSD that has been dissolved and diluted in alcohol. The blotter paper is often stamped with the distributor's trademark design.

Source: ©Drug Identification Bible



LSD being ingested via blotter paper on the tongue. Although the drug is almost always taken by means of oral absorption, it can also be injected, absorbed through the skin, or swallowed.

Source: ©Drug Identification Bible

Many sites substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner.

In a study released in early 2004, the National Center on Addiction and Substance Abuse (CASA) documented the explosion of illegal distribution of prescription drugs over the Internet. The exact number of online pharmacies is difficult to ascertain. Of 495 websites offering prescription drugs identified by the CASA study, only one-third were "anchor" sites, where customers actually purchase the drugs; the rest were "portal" sites that direct customers to anchor sites. The report found that 73% of drugs offered on these websites were Schedule II and III controlled substances. Regardless of the number of such websites, their predominant characteristic is that very

few—6% in the CASA study—require customers to have a prescription in order to purchase drugs. The sites have no mechanism to prevent children from purchasing prescription drugs. About half of the sites offer only an online "consultation," an inadequate substitute which the American Medical Association has found not to meet appropriate standards of medical care.

III. Response to the Problem

A. Prevention

1. Current Efforts

Demand reduction is a critical component of any sound drug strategy. To be effective, drug prevention programs generally should be long-term and comprehensive, with the goal of preventing any illicit drug use, not just the abuse of one drug or class of drugs. Nevertheless, as evidenced by the increasing illegal use of certain licitly manufactured and compounds manufactured in clandestine laboratories, demand patterns can change quickly, often with significant risk to public health and safety. Effective prevention therefore also must include early warnings about such emerging drug threats and quick community response through education and outreach efforts.³⁸

Scientific research supports targeted short-term prevention efforts and more general long-term prevention efforts by identifying specific drugs subject to abuse and related demographic trends. These trends include patterns of drug use initiation and progression, motivation and risk factors associated with drug use, and factors that protect against drug use. Prevention programs should be based on this research, beginning with the scientific collaboration needed to identify and develop testing methods and products for specific synthetic drugs, and should address specific community needs, in some cases focusing efforts on one or more particular drugs. Furthermore, prevention programs should seek the voluntary participation of many community components—individuals, families, schools, religious institutions, businesses, law enforcement, social service agencies, the media, and other organizations—in a coordinated manner according to community needs and available resources.

In response to the rise in the use of synthetic drugs and diverted pharmaceuticals, more focused data-gathering and prevention programs are beginning to emerge. The Department of Health and Human Services' National Institute on Drug Abuse (NIDA)—which funds 85 percent of the world's research on drug use and addiction—has been a leader in this regard. Its Community Epidemiology Work Group (CEWG) provides ongoing monitoring of emerging trends in drug use, including the most up-to-date information on synthetic drugs and diverted pharmaceuticals. NIDA has also hosted conferences focused on important prevention issues concerning MDMA/Ecstasy and GHB. Moreover, NIDA has partnered with several national non-governmental organizations in an education, prevention, and research effort regarding the use of methamphetamine, MDMA, GHB, LSD, and Rohypnol. This partnership funds research on these drugs as well as a multi-media public education campaign that includes: the dissemination of a *Community Drug Alert Bulletin* on "Club Drugs" to approximately 500,000 health care and treatment providers; the distribution of a *Research Report on Methamphetamine Abuse and Addiction*; and the development of teaching aids for use in elementary and high school classrooms.

The Substance Abuse and Mental Health Services Administration (SAMHSA) in the Department of Health and Human Services has also increased its focus on preventing the consumption of synthetic drugs and diverted pharmaceuticals. SAMHSA has undertaken a research-based initiative to target high-risk groups with prevention messages regarding club drugs, and its Center for Substance

Abuse Prevention (CSAP) maintains an Internet site dedicated to model prevention programs targeting youth. CSAP further facilitates the dissemination of pertinent information on substance abuse prevention research through its National Clearinghouse, which is also available on-line. Under the Community-Initiated Prevention Interventions program, SAMHSA has funded 27 grants that will address the use of MDMA, other club drugs, methamphetamine, and inhalants, either through the development of prevention intervention models or prevention infrastructure programs.⁴⁰

In addition, SAMHSA oversees the day-to-day operation of the comprehensive Drug-Free Federal Workplace program and the National Laboratory Certification Program (NLCP). The NLCP provides for the development, validation, dissemination, and ongoing quality assurance of workplace forensic drug testing methods. The use of specific drug tests in NLCP-certified laboratories is required for all federal agencies, the industries regulated by the Department of Transportation, the Nuclear Regulatory Commission, private industry, and, increasingly, the Department of Homeland Security. Under existing regulations, tests are specifically required to be capable of detecting methamphetamine use. New federal regulations that are nearing completion will mandate testing for MDMA, and tests for other drugs, including a number of high abuse-potential synthetic drugs, are being considered as well. The Department of Health and Human Services is also focusing on methamphetamine through its Targeted Capacity Expansion Grant program, which has a general mission to identify and respond to emerging drug problems, and is promoting programs that target drug use in families and in the workplace.

The Office of Safe and Drug-Free Schools (SDFS) in the Department of Education is the primary vehicle of the federal government for reducing drug, alcohol, and tobacco use and violence in schools. The SDFS administers, coordinates, and recommends policy for improving the quality of programs and activities that are designed to provide financial assistance for drug and violence prevention and to promote the health and well being of students in elementary and secondary schools and institutions of higher education. Activities may be carried out by state and local educational agencies and by other public and private nonprofit organizations. The office also: participates in the formulation and development of Administration policies related to violence and drug prevention; coordinates with other federal agencies on issues related to comprehensive school health; and participates with other federal agencies in the development of a national research agenda for drug and violence prevention.

The Office of National Drug Control Policy (ONDCP) promotes effective prevention activities through ONDCP-directed programs such as the National Youth Anti-Drug Media Campaign and through federal government coordination efforts, such as the Interagency Demand Reduction Group. In August 2000, the Media Campaign began a nationwide radio and Internet initiative designed to educate people about the dangers of MDMA and address faulty perceptions that the drug is harmless. ⁴² More recently, the Media Campaign ran an extensive, \$40 million ad campaign calling attention to the dangers of Ecstasy.

DEA is also heavily involved in programs to prevent the use of synthetic drugs and diverted pharmaceuticals. Thirty-three full-time special agents are dedicated to work on demand reduction programs throughout DEA field divisions. Since an August 2000 international conference on club drugs, DEA has co-sponsored regional conferences along with community coalitions and local law enforcement in almost all DEA field divisions to disseminate general and scientific information on club drugs to law enforcement personnel, medical and treatment professionals, teachers, parents, and community organizations. ⁴³ In addition, DEA's "Operation X-Out" adds a strong public awareness

component to its enforcement facets through "town hall" meetings featuring discussions between local residents and panels of local and national experts. DEA also provides several informative pamphlets regarding synthetic drugs and diverted pharmaceuticals, including *Ecstasy and Predatory Drugs and Tips for Parents: The Truth About Club Drugs*. ⁴⁴

2. Recommendations

Develop an Early Warning and Response System: - (NDIC, DOJ, HHS, ONDCP)

Establish a comprehensive, interagency, early warning and response system to detect the emergence of new drugs and trends. Appendix A lays out the possible parameters of such a system in detail, but it should include increased research efforts to develop and disseminate accurate, reliable, and cost-effective tests for identifying new synthetic drug use trends. ⁴⁵ Particular focus should be given to earlier identification and routine detection of licitly produced drugs with high illicit use potential. ⁴⁶

Enhance Public Outreach Efforts Focusing on Synthetic Drugs: - (SAMHSA, DOJ, ONDCP)

Develop a multimedia education campaign on the consumption of synthetic drugs, focusing initially on methamphetamine. The program should, as appropriate, incorporate messages about the environmental threat and risks to children from clandestine labs. Ensure adequate dissemination of all pertinent materials and information on synthetic drugs through the Department of Education's Office of Safe and Drug-Free Schools.

Improve Education and Training on Pharmaceuticals: - (DEA, FDA, SAMHSA, ONDCP)

Ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances, including full disclosure of safety issues associated with pharmaceuticals. Develop a mechanism for the wider dissemination and completion of approved Continuing Medical Education courses for physicians who prescribe controlled substances. Develop Internet public service announcements regarding the potential dangers and illegality of online direct purchases of controlled substances.

Develop Best Practices to Assist Drug-Endangered Children: - (HHS, EPA, DOJ, DEA, ONDCP) Develop protocols for assisting drug-endangered children that generally address staff training; roles and responsibilities of intervening agencies; appropriate reporting, cross reporting, information sharing, and confidentiality; safety procedures for children, families, and responding personnel; interviewing procedures; evidence collection and preservation procedures; medical care procedures; and community resource development.

Research and Develop Targeted Prevention Programs: - (NIDA, ONDCP)

Support research on the initiation of methamphetamine use and the progression of use leading to addiction. Programs should be developed to target high-risk groups or communities and to increase community involvement in prevention efforts.

Improve Data on Afflicted Geographic Areas: - (NDIC, SAMHSA, DOJ, ONDCP)

Build on existing Geographical Information System (GIS) resources and databases to integrate federally mandated drug test results, crime laboratory evidence analysis, population demographics, and other meaningful data pertaining to synthetic drugs and diverted pharmaceuticals in a manner that supports geographically based prevention and intervention efforts.⁴⁷

Examine the Use of Prescription Narcotics: - (NIDA, SAMHSA, FDA, NIJ, DEA)

Assess the scope and magnitude of the licit and illicit use of prescription narcotic analgesics, in particular OxyContin, including the pursuit of additional data sources in cooperation with the Food and Drug Administration (FDA), the National Institute for Justice (NIJ), private entities, and others.

B. Treatment

1. Current Efforts

While prevention programs are important for ensuring that individuals do not fall victim to the lure of illegal drugs, treatment initiatives are critical for providing those who do develop a dependency with an opportunity to reclaim control of their lives. Treatment is therefore a key component of our national efforts to eliminate the scourge of illegal drugs from society. The research-based efforts of NIDA and SAMHSA form the foundation for all future progress in the treatment of synthetic and diverted pharmaceutical drug dependencies.

In addition to the major role it plays in prevention-based research, NIDA is also a leader in studies of the pharmacology and toxicity of methamphetamine, MDMA, and other synthetic drugs, and in developing treatments for their abuse. For example, in 2002, NIDA launched a Methamphetamine Clinical Program to implement recommendations of the Methamphetamine Addiction Treatment Think Tank. NIDA has also established clinical treatment trials and studies involving behavioral therapies and medication alternatives for methamphetamine-dependent patients in several cities plagued by the methamphetamine epidemic (including Des Moines, Kansas City, San Antonio, Los Angeles, San Diego, and Honolulu). Following up on conferences dedicated to GHB and MDMA in 2000 and 2001 respectively, NIDA is now assessing needs and strategies with respect to MDMA and GHB abuse treatment through venues such as a "club drug" working group, a panel of experts from across the Institute. Moreover, as a result of the many insights that have been developed through the research that it supports related to treatments for drug addictions, NIDA has produced several helpful pamphlets, including *Principles of Drug Addiction Treatment: A Research-Based Guide*, which outlines the essential components of effective treatment programs.

SAMHSA has also been actively involved in efforts aimed at the treatment of synthetic and diverted pharmaceutical drug use. SAMHSA maintains treatment-related online tools for finding a qualified treatment center (the Substance Abuse Treatment Facility Locator), exchanging information with concerned State agencies (the Treatment Improvement Exchange), and accessing the National Clearinghouse for Alcohol and Drug Information. SAMHSA's Center for Substance Abuse Treatment (CSAT) coordinates several programs that help communities establish effective treatment services for emerging drug epidemics, and has recently targeted the expansion of methamphetamine treatment in certain geographical areas. CSAT has released a book titled *Treatment for Stimulant Abuse* as well, which outlines a comprehensive series of best practices guidelines, including treatment approaches with documented success, practical applications, and explanations of treatment issues for special groups and settings.

Additionally, CSAT administers the Programs of Regional and National Significance, which provide funding to increase the availability and study the efficacy of treatment programs for synthetic and other drugs, and to disseminate information learned from research on treatments of substance dependencies. In particular, the Programs have allocated resources for determining the effectiveness of available methamphetamine addiction treatments and the cost-effectiveness of the various treat-

ment approaches. For example, CSAT has awarded grants for testing, and a contract for conducting follow-up studies on, a 16-week treatment plan for methamphetamine use developed by UCLA's Integrated Substance Abuse Programs (ISAP)/Matrix Institute. During this vanguard three-year study, the grants supported training of treatment and research staff, as well as development of additional clinical capacity supporting approximately 1,000 clients at eight sites. Follow-on research continues.

2. Recommendations

Increase Treatment Capacity: - (HHS)

Assess treatment needs for synthetic and diverted pharmaceutical drug addiction and, if necessary, expand that capacity in the community and in correctional facilities. Particular emphasis should be given to the development of additional treatment capacity for methamphetamine users, to include follow-up services that address the protracted recovery period associated with methamphetamine dependency.

Research Treatment for Synthetic Drug Abuse: - (HHS, NIDA, SAMHSA, ONDCP)

Increase research on the physical and psychological effects of methamphetamine and other synthetic drugs, as well as on the development of effective treatment protocols for synthetic drugs.

Develop Guidelines for Juvenile Drug Treatment: - (NIDA, SAMHSA)

Fund research on, and pursue the development of, guidelines with respect to the treatment of juveniles, who often are not adequately served in existing drug treatment programs designed for adults.

Develop Early Response Treatment Protocols: - (NIDA, SAMHSA)

Develop and disseminate early response protocols addressing requests for treatment of dependency on emerging synthetic drugs and diverted pharmaceuticals.

Study Options for Criminal Justice System Treatment: - (NIDA, SAMHSA, NIJ)

Invest in additional studies on the efficacy of various comprehensive treatment programs for synthetic drug abuse and on their adaptability to diverse individual and community needs, especially those unique to the criminal justice system.

Expand Dissemination of Treatment Best Practices: - (NIDA, SAMHSA, ONDCR, DEA)

Expand capabilities to disseminate pertinent research results and best practices training techniques as part of the overall effort to increase access to effective treatments for dependencies on synthetic and diverted pharmaceutical drugs.

C. Regulation of Chemicals and Drugs

1. Current Efforts

a. Introduction

Regulatory measures to control key precursor and essential chemicals are critical to preventing the production of the clandestinely synthesized drugs discussed in this Action Plan. Effective chemical control has increased the difficulty, risk, and cost of methamphetamine production. In the United States, DEA has the lead role in this endeavor. However, two organizations within the Department of

Homeland Security—the Bureau of Immigration and Customs Enforcement (ICE) and the Bureau of Customs and Border Protection (CBP)—perform integral functions on the import/export side of the chemical control system. As the agencies supervising U.S. ports-of-entry, these organizations monitor commercial imports and exports of chemicals to ensure compliance with DEA registration and permit requirements.

CHEMICALS USED IN METHAMPHETAMINE PRODUCTION		
CHEMICAL	HAZARDS	
Pseudoephedrine	Ingestion of doses greater than 240 mg. causes hypertension, arrhythmia, anxiety, dizziness, and vomiting. Ingestion of doses greater than 600 mg. can lead to renal failure and seizures.	
Acetone/Ethyl Alcohol	Extremely flammable, posing a fire risk in and around the laboratory. Inhalation/ingestion causes severe gastric irritation, narcosis, or coma.	
Freon	Inhalation can cause sudden cardiac death or severe lung damage. Corrosive if ingested.	
Anhydrous Ammonia	Inhalation causes edema of the respiratory tract and asphyxia. Contact with vapors damages eyes and mucous membranes.	
Red Phosphorus	May explode on contact or friction. Ignites if heated above 260°F. Vapor from ignited phosphorus severely irritates the nose, throat, lungs, and eyes.	
Hypophosphorus Acid	Extremely dangerous substitute for Red Phosphorus. If overheated, deadly phosphine gas is released. Poses a serious fire and explosion hazard.	
Lithium Metal	Extremely caustic to all body tissues. Reacts violently with water and poses a fire or explosion hazard.	
Hydriodic Acid	A corrosive acid with vapors that are irritating to the respiratory system, eyes, and skin. If ingested, causes severe internal irritation and damage that may cause death.	
lodine Crystals	Gives off vapor that is irritating to respiratory system and eyes. Solid form irritates the eyes and may burn skin. If ingested, it will cause severe internal damage.	
Phenylpropanolamine	Ingestion of greater than 75 mg. causes hypertension, arrhythmia, anxiety, and dizziness. Quantities greater than 300 mg. can lead to renal failure, seizures, stroke, and death.	

Source: US Department of Justice, Information Bulletin: Children at Risk (7/2002)

Since the chemical industry is highly international, multilateral cooperation in chemical control is critical. The United States is currently involved in several multilateral initiatives to track chemicals used in the manufacture of amphetamine, methamphetamine, amphetamine-type stimulants such as MDMA, and other synthetics, with the goal of involving China, India, the Netherlands, Canada, Mexico, Eastern European nations such as Poland and the Czech Republic, and other countries in cooperative chemical control efforts. The legal framework for international chemical control is provided by Article 12 of the 1988 United Nations (UN) Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. This Convention establishes obligations and international stan-

dards for member nations to control domestic and international chemical commerce and prevent the diversion of 23 specified chemicals. Parties to the Convention pledge to cooperate with one another toward this objective. Other international vehicles that have promoted chemical control include:

- The June 1998 United Nations General Assembly Special Session (UNGASS), at which two of the five action plans adopted addressed precursors generally and amphetamine-type stimulants and their precursors in particular.
- The May 1997 United States/European Union (EU) Chemical Control Agreement, which
 included a commitment to consult and inform participating nations on shipments of
 controlled chemical substances in order to prevent their diversion from legitimate to illicit
 purposes; a Follow-Up Working Group continues to solidify U.S.-EU cooperation in
 chemical control.
- The annual meetings of the UN Commission on Narcotic Drugs (CND), which highlight emerging chemical control concerns.

b. U.S. Chemical Controls

The linchpin of U.S. efforts to curtail international chemical diversion is a 15-day advance notification requirement that enables DEA to verify the legitimacy of a proposed shipment and suspend suspicious transactions. In 1995, DEA initiated a "letter of non-objection" (LONO) process for imports of ephedrine and pseudoephedrine from China, the Czech Republic, and India. This system facilitates international cooperation under the 1988 UN Convention and meets the needs of governments in chemical exporting countries to ensure that chemical exports are for legitimate purposes. 15

The history of chemical regulation and related enforcement provisions in the United States has followed a continuing cycle of government action and trafficker reaction. Each new regulatory measure gives rise to one or more counter-measures by traffickers, but the system of laws and regulations has, on the whole, made it more difficult and costly for traffickers to procure the chemicals they need. Following is a summary of major legislation:

- Comprehensive chemical control began in earnest in the United States with the Chemical Diversion and Trafficking Act of 1988, which established the basic scheme of chemical regulation in place today for 20 chemicals, including twelve "precursors" and eight "essential chemicals." ⁵²
- The Crime Control Act of 1990 added twelve chemicals to the list of precursors. 53
- The Domestic Chemical Diversion and Control Act of 1993 brought over-the-counter ephedrine products under regulatory control, required registration of handlers of "List I" chemicals (most of which were formerly termed "precursors"), and increased DEA's flexibility in applying the 15-day advance notice requirements for exports and imports of specified listed chemicals to specified countries.⁵⁴
- The Comprehensive Methamphetamine Control Act of 1996 (MCA): (1) narrowed the exemption for sales of certain drug products containing methamphetamine and amphetamine precursor chemicals by regulating retail sales of 24 grams or more, although it created a "blister pack" exemption to that rule; (2) required monthly reporting by "mail order" firms that sell

- methamphetamine and amphetamine precursor chemicals; and (3) added iodine and hydrochloric gas to the list of regulated chemicals.⁵⁵
- The newest legislation targeting the illicit manufacture and distribution of methamphetamine is the Methamphetamine Anti-Proliferation Act (MAPA), signed into law on October 17, 2000. MAPA retained the blister pack exemption established by the Comprehensive Methamphetamine Control Act of 1996. However, it amended that Act by reducing the retail sale recordkeeping and reporting threshold quantity of non-exempt pseudoephedrine and phenylpropanolamine products to nine grams in a single transaction with a maximum three-gram package size.

An increasingly critical layer of chemical control occurs at the state level. Some states that have felt the brunt of the clandestine laboratory problem - notably in the West and Midwest - have imposed restrictions on chemical sales that supplement federal law. Appendix F includes a short description of the recent amendments in the Oklahoma and Missouri state chemical control laws. In Oklahoma, products containing pseudoephedrine may be sold only by a licensed pharmacist or pharmacy technician, and purchasers must sign a log book and present identification. This law, enacted in April 2004, already appears to have led to a sharp reduction in lab activity in that state. Aggressive chemical control schemes of this type are examples of states performing a function honored by Supreme Court decisions over the years, to serve "their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." States may well lead the next wave of innovation in the area of chemical control, implementing approaches that could serve as models for other states and even for the Federal Government.

The federal legal/regulatory system remains dynamic. As DEA continues to tighten the system, the list of chemicals subject to control has expanded. In addition to the items listed in the summary above, regulations effective November 16, 2001 made red phosphorous, white phosphorous, and hypophosphorous acid List I chemicals. In consultation with the Department of Justice, DEA promulgated new "chemical mixture" regulations to clarify which characteristics and concentrations of dietary and nutritional supplements—many of which contain ephedrine and pseudoephedrine—will fall under the chemical regulatory scheme.

However, the regulatory system is meaningful only insofar as it is enforced. DEA has increased its scrutiny of businesses' applications for registration to distribute, manufacture, import, or export List I chemicals. Pre-registration screening is more rigorous than ever. For example, between 2003 and early June 2004, 43 firms surrendered their registrations, three registrations were revoked, 19 were denied, and 358 applications were withdrawn. DEA has also intensified its administrative litigation against registrants and applicants. From January 2003 through June 2004, DEA issued 38 "orders to show cause" why registrations for List I chemicals should not be revoked or why pending applications should not be denied. Of those 38 orders, three involved immediate suspension based on a threat to public health and safety. The number of chemical investigations initiated by DEA since FY 1999 has climbed from 133 cases in FY 1999 to 528 cases in FY 2003.

DEA has increased scrutiny of methamphetamine-related chemical imports in particular. The tables below show the amounts of raw material and the number of tablets of bulk pseudoephedrine and ephedrine that were imported into the United States during calendar year 2003 and January-March 2004, and how much of it has been withdrawn. The low number of shipments withdrawn is significant and may be attributed to several factors: (1) closer scrutiny of potential imports;

(2) decline in the affected chemical registrant population due to criminal and civil actions against rogue companies; and/or (3) successful use of the "order to show cause" process as a control mechanism. DEA's ability to vigorously investigate potential shipments for possible downstream diversion prior to import into the U.S. has forced importers either to comply with federal regulations or reduce the amounts of their imports. Often, importers will withdraw their request for an import when concerns about downstream diversion are expressed by DEA, opting to avoid a possible DEA administrative proceeding to suspend a suspicious shipment.

	Raw & Table	t Pseudoephed	Raw & Tablet Ephedrine Imports				
Year	Total Permitted (kilograms)	Total Stopped (kilograms)	Percent Withdrawn	Total Permitted (kilograms)	Total Stopped (kilograms)	Percent Withdrawn	
2003	707,528.3	900	<1%	208,815.6	4,297	<1%	
2004 (March)	265,033.8 4,000		<1%	79,492.27	500	<1%	

Figure 22: Raw and tablet Pseudoephedrine and Ephedrine Imports, Calendar Year 2003 – March 2004⁵⁹

An important component of chemical control is law enforcement's partnership with the retail and pharmaceutical industries. DEA officials in the Office of Diversion Control met in September 2002 with representatives of distributors and wholesalers of listed chemical products and in February 2003 with representatives of retailers. A national chemical industry conference was held in boston in 2004. Outside of these meetings, some companies have taken significant steps on their own. Some retail chains have voluntarily decided to limit the sales volumes of pseudoephedrine pills at levels below those required by state and federal law. Additionally, some pharmaceutical companies are attempting to develop new technologies that would hinder methamphetamine traffickers' ability to use the pseudoephedrine in licit pharmaceutical products for illicit purposes.

c. The International Challenge

The smuggling of pseudoephedrine products into the United States from Canada and other nations poses a major regulatory, law enforcement, and diplomatic challenge. Since most raw (or bulk) pseudoephedrine is not produced in the Americas (with the exception of two U.S. firms that convert imported ephedrine into pseudoephedrine), Canadian firms, like most U.S. firms, import these chemicals in bulk quantities, process them into dosage forms, and distribute the drug products in domestic and international commerce. Until recently, Canada had no comprehensive chemical control law or system. That shortcoming has undoubtedly facilitated excessive imports of bulk chemicals by Canadian firms from overseas, as well as the diversion and smuggling of pseudoephedrine pills from Canada to the United States.

U.S. law enforcement agencies seized 236 million pseudoephedrine tablets of Canadian origin in 2002 and 206 million Canadian tablets in 2001. Law enforcement authorities have also discovered 1,000- and 23,000-count bottles and 80,000-count buckets of Canadian pseudoephedrine tablets in large West Coast methamphetamine labs operated by Mexico-based criminal groups. Additionally, recent seizures have yielded unprocessed pseudoephedrine powder, as well as ephedrine tablets,

which are used interchangeably with pseudoephedrine tablets in the clandestine production of methamphetamine.

In 2003, Canada took steps toward a more effective chemical control system. The Precursor Control Regulations, effective in January 2003, impose registration, licensing, and import/export permit requirements, all administered by the Canadian Health Ministry, commonly known as "Health Canada." Law enforcement authorities have noted a sharp decrease in seizures of some precursors from Canada, particularly pseudoephedrine, since a series of arrests were made as part of Operation Mountain Express (discussed in detail in the Law Enforcement section, below). The new Canadian Precursor Control Regulations may have also contributed to this positive trend.

Concurrently, perhaps due to the increased law enforcement focus on pseudoepehdrine, increases have been observed in the amount of ephedrine imported into Canada and in ephedrine seizures along the U.S.-Canada border. This suggests that bulk pseudoephedrine movements from Canada supporting methamphetamine production may have been partially replaced by bulk ephedrine shipments. For example, law enforcement personnel intercepted a 600-pound load of bulk ephedrine near Detroit in May 2003. Authorities in Canada and the United States will continue to monitor the results of the latest Canadian regulations.

Nonetheless, traffickers may be shifting their chemical diversion efforts and manufacturing operations south to Mexico. In March and April 2003, authorities made four large seizures totaling 22 million pseudoephedrine tablets from Asia destined for Mexico, and dozens of similar, prior shipments were identified. Mexican press reports of clandestine lab discoveries signal an apparent increase in methamphetamine production, especially in the Mexicali/Tijuana area.

Since May 1996, the U.S. and Mexico have worked formally through a Bilateral Chemical Control Working Group, which meets as needed to exchange information on regulatory systems and shipment data, to discuss possible joint initiatives, and to share case information. The current Mexican government has shown revitalized interest in cooperation against the diversion of chemicals as well as pharmaceutical drugs. DEA is now working to help Mexican law enforcement officials to identify and seize clandestine methamphetamine labs, and to investigate and prosecute the associated chemical and drug traffickers.

On the multilateral front, DEA has encouraged international consensus for voluntary, informal, flexible, and rapid systems of international information exchange on precursor chemical shipments. For example, under the Multilateral Chemical Reporting Initiative (MCRI), countries report chemical transactions on a single form, using the International Narcotics Control Board (INCB), a UN-based body, as a clearinghouse. In an effort targeting synthetic drugs in particular, Project PRISM was initiated in 2002 in a meeting sponsored by the INCB and hosted by the United States and EU. This operation involves some 38 countries that are major manufacturers, exporters, importers, or transit countries of chemicals diverted to synthesize amphetamine-type stimulants, such as MDMA/Ecstasy and methamphetamine. The initiative assists governments in developing and implementing operating procedures to more effectively supervise trade in the precursors of amphetamine-type stimulants in order to prevent diversion.

DEA also conducts one- and two-week training seminars on Clandestine Laboratory and Precursor Chemical Diversion Investigations and is coordinating an eleven-country initiative with countries in the Far East to prevent the diversion of MDMA precursor chemicals. In addition, DEA is working directly with host nations through their attaches in key Far East locations, including China, Hong Kong, and Thailand.

The placement of international organizations, particularly the INCB, in lead roles in multilateral chemical cooperation encourages participation by countries that might be reluctant to participate in an operation led by any single country or group of countries. The annual meeting of the UN Commission on Narcotic Drugs is the best, and most visible, vehicle for encouraging the INCB to take a lead role, to shape how it performs that role, and to promote participation by the most relevant countries. Other multilateral organizations, such as the Organization of American States' Inter-American Drug Abuse Control Commission (OAS-CICAD), are also proving instrumental in building regional and international coordination, cooperation, and adoption of harmonized control procedures.

The current international chemical control system is not without shortcomings. It has evolved on an ad hoc basis, drug by drug, chemical by chemical, operation by operation. It is voluntary; some countries do not participate, and traffickers are avoiding controls by shipping to those countries. Also, some countries are more diligent than others in investigating shipments after receiving pre-export notifications. In general, the system, which is flexible and informal by design, would now benefit from becoming more universal, formal, and institutionalized.

In addition, countries apply the 1988 UN Convention provisions variably. For example, some chemical importing countries have not asked the UN for pre-export notification pursuant to Article 12(10) of the Convention. Some critical exporting countries do not impose legal controls on precursor chemicals that are contained in pharmaceutical preparations—a lapse which has permitted the un-notified exportation and diversion of millions of pseudoephedrine pills.⁶⁴

Another obstacle to effective national and international chemical control is that many countries place responsibility for chemical control with health or commerce ministries. The natural tendency of these ministries is to consider chemical control a health or commercial issue, and not a law enforcement issue. Law enforcement agencies are more oriented to exchange information about chemical shipments and to act on suspicious information. (In the United States, DEA has responsibility for both chemical regulation and enforcement).

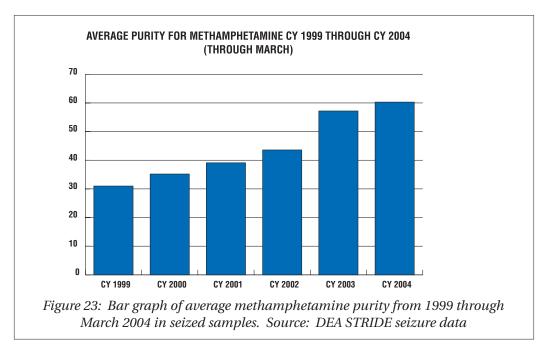
The United States has been successful at convincing our international partners of the importance of chemical control, stressing the fact that effective domestic control and international cooperation require a viable enforcement component. We have seen other countries build cooperation between their law enforcement agencies and their health and commerce ministries. Diplomatic agreements have also facilitated cooperation between sometimes bureaucratic and turf-conscious ministries. For example, the 1997 chemical control agreement between the United States and the EU has been instrumental in facilitating our cooperation with individual EU member law enforcement agencies, despite the fact that responsibility for chemical control may rest with health or commerce ministries.

d. Chemical Control Results

Chemical control has been an area of largely unheralded law enforcement success. Taking together the international, federal, and state measures, combined with voluntary efforts by private industry, chemical control remains a promising, proactive approach to disrupting synthetic drug production and trafficking.

One way to track success, in chemical control as in other efforts, is to monitor the availability, price, and purity of synthetic drugs. Although data vary over time and by region, methamphetamine prices have generally held steady within a range since 1998. In 2003, methamphetamine sold for \$3,000 to \$12,000 per pound and \$270 to \$1,500 per ounce. The market trend is decidedly towards the "ice" or

crystal form of methamphetamine; prices for ice have also been steady since about 2001, a little higher than the non-ice form. Methamphetamine purity trends paint a more sobering picture, for purity has risen steadily since about 1999, as shown in the figure below. However, the data in this chart, showing average purity of drug samples at 60% for the beginning of 2004, should be kept in perspective: purity levels are still well below the 1994 average of 72%.



On a more encouraging note, chemical prices on the illegal "gray market" have risen in a way that continues to indicate scarcity. A trafficker might pay as much as \$4,800 for a case of 144 bottles of pseudoephedrine that has a legitimate market of \$1,000. Red phosphorous, used to make hydriodic acid in the "ephedrine reduction" method of methamphetamine production, sells for approximately \$500 per pound (approximately 450 grams) on the street, compared to its licit market price of approximately \$34 for 500 grams in legitimate commerce. Red phosphorous also sells for about \$1 per gram at Internet auction sites.

Overall, the price and purity data suggest that aggressive new approaches may be needed on the regulatory front if the nation is to make additional headway against the problem of methamphetamine production.

e. Control of OxyContin and Other Diverted Pharmaceutical Products

Controlling the diversion of pharmaceutical products containing controlled substances, including OxyContin, is a shared federal-state responsibility. Federal laws focus on the import, export, manufacturing, and distribution levels. For example, there are federal requirements for tracking transactions from distributors to the retail pharmacy or hospital level and for reporting events that compromise the "closed system" of controlled substance distribution (such as thefts or significant losses). State laws focus on the dispensing level, mostly in pharmacies.

Control of prescriptions and dispensing is primarily a state responsibility. Prescription monitoring programs can enable states to exercise greater control in this area by facilitating the collection, analysis, and reporting of information on the prescribing, dispensing, and use of pharmaceuticals. This

data can be used to alert licensing, regulatory, or law enforcement officials to cases of inappropriate prescribing or dispensing of controlled substances.

The effectiveness of these prescription monitoring programs has already been demonstrated, as explained in the 2004 National Drug Control Strategy. One year after Nevada established its prescription monitoring program in 1997, for example, the number of narcotic drug doses dispensed to suspected abusers was cut by 46 percent. The Strategy also points out that in 2002 the five states with the lowest number of OxyContin prescriptions per capita all had prescription monitoring programs, while the five states with the highest number did not.

Twenty states currently have some form of prescription monitoring program in place, and several others have programs under development. All remaining states should be urged to develop prescription monitoring programs of their own. The National Alliance for Model State Drug Laws (NAMSDL) has created several model programs and can provide support for the evaluation and initiation of drug monitoring programs.

2. Recommendations

Support Stronger State Controls on Precursor Chemicals: - (DOJ, ONDCP, DEA)

States that face significant levels of clandestine lab activity and chemical diversion are urged to consider the imposition of more stringent controls than those currently in place at the federal level. Several states, notably Oklahoma, have recently enacted strict retail-level controls. (See Appendix F.) Additional state-level controls could include, for example: allowing only licensed pharmacists and pharmacy technicians to sell products containing precursor chemicals; placing such products behind the sales counter and/or in a locked display case; purchase limits imposed on a transaction and/or monthly basis (with an appropriate tracking mechanism); and requirements of customer identification sales record keeping.

Remove the Blister Pack Exemption: - (DEA, DOJ)

Support legislation that removes the blister pack exemption and eliminates distinctions based on the form of packaging, as recommended in DEA's November 2001 report to Congress. ⁶⁵

Regulate Chemical Spot Market: - (DEA, DOJ)

As an extension of existing authority over imports, ⁶⁶ law enforcement should seek the legislative authority to regulate sales of bulk chemicals on the domestic spot market by notification and approval of any deviations in quantity or customer from the import declaration. ⁶⁷

Determine Licit Chemical Needs: - (**DEA**, DOJ, ONDCP)

In cooperation with industry, commission a statistical analysis to estimate the legitimate needs for pseudoephedrine and ephedrine products—including combination products such as ephedrine with guaifenesin—both nationwide and regionally .

Enable Import Controls on Bulk Ephedrine and Pseudoephedrine: - (DEA, DOJ, ONDCP)

Seek legislation that would treat the post-importation handling of bulk ephedrine and bulk pseudoephedrine in a similar manner, for regulatory purposes, as federal laws now treat the post-importation processing of Schedule I and II controlled substances. Impose such controls on these critical precursors as are needed to limit imports to those necessary for legitimate commercial needs and for maintenance of effective control over chemical diversion. 68

Limit Online Chemical Sales: - (**DEA**, DOJ)

Continue ongoing efforts to advise the owners and operators of major on-line auction websites of the use of precursor chemicals in clandestine labs, and urge them to consider banning the sale of precursor chemicals over their web sites.

Strengthen Cooperation with Mexico: - (**DEA**, DOJ, State, ONDCP)

Solidify significant recent advancements by Mexico to increase the effectiveness of bilateral chemical control with the United States through continued partnership and meetings with the pertinent Mexican components, including their drug intelligence center (CENAPI), the Federal Investigative Agency (AFI), the chemical regulatory entity in the Ministry of Health (COFEPRIS) and the Health Commission.

Enhance Coordination and Information Exchange with Canada: - (DHS, ICE, CPB, DEA)

Enhance ongoing coordination with Canada Customs and Revenue Agency on border detection, targeting, and interdiction efforts, and ensure appropriate focus by Canada-U.S. joint Integrated Border Enforcement Teams on the precursor chemical and synthetic drug threats. Further expand the ongoing exchange of information concerning Canadian businesses involved in the importation, production, and distribution of pseudoephedrine—particularly those firms whose products have frequently been diverted or smuggled into the United States.

Strengthen the Multilateral Chemical Control System: - (DEA, DOJ, State, ONDCP)

Garner international support for making existing multilateral chemical controls more universal, formal, and well-supported by international institutions, including UN bodies such as the International Narcotics Control Board and regional bodies such as the Organization of American States' Inter-American Drug Abuse Control Commission (CICAD). Work to realize the full potential of Project PRISM, and build support for the application of the 1988 UN Convention to pharmaceutical preparations containing precursor chemicals that can be easily recovered for use in illicit drug production.

Exchange Information with Chemical Producing Countries: - (**DEA**, DHS, State, USTR)

Continue ongoing information-sharing efforts with the countries that produce precursor chemicals used to make amphetamine-type stimulants, particularly China, India, Germany, and the Czech Republic.

Educate Store Employees: - (**DEA**, DOJ)

Building on efforts begun in a number of states, work to develop a model training program for pharmacists, retail management, and store employees concerning suspicious pseudoephedrine purchases, as well as suspicious sales of chemicals and items used in the manufacture of methamphetamine. 69

Encourage Voluntary Controls by Retail Pharmacies and Stores: - (**DEA**, DOJ, ONDCP)

Seek the voluntary participation of major retail chains in programs to control pseudoephedrine product sales through restrictions on the quantity that can be purchased at a single time. Also support the voluntary movement of pseudoephedrine products from stores' open shelves to behind pharmacy counters or other manned counters in retail settings where pharmacies are not on site. ⁷⁰

Work with Manufacturers to Reformulate Abused Pharmaceutical Products: - (DEA, FDA)

Continue to support the efforts of firms that manufacture frequently diverted pharmaceutical drugs to reformulate their products so as to reduce diversion and abuse. Encourage manufacturers to

explore methods to render products containing key precursors such as pseudoephedrine ineffective in the clandestine production of methamphetamine and pain control products such as OxyContin less suitable for snorting or injection.

Support State Prescription Monitoring Programs: - (DEA, ONDCP)

Support states' creation of prescription monitoring programs designed to detect inappropriate prescribing patterns and prescription fraud. Law enforcement and regulatory entities should have access to information in case of apparent diversion or inappropriate prescribing of controlled substances, and some provision for state-to-state communication of adverse information should be examined. Supporting legislation should be explored.

D. Law Enforcement

1. Current Efforts

Following the release of the National Methamphetamine Strategy in April 1996, federal law enforcement agencies have launched several initiatives to combat the methamphetamine problem as well as threats posed by other synthetic drugs and diverted pharmaceuticals. Some obstacles continue to hamper fully effective enforcement: lack of properly trained personnel to conduct chemical and lab investigations and seizures; limitations in funding to support such police work and for cleanup of lab sites; and reluctance of some federal and state prosecutors to handle chemical and small lab cases. Steps have been taken, however, to rectify all of these challenges.

DEA has intensified its institutional focus on methamphetamine and other synthetic drugs of abuse, establishing methamphetamine in particular as one of its five priority areas. A new Dangerous Drugs and Chemicals Section has been formed at DEA Headquarters, and more methamphetamine-targeted teams of agents and diversion investigators now work in field offices. Through the Priority Target System, DEA provides funding and operational assistance to chemical and club drug investigations that are designated priority targets within their respective field divisions.

Of particular relevance to investigations of club and predatory drugs, DEA has recently established two new units to support Internet-based investigations. Overall, DEA has implemented a multi-faceted initiative to counter the threat posed by club and predatory drugs through raising public awareness and strengthening law enforcement. This initiative, "Operation X-Out," was started in November 2002, and is ongoing. It is expected to increase the number of club and predatory drug investigations nationwide and raise public awareness of the MDMA problem.

a. Methamphetamine: Planning and Coordination

The National Methamphetamine Chemicals Initiative (NMCI), along with its component regional groups including the California Precursor Committee, the Tri-State Precursor Committee (Arizona, New Mexico, and Nevada), and the Mountain States Precursor Committee (Colorado, Montana, Utah, and Wyoming), is an active coordinating and training mechanism. NMCI brings together federal, state, and local law enforcement officers, chemists, and intelligence analysts, as well as criminal and civil prosecutors to discuss legal and regulatory issues, trends, and successful strategies that target rogue firms and violators that funnel chemicals to clandestine laboratories. ⁷²

Over the past four years, the NMCI has established working groups to address important issues, including Canadian pseudoephedrine, the domestic iodine diversion problem, iodine smuggling

from Mexico, the need to regulate red phosphorous and related chemicals (which has been accomplished), and voluntary initiatives with industry to reduce diversion from stores. As a result of the recent arrests of a number of people associated with a treatment, storage, and disposal facility in Arizona, the NMCI created a task force composed of federal, state, and local officials in multiple states to address the potential diversion of hazardous chemicals from hazardous waste contractors. The NMCI has also supported the creation and dissemination of a training video for law enforcement and utility personnel that explains the hazards associated with clandestine drug labs.

HIDTA partnerships are also responsive to methamphetamine trafficking concerns. In particular, the Midwest HIDTA focuses on the investigation and reduction of methamphetamine production and distribution in an area covering six states (Iowa, Kansas, Missouri, Nebraska, North Dakota, and South Dakota). HIDTA funds also support NMCI activities.

Local agencies handle the majority of synthetic laboratory investigations, and some states are performing their own cleanups. In the appropriations for the Department of Justice in both 2002 and 2003, DEA was allocated \$20 million to help state and local law enforcement clean up clandestine labs. DEA is implementing contracts nationwide to provide cleanup services for DEA as well as state and local law enforcement agencies. DEA and the Environmental Protection Agency (EPA) are also working together to redraft guidelines for cleaning up clandestine drug laboratories.

b. MDMA: Planning and Coordination

The Department of Homeland Security's Bureau of Immigration and Customs Enforcement established the National Ecstasy Task Force to serve as a command-and-control center for coordinating MDMA interdiction and investigation efforts, and also to collect actionable intelligence on developing patterns and trends for dissemination to the field. Increased border interdiction efforts have resulted in the identification and investigation of large-scale MDMA smuggling organizations in the United States as well as in Europe. Conducted jointly by DEA, foreign law enforcement entities, and state and local agencies, these investigations have resulted in significant seizures of MDMA and other synthetic drugs and currency, both at and away from border areas, and have led to the arrest of organization members at all levels.

In addition, the 28 HIDTA regional partnerships between federal, state, and local law enforcement officials are evaluating the MDMA threat in their respective regions. In cases where the MDMA threat is judged to be significant, appropriate shifts in enforcement strategies are being made.

On the international level, bilateral meetings in March 2003 between the United States and the Netherlands yielded an action plan for enhancing law enforcement and judicial cooperation on drugs, crime, and terrorism. The two countries are now working actively and cooperatively to implement these plans. Results have included the exchange of information on U.S. and Dutch judicial systems; collaboration with U.S. law enforcement agencies on more investigations; exchange of information on MDMA seizures; Dutch development of a risk indicator and profiles for targeting traffickers; creation of a bilateral discussion group on demand reduction; and cooperation internationally in the framework of the INCB Project Prism.

c. Training

Training efforts have gone forward on several fronts. The NMCI has conducted training on the topics of chemicals investigation and prosecution for hundreds of federal criminal and civil prosecu-

tors, intelligence analysts, and federal, state, and local officials. The Department of Justice's Bureau of Justice Assistance has also funded methamphetamine-related training programs for state and local officials. DEA has intensified its domestic training efforts by offering Clandestine Laboratory Safety Schools and OSHA-certified training to federal, state, and local law enforcement officers. Since 1998, DEA has provided OSHA-certified lab training to over 4,174 police officers throughout the nation, along with approximately \$2,500 in equipment for each trainee. As part of the basic drug training course, all new DEA and FBI agents receive training concerning MDMA and other "club" and "predatory" drugs like GHB. MDMA is also covered in the training that DEA offers each year to approximately 300 state and local investigators at the Drug Unit Commander's Academy and to about 150 law enforcement executives at the FBI National Academy. In addition, DEA's Chemical Control Section has trained hundreds of foreign officials in more than two dozen countries on the diversion and smuggling of all chemicals used in illicit drug production.

d. Seizures, Investigations, and Prosecutions

The ready availability of pseudoephedrine from Canada largely mitigated any temporary scarcities and higher "gray market" prices for pseudoephedrine and illicitly produced methamphetamine. DEA-led enforcement initiatives against "rogue" chemical firms, particularly "Operation Mountain Express" in the summer of 2000, have been extremely effective at countering this illicit chemical flow. A follow-on "Operation Mountain Express" targeted traffickers who illegally smuggled pseudoephedrine from Canada, and culminated in January 2002 with the arrests of over 130 defendants and the seizure of 35.8 tons of pseudoephedrine.

In April 2003, another joint investigation—"Operation Northern Star"—resulted in the arrests of, among others, six executives of three Canadian chemical companies that manufactured bulk pseudoephedrine in Montreal. The drugs were stockpiled in Ottawa, then smuggled across the border to methamphetamine manufacturers in the United States. The Royal Canadian Mounted Police and DEA were the lead agencies in this investigation, which ultimately produced arrests in 10 cities and charges against the three Canadian chemical companies involved.⁷⁶

The progress of CBP and ICE border seizure initiatives also continues. Authorities at the U.S.-Mexico border seized two tons of iodine in both 2001 and 2002. Similar seizure rates were reported in 2003 as well.

Moreover, the Department of Justice has enhanced prosecution efforts for all synthetic drugs, particularly methamphetamine and club drugs. The number of Organized Crime Drug Enforcement Task Force (OCDETF) cases focusing on methamphetamine has increased in recent years, both in absolute numbers and as a percentage of all OCDETF cases. Law enforcement agencies are devoting more resources to club drug investigations as well. One prominent investigation, "Operation Webslinger," was a multi-agency effort targeting the illegal Internet trafficking of GHB and its analogues, GBL and 1,4-butanediol. Culminating on September 19, 2002, the operation led to the arrest of more than 130 defendants in over 100 cities and the seizure of more than 25 million dosage units. DEA agents more than tripled their work hours on club drug cases between 1999 and 2001 (to over 250,000) and also made more than three times as many arrests for club drug offenses in 2001 (1,929 arrests) as in 1999 (577 arrests).

The number of defendants sentenced on federal MDMA trafficking charges has also climbed from 117 defendants in 1999 to 372 defendants in 2001, which is the last year for which data are available. However, there have been a number of notable federal MDMA cases since the beginning

of 2001. In August 2001, 55 people were arrested, including the leader of a poly-drug ring, in connection with the distribution of "green clover" MDMA tablets in Colorado; one of the tablets caused the widely publicized death of a 16-year-old girl. An MDMA and methamphetamine lab in California capable of producing millions of tablets was seized in October of 2001, and 20 people associated with the organization were arrested. Several large-scale MDMA traffickers from Israel, including the leader of the world's largest MDMA smuggling ring, were arrested in 2002. In addition, an MDMA smuggling ring operated by Dominican nationals in New York and the Netherlands was disrupted in November 2002 through the arrest of 20 traffickers within the organization. Most recently, Operation Candy Box, a joint U.S.-Canada effort, netted arrests in March 2004 of more than 130 people associated with a large organization that manufactured and trafficked MDMA and marijuana.

Federal authorities have also had success pursuing rave venues and promoters under the federal "crack house" statute⁷⁹ for conduct that facilitates the trafficking of club drugs. In 2000 a DEA investigation and raid of the State Palace Theater in New Orleans contributed to a 90 percent drop in MDMA overdoses in that city. Investigations in the Boise, Idaho, area into the sale of MDMA, ketamine, and other drugs led to convictions of 30 people on trafficking charges, including a rave promoter who pleaded guilty to crack house charges. A New York state rave promoter was also charged under the crack house statute in November 2002.

Finally, local law enforcement personnel have discovered that conducting reverse buys of precursor chemicals from suspects has limited the amount of pseudoephedrine on the streets. In these cases, undercover officers use confiscated pseudoephedrine and attempt to engage precursor traffickers and methamphetamine producers in buying the product for illicit purposes. Arrests and leads allow law enforcement to continue to build upon these investigations by locating synthetic labs. Southern California law enforcement agencies credit this tactic with bringing about the recent reduction in the number of local synthetic drug labs.

2. Recommendations

Target Pseudoephedrine and Iodine Smuggling to and from Mexico: - (DEA, ICE, CBP)

Focus resources on stopping the recently noted flow of suspicious shipments of precursor chemicals, notably pseudoephedrine, from Asia to Mexico, apparently destined for clandestine methamphetamine labs in the U.S. and Mexico. Also focus on the smuggling of iodine from Mexico. In all such cases, law enforcement should identify and aggressively pursue the persons and firms responsible.

Focus on Canadian Synthetics and Chemical Smugglers: - (DEA, ICE, DOJ)

Expand joint U.S.-Canadian investigations into the smuggling of chemicals, methamphetamine, MDMA, and other club drugs and diverted pharmaceuticals. Assign high priority to investigations of large seizures of pseudoephedrine and ephedrine from Canada, and develop prosecutable cases against rogue Canadian companies and their principals.

Investigate Ties between Canadian and Mexican Criminals: - (DOJ, DEA, ICE, NDIC)

Analyze law enforcement reporting and intelligence with respect to Canadian pseudoephedrine and ties between Canadian sellers and Mexican lab operators in California. Analysis of the flow of funds generated from sales of pseudoephedrine in Canada and the United States should be coordinated by the appropriate agencies within the concerned Departments.

Investigate Asian and European Sources of Synthetic Drugs: - (DEA, ICE, State)

Work with international law enforcement partners and regional groups to investigate Asian criminal groups in North America and in Asia that increasingly may be engaged in producing and trafficking synthetic drugs and their precursor chemicals. Enhance bilateral efforts with the Netherlands and other MDMA-producing countries in Europe to build investigations, share information, and extradite criminals where appropriate.

Enhance Methamphetamine Profiling Efforts: - (DEA, DOJ, ONDCP)

Increase the number of samples available for analysis in DEA's methamphetamine profiling program by incorporating samples of the drug seized by state and local law enforcement at super labs, or from shipments strongly suspected of originating from such large-scale operations. Also leverage information on chemicals, adulterants, cutting agents, and equipment found at the sites.

Review Lab Cleanup Resources: - (DEA, DOJ, EPA)

Ensure adequate funding sources for clandestine laboratory and dumpsite cleanups, including funding for sufficient personnel to support laboratory cleanups and hazardous waste disposal, so that cleanup costs are not a disincentive to laboratory investigations or takedowns. Federal officials, in collaboration with state agencies, should conduct a needs assessment to identify potential program improvements and make recommendations on the specific support needed and the funds required.

Apply Updated Clandestine Lab Cleanup Guidelines: - (DEA, EPA)

Disseminate and apply the latest guidelines for the cleanup of clandestine methamphetamine labs and, where necessary, coordinate environmental remediation by appropriate entities. These protocols for adulteration and destruction of precursor and essential chemicals, glassware, and methamphetamine waste should be part of clandestine laboratory certification training.

Increase Prosecutor and LEA Training: - (**DOJ**, DEA, CBP)

Recognizing the unique issues presented by chemical and methamphetamine cases, the Federal Government should, as resources permit, offer training for criminal and civil prosecutors and federal, state, and local law enforcement agents more frequently and in different regions of the country.

Make Full Use of Charging and Sentencing Options: - (DOJ, DEA)

Prosecutors should make full use of federal Sentencing Guidelines provisions which set a sentencing floor (of 70-87 months) for any case involving methamphetamine manufacture that creates a substantial risk of harm to human life. Federal prosecutors should also make greater use of the environmental enhancement for clandestine drug manufacturing involving "unlawful discharge, emission, or release into the environment of a hazardous or toxic substance or for the unlawful transportation, treatment, storage, or disposal of a hazardous waste".

Increase Access to Civil Penalty Case Experts: - (DOJ)

The Department of Justice should develop and disseminate a list of attorneys who have experience in civil penalty cases under the Controlled Substances Act and are available to assist U.S. Attorney's Offices in districts where such cases have never or rarely been referred or pursued.

Prevent Exploitation of Mail Services: - (DEA, CBP, ICE, State, NDIC, FDA)

Work with the U.S. Postal Service and private express mail delivery services to target illegal mail-order sales of chemical precursors, synthetic drugs, and pharmaceuticals, both domestically and internationally .

Improve Intelligence Efforts Related to Synthetic Drugs: - (NDIC, DEA, CIA, CBP, ICE, State) Intensify intelligence components' focus on gathering and sharing information regarding the nature and scope of synthetic drugs trafficking. Make full use of NDIC's real-time analytical database for both pre- and post-operation link analysis and document exploitation. Strengthen mechanisms for sharing actionable intelligence, trend analysis, and information on criminal organizations among the United States and concerned Western European countries.

Target Raves Where Drug Use is Facilitated: - (DEA, DOJ)

Focus attention on the promoters and operators of rave events that facilitate the trafficking and abuse of MDMA and other club drugs, making innovative and effective use of the federal "crack house" statute, including amendments in the Rave Act.

Consider New Legislation on Club Drugs: - (**DOJ**, DEA)

Federal officials should continue efforts to develop additional legislation to address legal issues that often arise with respect to club drugs and rave-type events. For example, the distribution of imitation controlled substances could be explicitly criminalized at the federal level, and the provisions governing controlled substance analogues and counterfeits could be clarified.⁸²

Strengthen Controls on Internet Sales: - (**DOJ**, DEA)

Support legislation that regulates the burgeoning business of Internet sales of drugs, particularly controlled substances, by prohibiting the dispensing of controlled substances online without a valid prescription. The new law would define a valid prescription as one issued for a legitimate medical purpose in the usual course of professional practice, and would require at least one in-person medical evaluation by the prescribing doctor.

Increase Internet Investigations: - (**DEA**, DOJ, NDIC, ICE, FDA, State)

Expand investigations and prosecutions of Internet-based synthetic and illegal pharmaceutical drug diversion and sales, to include the establishment of task forces and coordination mechanisms dedicated to this purpose. Agencies should work with Internet Service Providers to assist them in limiting children's access to illegal drug sites.

Target OxyContin and Vicodin Diversion: - (DEA, DOJ)

Support efforts to target individuals and organizations involved in the diversion, illegal sale, pharmacy theft, fraud, and abuse of OxyContin and other drug products containing oxycodone or hydrocodone, such as Vicodin and Lorcet.

Seek Updated Sentencing Guidelines for Club Drugs: - (**DEA**, DOJ)

Work with the U.S. Sentencing Commission to review data on the impact and effectiveness of current sentences for trafficking in ketamine, GHB and its precursors and analogues, and other club drugs, and, if advisable, propose enhanced guidelines sentences.

Share Law Enforcement Best Practices: - (**DEA**, DOJ)

Based on the successes achieved by local law enforcement in Southern California using reverse-buy investigations and by communities in the Midwest that have set more strenuous penalties and regulations regarding synthetic drugs, establish a mechanism for sharing best practices among federal, state, and local law enforcement as well as with international partners who are confronting synthetic drug threats.

Appendix A:

Outline of an Early Warning and Response System for Emerging Drugs of Abuse

Participants in all aspects of drug abuse control efforts—whether on the "demand" or "supply" side—have sometimes complained of being caught off guard by the apparently sudden emergence of new drug abuse trends in the United States. Recent examples include MDMA ("Ecstasy") and GHB (one of the "date rape" drugs). This phenomenon occurs despite the existence of several sophisticated and comprehensive data systems by which drug abuse is measured across the country. This outline of an "early warning" template and a means of first response is an effort to address this problem.

The model portrayed in this Appendix is not intended to dictate any specific agency action, but rather to give structure to the government's system of detecting and responding to new trends. Consistent with their respective missions, many governmental agencies, acting individually and in collaboration, already undertake several of the activities discussed in this outline.

I. Identification of an "emerging drug problem." ("How do we know there's a problem?")

Step A. Intensive, selective sampling of specific data sources is most likely to yield a reliable "early warning" of a new drug threat.

Discussion of data systems:

- The objective: A system that yields rapid data with a scope as comprehensive as possible.
- Current national data systems tend to emphasize accurate ("cleaned") and complete data over speed, so lag time is excessive for an "early warning" alarm.
- The idea behind the quantitative and qualitative data gathering activities outlined below is to produce a "quicklook" or "sentinel" product to support earlier government intervention if warranted by selected trend information. The format and process of transmitting such information could take the form of brief, informal, periodic (e.g., quarterly or mid-year) reports.
- The types of data that are most pertinent for an early warning system include data on:
 - (a) current use (versus treatment visits, drug deaths, perceived harm)
 - (b) new or growing drugs of abuse (versus cocaine, heroin, etc.)
 - (c) groups most likely to use new drugs (e.g., young people and "marginal" groups)

<u>Recommendations:</u> Existing data-gathering efforts should be honed to selectively harvest the most useful early warning data. In this regard, the following data sources should be explored:⁸³

- Quantitative: Sample the following data sources more intensively and frequently—yet more selectively, both in terms of geographic distribution and drugs of interest—for signs of emerging drug abuse:
 - ➤ Tap into state/local and federal (DEA) forensic lab data. There are two real-time forensic data systems. The National Forensic Laboratory Information System (NFLIS) collects

results of drug analyses from state and local forensic labs across the country. The federal equivalent is the DEA System to Retrieve Information from Drug Evidence (STRIDE).⁸⁴ It would be useful if all labs were encouraged to analyze samples of non-controlled substances, which might warrant DEA scheduling as drugs of abuse.

- ➤ Selectively expand collection of ADAM data. The DOJ/NIJ-administered Arrestee Drug Abuse Monitoring program (ADAM) reaches the high-risk drug population of people arrested and booked in NIDA data sites, but data are limited to the five most commonly used drugs. Selected sites could expand interviews and urinalyses to capture other drugs and trend information.
- ➤ Emergency Room (ER) data. The recently re-designed DAWN holds particular promise in providing early warning for drugs of abuse. It will include the capacity for real-time access and online queries of DAWN data; other sophisticated approaches to detection and information delivery are planned.
- ➤ CDC data: The Center for Disease Control is developing a methodology to identify incidents of poisoning. Part of this effort is to monitor regional trends of consumption of certain types of over-the-counter medications. This information could be used as one tool to indicate surges in the abuse of certain commonly available drugs or the diversion of products such as pseudoepehdrine for methamphetamine production.
- ➤ High school survey. For example, there could be a way to advance the survey process and data analysis of selected schools in the Monitoring the Future survey.

• Qualitative:

- ➤ Seek public input through an Internet-based vehicle, e.g., by linking a reporting website with the websites of professional organizations for emergency room and addictions personnel, law enforcement, and teachers. (See S. 151 § 323 (108th Cong.), authorizing a "cyber tipline")
- ➤ Regularly cull data from . . .
 - Internet chat rooms
 - Ethnographers who have contact with drug users
 - College campus health clinics
 - Faith organizations with a focus on cities and towns which have in the past proven to be harbingers of emerging drug problems.⁸⁵

Step B. Report findings to a designated "interagency early warning committee." Two inter-disciplinary entities currently serve an early-warning function; either could be adapted to suit this role more effectively.

- The Interagency Committee on Drug Control (ICDC) meets monthly to discuss emerging drug problems and consider responses. The ICDC involves the ONDCP, NIDA, FDA and DEA. The frequency of its meetings commends this group to being the early warning coordination body, but it may need to be expanded—and staffed—to perform this function better.
- The Community Epidemiology Working Group (CEWG) meets semi-annually to assimilate drug-related quantitative and qualitative data from multiple sources and provide current descriptive and analytical information.

II. Rapid analysis of the problem and follow-up on initial discovery. ("Now that we know there's something new out there, how do we determine how big it is and how we are equipped to address it?")

<u>Discussion of "rapid analysis" stage:</u> Some further efforts to analyze the problem presented by a newly discovered drug threat are critical; however, these should not be undertaken at the expense of considering appropriate responses. The most critical steps are included here.

Step A. Do we have the capacity to measure the problem?

- Data problems: Do we have the right survey and other tools to measure this drug problem? If not, can they be adapted? (Example: If it is primarily a drug used by the rural working poor, do we need to ramp up a means of measurement?)
- Detection problems: Can the drug be detected; by what means; and are those means adequate?

If current testing means are inadequate, foster the development and validation of new drugdetection tests and tools; disseminate methods and materials. Secure assistance and expertise from government, academia, assay and instrument manufacturers, clinical and forensic pathology, toxicology and their support laboratories.

Step B. What is our "first take" on the <u>main characteristics</u> of the problem?

- Demographics of abuse: age; gender; race or ethnic group; socioeconomic group; geographic impact; urban, suburban, or rural
- Degree of danger to public health and safety
 - short-, medium-, and long-term physiological and psychological effects and dependence profile
 - related social harm or criminal conduct (e.g., drug-seeking crime, domestic violence, or sexual assault)
 - "gateway" potential
- Sources of the drug; domestic and foreign manufacturing processes, including chemicals used; smuggling methods; distribution routes; diversion from licit pharmaceutical supplies
- Production/trafficking organizations and their financial structures
- Public awareness and attitudes
- Treatment protocols
- Are there unique and pressing research needs in any of these areas?
- III. Response (Now that we know there's a problem and have an idea of its scope and dimensions, what are we going to do about it?)
 - **Step A.** Assess response and structure of current system to address problem.
 - **Step B.** Recommend additional or novel approaches.

For both steps, the following areas of inquiry are pertinent.

1. Awareness. Is the awareness level adequate? Is greater awareness desirable? If answers are "no" and "yes" respectively, how best to raise awareness? (Examples: Government and NGO websites; media campaigns including ads and public service announcements, etc.)

2. Prevention and Education

- a. Canvass HHS components (e.g. NIDA, SAMHSA), Dept. of Education, state and local prevention groups, and NGOs to determine whether current prevention efforts are adequate, or might be easily adapted, to address the problem.
- b. If not, devise a new approach.

3. Treatment

- a. Assess our knowledge of acute and long-term treatment through emergency rooms and addiction treatment programs.
- b. If inadequate, how might we develop better treatment protocols?

4. Regulatory

- a. Is the substance <u>scheduled</u>? Does it need to be scheduled or placed on a higher schedule? Does it need and qualify for temporary, "emergency" DEA scheduling?
- b. Are there "immediate precursors" (as defined under the CSA); if so, should they be scheduled as such?
- c. Are there <u>precursor or essential chemicals</u> that should be brought under control as "listed chemicals"?
- d. Are there analogues that should be treated as the same substance?

5. Legislative

- a. Are current laws—both federal and state—adequate to address the problem? If not, what law reform is needed?
- b. Do current sentences appropriately reflect the seriousness of trafficking of the substance? If not, what adjustments are advisable?

6. Law enforcement

- a. Is there anything special about this drug or drug trend that requires a different law enforcement approach
 - by police or prosecutors; or
 - at the federal, state, or local level?
- b. If so, what new actions are needed?

7. International

- a. Does the problem have international dimensions?
- b. If so, what approaches would be effective through:
 - multilateral drug control entities (e.g., UN-based, such as INCB);
 - regional bodies (OAS-CICAD); and
 - bilateral approaches, if there is a manageable number of key foreign countries with whom we have working relationships?

Appendix B:

Overview of the New Drug Abuse Warning Network (DAWN) System Design and Implementation

Summary

The new Drug Abuse Warning Network (DAWN) is designed to provide real-time access to sentinel event data that will be used by participating facilities, clinicians, communities, and policy makers. In addition, it is designed to provide improved national and metropolitan estimates of drug-related emergency department (ED) visits and drug-related deaths investigated by medical examiners and coroners (ME/Cs). Expansion of DAWN's geographic coverage and case criteria will provide more complete and comprehensive surveillance of drug-related events. Deployment of the Sentinel Event Reporting System (SERS) will provide authorized users with real-time query access to DAWN records to detect emerging trends and new drug problems before they become widespread.

DAWN: Creation of a Warning Network

Following a 20-year evaluation of design alternatives and user needs, the Drug Abuse Warning Network (DAWN) has been redesigned. The new design, with a multi-year implementation schedule that began in 2003, is focused on accomplishing two goals:

Goal 1: Provide better national and metropolitan-area estimates of drug-related emergency department (ED) visits and drug-related deaths investigated by medical examiners and coroners (ME/Cs).

Goal 2: Become an active surveillance network with the ability to identify aberrant trends in known drug problems, detect new drug problems before they become widespread, and quickly make this information available to hospitals, clinicians, communities, and policy makers.

While the first goal represents and enhancement of DAWN's traditional analytical capabilities, the second is new. This goal will be achieved through completely new capabilities that will make the "warning" in DAWN's name a reality for the first time.

Multiple features of the new DAWN support this goal:

- DAWN is moving to complete electronic data collection. Data submitted electronically can be edited and cleaned on input, and then made available immediately for real-time queries and analysis.
- 2) Expanded DAWN case criteria now capture all types of drug-related ED visits and deaths, and revised data items capture more meaningful information about these events. Previously, many relevant drug-related events were missed by restrictive case criteria (for example, cases of drug-facilitated rape became reportable with the new design in 2003).

- 3) The geographic coverage of DAWN is expanding. When the expansion is complete, DAWN will cover the 48 most populous metropolitan areas across all regions of the United States with both hospital samples and ME/C jurisdictions. In addition, selected statewide ME systems will supply data on drug-related deaths for areas lacking in metropolitan coverage and where hospital samples are not feasible. Although data from ME/Cs will continue to lag behind data from hospitals in timeliness, expansion of the DAWN mortality component in target metropolitan areas and states will augment the ED data with an enhanced picture of the most severe consequences of drug abuse.
- 4) The Sentinel Event Reporting System (SERS) will be the real-time messenger for the DAWN warning network. SERS is being developed to query DAWN data, identify emerging trends in drug abuse, and supply timely information back to hospitals, clinicians, communities, and policy makers. SERS, which will allow users to access data in real-time without delays for statistical weighting or manipulation, is being deployed in stages.
 - Each of the SERS capabilities for querying ED data will have a counterpart for mortality data. Further enhancements will be designed and deployed based on user acceptance and information needs. Access rights will be limited as necessary to comply with statutory prohibitions against disclosure of identifiable information.

Appendix C:

DEA Action Plan to Prevent the Diversion and Abuse of OxyContin®

SUMMARY

In response to growing concern among federal, state and local officials about the dramatic increase in the illicit availability and abuse of the prescription drug OxyContin®, the Drug Enforcement Administration (DEA) has embarked on a comprehensive effort to prevent its diversion and abuse.

The pharmacological effects of OxyContin®, a brand name formulation of the Schedule II narcotic oxycodone, make it attractive to abusers as it offers reliable strength and dosage levels and may, in some instances, be covered by the abuser's health insurance. Abusers have discovered that the controlled release formula of OxyContin® can be easily compromised allowing inhalation or injection for a powerful, morphine-like high.

Reports of the diversion and abuse of OxyContin® are currently concentrated in rural areas of the eastern United States; however, DEA's Office of Diversion Control has identified this activity as a growing problem throughout the nation. It has been described by some local law enforcement officials as a national epidemic in the making. National indicators such as DAWN (Drug Abuse Warning Network) and STRIDE (System to Retrieve Information from Drug Evidence) show recent increases in oxycodone overdoses and law enforcement encounters. Some jurisdictions report as much as a 75% increase in property and other crimes that they specifically attribute to the abuse of OxyContin®. Tazewell County, VA, estimates that OxyContin® addiction is behind 80% to 95% of all crimes committed there.

Criminal activities resulting from the abuse of OxyContin® are quickly depleting the resources, financial as well as human, of local law enforcement. Some states, such as Maine, Virginia and Kentucky, have become so alarmed by this problem that they have begun to take extraordinary action to deal with it. Officials in Kentucky are utilizing a powerful new tool called KASPER (Kentucky All-Schedule Prescription Electronic Reporting), a database of all controlled substances dispensed by Kentucky pharmacists, in their investigations of OxyContin® -related crime. The Attorney General of Virginia recently convened a meeting of officials from five states to discuss ways to halt illegal trafficking in OxyContin®.

THE PROBLEM

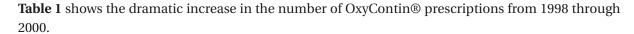
OxyContin® is a Schedule II controlled release form of the narcotic oxycodone manufactured by Purdue Pharma L.P. in 10mg, 20mg, 40mg, 80mg, and 160mg tablets.³ The controlled release method

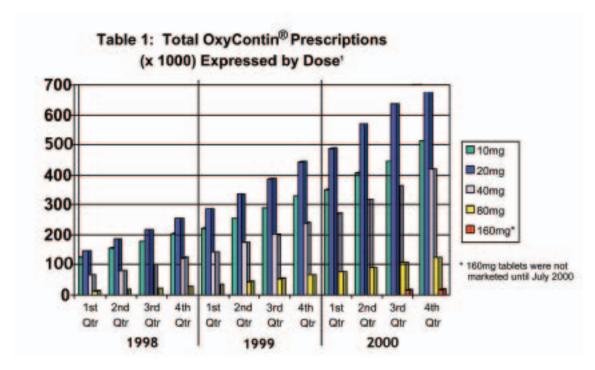
Data from the Office of Diversion Control Quarterly Reports indicate that OxyContin® has risen dramatically in recent months in terms of mention by the field offices as a 'most abused' drug.

 $^{^{2}}$ Article published in the Louisville, KY, *The Courier-Journal*, February 8, 2001

³ After this report was drafted, Purdue Pharma L.P. announced an indefinite suspensions of the distribution of OxyContin® in the 160-mg form.

of delivery used in OxyContin® allows for a longer duration of drug action and, consequently, the manufacture of tablets containing larger doses of the active ingredient. It is legitimately used as a medication to treat moderate to severe pain and is becoming the drug of choice in many pain management clinics. In a little over four years, sales have reached \$1 billion.





Oxycodone has been marketed in combination products with aspirin and acetaminophen (Percodan® and Percocet®) for many years. Diversion and abuse of these products continue. However, because they contain these other ingredients and only 5 to 10mg of oxycodone, they are primarily abused orally. While prescriptions for oxycodone combination products have increased during the period from 1996 to 2000, prescriptions for oxycodone single entity products (such as OxyContin®) have increased over fourteen-fold.

OxyContin® has become a target for diverters and abusers of controlled substances because of the larger amounts of the active ingredient in relation to other previous oxycodone products and the ability of abusers to easily compromise the controlled release formulation. Simply crushing the tablet can negate the timed effect of the drug, enabling abusers to swallow, inhale, or inject the drug, which is water soluble, for a powerful morphine-like high.

Common means of OxyContin® diversion are fraudulent prescriptions, doctor shopping, over-prescribing, and pharmacy theft. There have been many instances of pharmacies being robbed strictly for their supply of OxyContin®. Investigations have uncovered organized rings of individuals diverting, selling, and abusing OxyContin®. Intelligence has also shown that foreign diversion is another source of the OxyContin® being sold and used illegally in the United States.

OBJECTIVE

Continued increases in the diversion and abuse of OxyContin® are considered likely unless firm and immediate action is taken. It is the goal of this action plan to reduce the existing and potential costs to public health and safety by having a significant and immediate impact on the diversion and abuse of OxyContin®.

ACTION PLAN

In order to combat the serious and growing problems stemming from the diversion and abuse of OxyContin®, DEA has developed a four-part action plan. The elements of the plan are as follows:

1) Enforcement and Intelligence: DEA must focus existing resources and management attention on investigations of the diversion and abuse of OxyContin®. These investigations require coordination and support from enforcement, diversion, and intelligence groups. Coordinated operations have been initiated in field offices to target individuals and organizations involved in the diversion, illegal sale, pharmacy theft, fraud, and abuse of OxyContin®. DEA is using all available enforcement tools to disrupt these illegal operations. This includes interagency efforts on the federal, state, and local levels and extends to the international as well as the domestic arena.

DEA is continuing to identify large volume purchasers of OxyContin® for referral to field offices for appropriate action. All exports of OxyContin® are being closely scrutinized in order to detect possible diversion trends, particularly in those countries having limited controls on pharmaceutical products.

A complete assessment of the scope and magnitude of OxyContin® legitimate use and abuse is being undertaken utilizing traditional and novel data sources. DEA has initiated contact and continues to work with the National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, the National Institute of Justice, and others to modify data sources (e.g., the Monitoring the Future survey) to improve the specificity of the data collected to reflect OxyContin® abuse.

2) Regulatory and Administrative: DEA is utilizing its full range of regulatory and administrative authority to pursue action as necessary to prevent the diversion and abuse of OxyContin®. In doing so, it is essential that DEA elicit the support of other regulatory agencies. These actions are not intended to impact on the availability of legitimate drug products for medical use.

DEA continues to examine the rapid increase in the requested levels of oxycodone quota by the manufacturer of OxyContin®.

DEA continues to work closely with the Food And Drug Administration (FDA) in strongly urging the rapid reformulation of OxyContin® to the extent that it is technically possible, in order to reduce the abuse of the product, particularly by injection. Additionally, both agencies will continue monitoring practices that may contribute to diversion or abuse.

DEA continues to work with the Interagency Narcotic Treatment Review Board and the Federation of State Medical Boards to develop further cooperation on such issues as physician education on the treatment of pain, the recognition of addiction, and implementation of the Federation's Model Guidelines on Pain Treatment.

DEA will pursue legislative initiatives to assist states with funding for prescription data collection and analysis.

3) Seek Industry Cooperation: DEA continues to stress the importance of voluntary cooperation from industry in adhering to the spirit and substance of existing law and regulations. The agency is increasing its cooperative efforts with all levels of industry in order to stem the abuse and diversion of OxyContin®.

The cooperation of Purdue Pharma L.P., the sole manufacturer of OxyContin®, is integral to the success of DEA's Action Plan in preventing the abuse and diversion of OxyContin®.

Purdue Pharma has been encouraged to develop a balanced marketing strategy that ensures appropriate use of OxyContin®. Purdue agrees that OxyContin® should be prescribed only to patients where use of an opioid is appropriate for moderate to severe pain lasting more than a few days. Moreover, OxyContin® should be prescribed only by physicians who are knowledgeable about the use of opioids in the treatment of pain. Purdue Pharma will be encouraged to support and provide educational programs alerting legitimate patients as well as the general public to the dangers inherent in the abuse of such drugs.

In order to assist in identifying sources of diversion, DEA proposes that Purdue Pharma modify the shape, indicia, and color of OxyContin® tablets manufactured for export from the United States.

DEA is working with medical organizations and institutions, government agencies, and international health care groups to better assess the legitimate medical needs for narcotic analgesics including OxyContin®. Such groups include the American Pain Society, American Academy of Pain Medicine, the Joint Commission on Accreditation of Healthcare Organizations, the World Health Organization, and the National Institutes of Health.

4) Awareness / Education / Outreach Initiatives: Recognizing the importance of the appropriate use of opioids in the treatment of pain, DEA must work to increase national awareness of the dangers associated with the abuse of OxyContin®. An aggressive, national outreach effort to educate the public, schools, the healthcare industry, and state and local governments on the dangers related to the abuse of OxyContin® will be implemented.

DEA must work proactively with the American Medical Association, Federation of State Medical Boards, National Association of Chain Drug Stores, and National Association of Boards of Pharmacy, among others, to alert the healthcare industry to the growing problems associated with OxyContin® abuse. DEA is enhancing existing public awareness programs, including the Demand Reduction Program and the DEA's public internet web sites, in order to educate the public on the dangers of OxyContin® abuse.

Appendix D:

Schedules and Regulatory Controls Applicable to the Subject Controlled Substances

Overview: Controlled Substance Schedules and Chemical Lists

The Controlled Substances Act, at 21 U.S.C. § 812, establishes five lists, or "schedules," of controlled substances. The criteria for each schedule are based on the potential for abuse and the degree of accepted medical use in treatment. Schedules also consider the degree and likelihood of physical or psychological dependence. Schedule I controlled substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and lack of accepted safety for use under medical supervision. Schedule II controlled substances have high potential for abuse, currently accepted medical use in treatment in the United States or use with severe restrictions, and abuse may lead to severe physical or psychological dependence. Schedule III controlled substances have lower potential for abuse than those in Schedules I and II, currently accepted medical use, and abuse may lead to moderate to low physical dependence or high psychological dependence. Controlled substances on Schedules IV and V have accepted medical use and progressively lower potential for abuse. While Congress initially placed many substances on the five schedules when it passed the CSA in 1970, it vested authority in the Attorney General, since delegated to DEA, to add, remove, or transfer substances among the schedules.

The up-to-date listing of schedules appears at 21 C.F.R. §§ 1308.11 through 1308.15. "Listed chemicals" are chemicals frequently used in the illicit manufacture of controlled substances. "List I" chemicals (mostly "precursor chemicals" scientifically) are "important" to the illicit manufacture of a controlled substance (see 21 U.S.C. § 802(34)); the up-to-date list appears at 21 C.F.R. § 1310.02(a). "List II" chemicals (scientifically, mostly agents, reagents, catalysts, and solvents), which are also used in unlawful drug production, appear at 21 C.F.R. § 1310.02(b). Listed chemicals are monitored through a domestic and international regulatory scheme that involves registration (for certain handlers of List I chemicals), record-keeping, and reporting (notably of unusual or suspicious proposed transactions). See 21 U.S.C. § 830.

Methamphetamine and MDMA

DEA regulates methamphetamine and amphetamine as "Schedule II" controlled substances, the strictest level of control for any drug that has been accepted for medical use. Because of the strict accountability requirements under the regulatory scheme, very little of the methamphetamine or amphetamine abused in this country is diverted from legitimate channels; rather, these drugs are manufactured in clandestine laboratories here or abroad. The principal chemicals used to manufacture methamphetamine or amphetamine clandestinely—including ephedrine, pseudoephedrine, phenylpropanolamine, phenyl-2-propanone, hydriodic acid, and iodine—are regulated under domestic law as "List I" or "List II" chemicals, or as immediate precursors in Schedule II, and most are regulated by international law under the 1988 United Nations Convention Against

Illicit Traffic in Narcotic Drugs and Psychotropic Substances (hereafter referred to as "1988 UN Convention"). Listed chemicals are not as strictly regulated as controlled substances. Ephedrine and pseudoephedrine are the precursors of choice in most regions in the process to make methamphetamines because the chemical process is simple, a better yield is obtained and both are more widely available than phenylacetic acid and P-2-P. These chemicals are used extensively as decongestants in "over the counter" pharmaceutical preparations.

MDMA is a Schedule I controlled substance; its legitimate use is limited to approved medical and scientific research. During 2002, DEA scheduled two substances that had been marketed on the Internet as legal alternatives to MDMA—benzylpiperazine (BZP) and 2,5-dimethoxy-4-n-propylthiophenethylamine (2C-T-7). These two substances were recommended for Schedule I control and subsequently both were permanently controlled. In early 2003, DEA temporarily placed in Schedule I two other hallucinogenic/stimulant substances popular at raves and other social venues: alphamethyltryptamine (AMT) and 5-methoxy-N, N-diisopropytryptamine (5-Meo-DIPT—known as "Foxy").

The precursor chemicals used to manufacture MDMA—safrole, isosafrole, 3,4-methylene-dioxyphenyl-2-propanone (MDP-2-P) commonly known as PMK, and piperonal—are subject to domestic control as List I chemicals and international control under the 1988 UN Convention. PMK is the precursor favored by clandestine lab operators, who are concentrated in rural parts of the Netherlands. Produced only in China and India, there appears to be only limited legitimate commercial use for PMK, which has been seized in large quantities in Europe. Safrole, isosafrole, and piperonal have commercial uses in fragrances and flavorings.

Various essential oils, such as sassafras and camphor, contain large percentages of safrole. These oils are being found in illicit laboratories where they are used for the illicit manufacture of MDMA and its analogues. In many cases these oils are used directly in the manufacturing process, as it is not necessary to first extract or distill the safrole. More simply, it requires less work to use safrole than other precursor chemicals to manufacture MDMA. Vietnam appears to be one of the foremost illegal exporters of sassafras oil and safrole.

Other Club Drugs

GHB is, for most purposes relevant to law enforcement, a Schedule I controlled substance, as a result of Congressional and regulatory action in 2000. See the "Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000" (P.L. 106-172), signed on February 18, 2000, and a DEA regulation following from that law, effective March 13, 2000, and published at 65 Fed. Reg. 13,235. The limited exception is that the manufacture, distribution, and dispensing of FDA-approved drug products containing GHB are subject to the less stringent physical security requirements applicable to Schedule III controlled substances. For example, storage in a steel cage, rather than a vault, is sufficient for Schedule III substances. See 21 C.F.R. § 1301.72.

As a result of the same law, on February 18, 2000, the precursor gamma butyrolactone—commonly known as GBL—became a List I chemical under the Controlled Substances Act (CSA). GBL is unique among precursors, however, in that it converts into GHB when ingested. For this reason, it is often trafficked not as a precursor chemical but as a drug of abuse in itself. In those cases, because of its similarity to GHB in structure and effect, GBL may be treated as a controlled substance analogue

under the CSA, subjecting traffickers to the penalties applicable to Schedule I controlled substances. See 21 U.S.C. §§ 813 and 802(32).

Ketamine was placed in Schedule III of the CSA on July 13, 1999. It is a legitimate pharmaceutical product for both human and veterinary use. Flunitrazepam (Rohypnol) is a Schedule IV controlled substance.

Controlled Substance Analogues

A substance is a controlled substance analogue if (1) its chemical structure is substantially similar to that of a Schedule I or II controlled substance, (2) it has a stimulant, depressant, or hallucinogenic effect that is substantially similar to or greater than that of a Schedule I or II controlled substance, or (3) it is represented or intended to have a stimulant, depressant, or hallucinogenic effect that is substantially similar to or greater than that of a Schedule I or II controlled substance. See 21 U.S.C. § 802(32). Thus, whether GBL is treated as a List I chemical or a controlled substance analogue depends on the circumstances of its distribution. Another chemical, 1,4-butanediol, another analogue of GHB, also converts into GHB when in the body. Unlike GBL, however, it is not used to manufacture GHB and, therefore, is not regulated as a listed chemical. If it is intended for human consumption, then 1,4-butanediol, like GBL, may be treated as a controlled substance analogue. The schedules of controlled substances discussed in this Action Plan are as follows:

DRUG **SCHEDULE** Methamphetamine Ш Ш Amphetamine MDMA ("Ecstasy") I GHB (except FDA-approved Xyrem) Ι PCP Ш LSD Ι Ketamine Ш Hydrocodone (including Vicodin) III for drug products, bulk is II Oxycodone (including OxyContin) Ш IV Flunitrazepam (Rohypnol)



Methamphetamine and MDMA

Methamphetamine penalties are among the most severe provided for in the Controlled Substances Act. The law sets a dual / alternative formulation for determining quantity-based sentences for methamphetamine, in which "actual" or "pure" methamphetamine is distinguished from "a mixture or substance containing" methamphetamine. A 10:1 quantity ratio triggers both statutory and guidelines penalties for methamphetamine-mixture versus methamphetamine-actual. "Ice" methamphetamine, defined by the guidelines as d-methamphetamine hydrochloride of at least 80 percent purity, is sentenced like "actual" methamphetamine. Pursuant to the Methamphetamine Anti-Proliferation Act of 2000, the U.S. Sentencing Commission increased guidelines sentences for amphetamine to equal those for methamphetamine (although amphetamine still has no statutory minimum penalties). Additionally, the Commission increased sentences for key methamphetamine precursor chemicals.

The Commission has also increased its focus on MDMA sentences. As of May 2001, the Commission raised the guidelines for MDMA by lowering the quantities triggering the five- and ten-year guidelines sentences. As of November 2002 the Commission introduced a standard, assumed pill weight for MDMA of 250 mg/tablet, which clarified an issue that had produced inconsistent sentencing decisions among the courts.

Quantities triggering five- and ten-year sentences for methamphetamine, amphetamine, MDMA, and the major methamphetamine precursor chemicals under the Sentencing Guidelines are summarized in the following table.

	5 years (Level 26)	10 Years (Level 32)		
Methamphetamine, Amphetamine	5 gm pure / 50 gm mixture	50 gm pure / 500 gm mixture		
Ice (80% pure d-meth)	5 gm	50 gm		
MDMA (Ecstasy)	200 gm (about 800 tablets)	2 KG (about 8,000 tablets)		
Pseudoephedrine, Ephedrine, PPA (Norephedrine)	10 gm	100 gm		

Also, pursuant to the 2000 enactment, the Sentencing Commission increased the base offense level for manufacturing amphetamine or methamphetamine to at least 27 (i.e., 70-87 months for offenders with no or minimal criminal histories) if the offense created a substantial risk of harm to human life or the environment (typical of most clandestine lab cases). The sentence is at least level

30 (i.e., 97-121 months) if the life in question was that of a minor or incompetent. The Act also criminalized the theft or interstate transport of anhydrous ammonia for the purpose of unlawful drug manufacture, as set forth at 21 U.S.C § 864, subject to a penalty of up to 10 years imprisonment and a fine. Effective November 1, 2001, the Sentencing Commission adopted guideline amendments that in practical effect, result in a level 14 sentence for this offense (i.e., 15-21 months).

Other Club Drugs

Effective November 1, 2004, sentences for GHB trafficking will be significantly enhanced. At that time, the guideline will provide for sentences of approximately five years for trafficking in three gallons of GHB (or its analogues) and ten years for thirty gallons. These changes result from a Congressional directive in legislation enacted in April 2003. Before November 2004, the five- and ten-year guideline sentences are triggered by approximately 13.2 and 132 gallons, respectively.

These amendments follow other recent revisions to strengthen the guidelines with respect to GHB. Effective November 1, 2001, the Sentencing Commission eliminated the "cap" at offense level 20 for "Schedule I and II depressants," including GHB. The previous guideline resulted in a sentencing range of 33-41 months for first-time offenders trafficking in 40,000 or more "units" (20 liters, or approximately 5.3 gallons). Even with this amendment, until November 2004, it still takes 100,000 "units" of GHB (over 13 gallons) to trigger a level 26 (i.e., 63-78 months) sentence.

The sentencing guidelines will also be strengthened for serious offenses involving the GHB precursor GBL. As of November 2004, sentences of about five years will be triggered by 227 liters (instead of 1,000 kilograms) of GBL. Sentences for GBL will still be "capped" at level 30 (97-121 months for a first offense) at 2,271 liters or more. We understand that the Commission will soon consider additional revisions to lower the thresholds for GBL.

The guidelines will also include a sentencing enhancement for mass marketing controlled substances through the Internet. This increase will be especially useful in the "club drug" context, as these drugs, and their analogues, are often advertised and sold via the Internet.

The "Drug Induced Rape Prevention and Punishment Act of 1996" (P.L. 104-305) established special penalties of up to five years imprisonment and a fine for offenses involving 30 milligrams or more of flunitrazepam (a Schedule IV controlled substance) and up to 20 years imprisonment and a fine for offenses involving 1 gram or more. In response to sexual assaults committed with this drug, the bill also enacted 21 U.S.C. § 841(b)(7), which makes distribution of a controlled substance to a person without that person's knowledge, and with the intent to facilitate a crime of violence, including sexual assault, subject to up to 20 years imprisonment and a fine.

Ketamine, a Schedule III depressant, is subject to a maximum 5-year sentence for a first offense, but is not subject to a mandatory minimum penalty. The Sentencing Guidelines establish a maximum offense level of 20 (i.e., 33-41 months).

Effective November 2002, the U.S. Sentencing Commission amended the federal sentencing guideline applicable to violations of 21 U.S.C. § 856, the so-called "crack house" statute, which may be used against promoters and operators of rave type events designed or intended to facilitate drug trafficking.

The new guidelines raise the previous, inadequate base offense level from Level 16 (i.e., 21-27 months in criminal history category I) to Level 26 (i.e., 63-78 months in category I).

In April 2003, Congress approved amendments to broaden the scope of 21 U.S.C. § 856 (the "crack house" statute) to make the provision more clearly applicable to "raves" and similar events, where appropriate. The legislation also introduces stiff civil penalties to remove the profit motive from sponsorship of drug-oriented rave type events.

Other Synthetic Drugs and Diverted Pharmaceuticals

Oxycodone, a Schedule II narcotic, is subject to a maximum 20-year sentence for a first offense, but is not subject to a mandatory minimum penalty. Effective November 5, 2003, the Sentencing Guidelines for oxycodone are based on the actual weight of the oxycodone in the tablet, not the total weight of the tablet; this differs from the treatment of most other controlled substances, including pharmaceuticals. At the equivalency set in the revised guidelines (1 gram of oxycodone = 6,700 grams of marijuana), a level 26 (roughly 5-year) sentence is reached at about 3,000 5-mg pills, 1,500 10-mg pills, 750 20-mg pills, and 375 40-mg pills. Level 32 (roughly 10-year) sentences apply for trafficking in 10 times those quantities, respectively. Before this recent change, the Sentencing Guidelines established base offense level 26 for trafficking in 200 grams of oxycodone and base offense level 32 for trafficking in 2,000 grams (2 kilograms). The weight of the pills, not just the active ingredient, determined the sentence. Use of the total pill weight led to incongruous results because the concentration of oxycodone in controlled release formulations such as OxyContin is much greater than that in standard, non-controlled release formulations (such as Percocet, Percodan, and Roxicet), which also contain other active ingredients like aspirin and acetaminophen. Concerns about disproportionate sentencing led the Sentencing Commission to examine and act upon this issue. DOJ provided input.

PCP shares with methamphetamine the unusual dual/alternative penalty structure, which distinguishes "pure" PCP from mixtures or substances containing it. Trafficking in 10 grams of PCP-actual or 100 grams of PCP-mixture triggers a 5-year mandatory minimum sentence. A 10-year mandatory sentence applies to trafficking in 100 grams of PCP-actual or 1 kilogram of PCP-mixture.

Statutory and guidelines penalties for LSD are not congruent. The statute sets five- and ten-year sentences at 1 and 10 grams, respectively, but includes the carrier medium, usually blotter paper, when determining the weight. See 21 U.S.C. §§ 841(b)(1)(A) and (B) and 960(b)(1) and (2) and *Neal v. United States*, 516 U.S. 284, 296 (1996). The Sentencing Guidelines exclude the carrier medium and treat each dose as 0.4 mg. Because the carrier medium is heavier than the actual LSD, and thus constitutes most of the weight, the interplay of these two provisions tends simply to result in imposition of the 5- or 10-year statutory minimum sentence.

Appendix F:

Examples of Notable State Laws with Respect to Precursor Chemical Control

Oklahoma

On 6 April 2004, Oklahoma enacted the nation's most stringent state methamphetamine precursor control law. Now, only licensed pharmacists or pharmacy technicians may sell products containing non-prescription pseudoephedrine. Products must be kept behind the pharmacy counter, or elsewhere if in a locked cabinet. The seller must obtain the purchaser's identification with date of birth; purchasers must be at least 18 years old, and they must sign a written log. Only nine grams may be sold to a person in 30 days. The pharmacist is responsible for keeping track of only his own store's sales until the state develops a real-time statewide electronic logbook. Exceptions are provided for compounds in liquid, liquid capsule, or gel capsule form, and the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control may, by rule, exempt other products that its Director finds are not used in the illegal drug manufacture. See Okla. Stat. Title 63, §§ 2-212 and 2-332, as amended by H.B. No. 2176.

Missouri

On 28 August 2003, Missouri enacted a law imposing additional restrictions on the sale of over-the counter-drugs containing the principal methamphetamine precursors. For products containing ephedrine, pseudoephedrine, or phenylpropanolamine as the sole active ingredient, stores may sell only two packages containing a total of six grams of precursor. Unless the retailer has an electronic anti-theft system, these products must be displayed either behind the checkout counter or within 10 feet of unobstructed view from an attended checkout counter. For "combination" products containing those precursors and other active medical ingredients, they may sell three packages containing no more than nine grams total. Knowing violations are subject to class A misdemeanor penalties; the store owner or operator may invoke in defense that an employee training program was in place. See Mo. Ann. Stat § 195.417 (2003).



- Raves are all-night dance parties, usually advertised as "alcohol free" to allow for the admission of under-age children and young adults. Techno, industrial, trance, and other music genres are the focus of the rave experience. "Circuit parties" are multi-day gatherings of gay and bisexual men that occur each year at around the same time, in the same town or city and centered on one or more large, late-night dance events that often have a theme. Rave events attract from hundreds to thousands of participants, while circuit parties may attract as many as 20,000 men to a local community. Widespread and open drug consumption appears to be the norm at some of these events.
- ² GHB (gamma hydroxybutyric acid), under the trade name Xyrem, was approved in July 2002 by the Food and Drug Administration (FDA) for the treatment of cataplexy, a sudden loss of muscle tone associated with narcolepsy. The availability of small quantities of legally manufactured GHB has not changed the fact that the vast majority of abused GHB is of illicit origin.
- ³ For more information, see the DEA FactSheet: <u>http://www.usdoj.gov/dea/pubs/pressrel/methfact01.html</u>
- ⁴ The Drug Abuse Warning Network (DAWN) Report, prepared under the auspices of the Department of Health and Human Services, compiles information from a survey of data on patients seeking hospital emergency department treatment related to their use of illegal drugs or non-medical use of legal drugs. Since 1988, DAWN data has been collected from a representative sample of eligible hospitals—non-Federal, short-stay general hospitals with a 24-hour emergency department—located throughout the United States, but excluding Alaska and Hawaii. The data is used to estimate the total number of emergency room drug episodes and mentions of specific drugs in all such hospitals. The DAWN system also collects data on drug-related deaths from a nonrandom sample of medical examiners. DAWN emergency room mentions for all drugs have remained relatively stable from 1999 through the first half of 2002.
- ⁵ SAMHSA Office of Applied Studies, DAWN 2001 data. Two out of three emergency room episodes involving ketamine involved alcohol or another controlled substance as well.
- The Monitoring the Future Study is conducted by the University of Michigan Institute for Social Research and funded by the National Institute on Drug Abuse (NIDA). The statistics reported here should be considered in the context of the overall U.S. drug use profile. The 2001 Household Survey estimates that the overall rate of "current illicit drug use" (defined in the survey as use within the past 30 days) increased slightly in 2001, but the rate had been stabilizing in previous years. The rate of current illicit drug use among youth age 12-17 (approximately 10.8 percent in 2001) is higher than the rate of use among the overall population age 12 and older (approximately 7.1 percent).
- ⁷ SAMHSA Office of Applied Studies, DAWN 2002 data.
- The National Institute of Justice's Arrestee Drug Abuse Monitoring (ADAM) program tracks trends in the prevalence and types of drug use among arrestees in urban areas. The program provides local area estimates of the rate of drug use among adult and juvenile arrestees based on voluntary and anonymous interviews and urine specimen collection undertaken within 48 hours of arrest. The program currently operates in 39 sites with data collection taking place for a period of time each calendar quarter. The ADAM program, however, does not report national estimates. Preliminary findings for 2001 are based on reports from 27 sites involving adult male arrestees. The reason for the regional variance in the data is unknown.
- ⁹ Community Epidemiology Working Group, *Epidemiologic Trends in Drug Abuse: Advance Report*, June 2003, p. 10. Hawaii HIDTA 2003 Threat Assessment, pp. 23-24. According to the Treatment Episode Data Set (TEDS), admissions for methamphetamine abuse increased overall from 498 in 1993 to 1,548 in 2000. Nearly 36 percent of all adult arrestees tested positive for methamphetamine use. The methamphetamine-associated death toll rose from 27 deaths in 1998 to 54 in 2001.
- SAMHSA Office of Applied Studies, *The DAWN Report: Club Drugs, 2002 Update*, July 2004, p. 1-3.
- The Community Epidemiology Work Group (CEWG) of the National Institute of Drug Abuse collects and analyzes drug data from a number of quantitative and qualitative sources, including, among others, ADAM, DAWN, and DEA seizure, price, purity, prescription/distribution, and arrest data. The CEWG reports that in the 21 areas that comprise its surveillance network, MDMA is readily available at raves and other dance parties and nightclubs, and MDMA use is spreading beyond these locales into more casual social settings. Deaths linked to MDMA occur, but are unpredictable, and are not necessarily related to the dose (DAWN statistics reveal 27 deaths possibly linked between 1994 and 1998). The June 2002 CEWG report also notes that mentions of MDMA and other club drugs in mortality data, while climbing, remain relatively low.

²⁸ EPIC National Clandestine Laboratory Seizure System, 2002 data. The number of labs seized in the United States during 1995-2002 is as follows:

Year	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004 thru Oct. 6
# Labs	3	5	4	4	13	8	11	10	10	13

One cause for concern is the entry of Mexican, Dominican, Asian, and Colombian trafficking groups into the MDMA distribution network

SAMHSA Office of Applied Studies, *The DAWN Report: Club Drugs*, 2002 Update, July 2004, p.1-3.

¹³ 2002 Monitoring the Future study.

SAMHSA Office of Applied Studies, *The DAWN Report: Club Drugs, 2002 Update*, July 2004, p. 1-3.

¹⁵ 2002 Household Survey.

¹⁶ SAMHSA Office of Applied Studies, *The DAWN Report: Oxycodone, Hydrocodone, and Polydrug Use, 2002*, July 2004, p. 1-3. The DAWN Report cautions that estimates for oxycodone mentions should not be attributed to any particular brand of analgesic containing oxycodone.

¹⁷ SAMHSA Office of Applied Studies, DAWN 2002 data. Also see Community Epidemiology Working Group, *Epidemiologic Trends in Drug Abuse: Advance Report*, June 2003, p. 42, which states that PCP indicators increased in Los Angeles, Philadelphia, Phoenix, Washington, DC, and Texas, and remained steady in Chicago.

¹⁸ 2000 Household Survey.

¹⁹ Monitoring the Future surveys of LSD use began in 1991 for grades 8 and 10 and in 1975 for grade 12. The 2001 survey results were mixed, with past month use increasing among 12th graders from 1.6 percent to 2.3 percent, while past year use declined among 10th graders from 5.1 percent to 4.1 percent. As of 2001, an estimated 10.9 percent of 12th grade students reported use of LSD at some point in their lives.

SAMHSA Office of Applied Studies, *The DAWN Report: Club Drugs*, 2002 *Update*, July 2004, p. 1-3.

²¹ Unless otherwise noted, the source of the data in this section is DEA Headquarters.

EPIC National Clandestine Laboratory Seizure System, 2003 data. Thanks to improved reporting, EPIC lab figures have become more comprehensive and reliable. The Bureau of Justice Assistance and the Community-Oriented Policing Services (COPS) program have agreed to require state and local governments to report lab seizures to EPIC as a condition of federal lab cleanup grants.

²³ EPIC National Clandestine Laboratory Seizure System, 2003 data.

²⁴ EPIC National Clandestine Laboratory Seizure System, 2003 data.

Based upon the number of labs seized, a very rough estimate is that there are 10 times as many labs in operation as are ever seized. Base upon the amount of methamphetamine produced by these labs, officials estimate that up to 2,844,000 pounds of toxic by-products of methamphetamine production have been dumped in California.

²⁶ EPIC National Clandestine Laboratory Seizure System, Drug Endangered Children, 2003 data.

²⁷ The Netherlands and Belgium are conservatively estimated as being the source of roughly 70 percent of the MDMA consumed worldwide.

Figure 18 reflects interagency data complied by EPIC, showing that approximately 1.5 million MDMA pills were seized in the U.S. arrival zone in 2003. This figure was down from approximately 3.6 million tablets in 2002, which was in turn less than the approximately 6.8 million tablets seized in 2001, the highest number ever; the figure for 2000 was about 5.8 million tablets. Domestic (non-arrival) seizure figures have shown a similar trend: approximately 3.5 million tablets in 2003, 8.3 million in 2002, 11 million in 2001, and 8.3 million in 2000.

Customs 2001 seizure data.

³² Community Epidemiology Working Group, EPIC, and DEA.

³³ Community Epidemiology Working Group, EPIC, and DEA.

- The National Institute on Drug Abuse (NIDA) conducts a comprehensive, multidisciplinary prevention research program examining the interaction of multiple factors that contribute to and protect against drug abuse. In 1997, based on more than 20 years of prevention research, NIDA identified fundamental principles of drug abuse prevention in the publication Preventing Drug Use Among Children and Adolescents. The publication also discusses community drug abuse risk assessment, prevention program implementation and evaluation, and scientific findings about the efficacy of several identified programs. This publication is currently being revised to account for new findings. NIDA's "InfoFacts" system and Research Report Series allow access to publications containing pertinent information with respect to prevention efforts targeting methamphetamine, the "club drugs," and OxyContin and other prescription drugs. Information is available on the Internet site www.clubdrugs.org. NIDA is now developing a Research Report publication that will focus on MDMA and possibly other synthetic drugs. Basic educational efforts include the teaching aid series "Mind Over Matter," a component of the "NIDA Goes to School" program that distributes information to schools and encourages students to learn about the effects of drugs on their bodies and brains. Research-based materials, such as a popular poster-magazine series, include a segment on methamphetamine, and NIDA is developing materials on MDMA. NIDA has completed a curriculum for high school students as well as curricula for second and third grade students; curricula for kindergarten, first grade, and fourth and fifth grade students are still under development. Furthermore, a teaching packet, "The Neurobiology of Ecstasy," now available on NIDA's Internet site, was developed for use by teachers and researchers primarily working with high school students. NIDA also recently set aside additional funding for the Prevention Research Initiative, which includes: (1) development of new approaches for prevention, building on scientific findings; and (2) enhancement of dissemination of effective prevention practices through multi-site studies in community settings.
- ⁴⁰ The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention (CSAP) has created a National Registry of Effective Prevention Programs (NREPP) to catalog programs found to be effective. Through this effort, CSAP has developed and implemented a comprehensive system to identify and disseminate scientifically proven model prevention programs to local communities. This effort directly supports the HHS State Incentive Grant program. Additionally, prevention research is funded through the Substance Abuse Prevention and Treatment Block Grant Program and the Programs of Regional and National Significance focus on more effectively delivering prevention services.
- In addition to urine-based tests conducted in specially inspected and certified laboratories, new federal regulations are nearing completion that would include alternative technologies allowing the testing of specimens such as hair, oral fluid, sweat, and allowing point of collection (onsite/immediate screening) tests. Further information can be found on the Internet at www.drugfreeworkplace.gov. The NLCP also collaborates with military, criminal justice, transportation, educational institution, clinical, and sports-related testing efforts nationally and internationally.

MDMA Trafficking in the United States, Epidemiologic Trends in Drug Abuse Advance Report, December 2001, Community Epidemiology Work Group. DEA uses various sources to assess the trafficking of MDMA in the United States. These included the United States Customs Service reports; the National Forensic Laboratory Information System (NFLIS); and the DEA Source Determination Program. DEA drug testing laboratories are located in seven CEWG areas: Miami, New York City, Washington, D.C., Chicago, Dallas, San Francisco, and San Diego. In addition, a special testing and research lab is located in Chantilly, Virginia.

³⁵ Rocky Mountain HIDTA 2002 Threat Assessment, p. 37. 2 labs were seized in Colorado Springs, and 1 lab was seized in Ft. Collins.

Rocky Mountain HIDTA 2002 Threat Assessment, p. 37. This takedown was part of Operation Green Clover.

 $^{^{^{37}}}$ An international ketamine smuggling organization was exporting thousands of vials at a time from Mexico on a frequent basis.

³⁸ Various sources within the Departments of Health and Human Services (HHS) and Justice provide data and analyses useful for detecting emerging drug trends that communities can target as part of their overall prevention efforts. Initiatives include State Incentive Grants for Community-Based Action distributed to 27 governors' offices and the mayor's office in the District of Columbia in support of planning for coordinated substance abuse prevention efforts.

⁴² The campaign involves \$5 million in purchased messages targeting youth and adults and an additional \$3.9 million in pro bono media-match messages targeting parents. In addition, ONDCP redesigned its newspaper and news-oriented magazine outreach efforts to better target parents and met with entertainment industry writers and executives in Los Angeles and in New York to discuss the dangers of synthetic drugs.

⁴³ Since 1998, DEA's Drug and Chemical Evaluation Section of the Office of Diversion Control, in conjunction with Demand Reduction and Training Coordinators from the 22 DEA field divisions, has provided scientific conferences on "club drugs" in over 70 communities across the U.S. that addressed and disseminated information to law enforcement, drug treatment pro-

fessionals, medical emergency technicians, physicians, and hospital staff on issues of health and safety regarding these drugs. It is estimated that over 10,000 state and local police officers have attended one of these conferences thus far.

- DEA is joining with anti-drug coalitions, the medical community, state legislators, community leaders, and ordinary citizens in "town hall" meetings that feature discussions between local residents and a panel of local and national experts. Meetings so far have taken place in San Diego, Kansas City, Miami, and New York, and more are planned. The campaign can be replicated and customized in communities across the nation. Additionally, "Integrated Drug Enforcement Assistance" (IDEA) is an integrated enforcement and community-based demand reduction program sponsored by DEA in six communities. The program features DEA enforcement activities followed by the implementation of a community developed strategy to prevent future illegal drug use. Additional pertinent DEA publications include *Get It Straight! A Prevention Book for Young Americans*. All publications are available on-line.
- ⁴⁵ The "early identification" of new illicitly used synthetic drugs, and the measurement and understanding of the true impact, require the development, validation, and dissemination of new drug detection tools and tests. The process includes a wide range of participants and resources from government, academia, instrument manufacturers, clinical and forensic pathologists, toxicologists, and their support laboratories. These groups network actively and recognize the need for new tests, but it remains a challenge to develop commercially available test products to specifically detect and measure the presence of some synthetic drugs.
- Much abuse trend information is collected by public health and law enforcement agencies. DEA is often able to undertake emergency regulatory action based on preliminary information about abuse and trafficking of non-controlled substances. For example, as noted in Appendix D of this Action Plan, from 2002 to the present, DEA has undertaken temporary, emergency scheduling of five club drugs, all of which had been marketed as legal alternatives to MDMA. As p[art of its function to monitor new and emerging drug problems, the Drug & Chemical Evaluation Section of DEA's Office of Diversion Control currently has a system which has identified specific drug problems well in advance of national crises as well. Likewise, institutionalized fora exist to review available data. An Interagency Committee on Drug Control (ICDC) meets monthly to discuss emerging drug problems and consider appropriate, multi-faceted responses. The ICDC involves the Office of National Drug Control Policy, the National Institute on Drug Abuse, the Food and Drug Administration, and the Drug Enforcement Administration. The Community Epidemiology Working Group meets twice a year to review current and emerging substance abuse data.
- ⁴⁷ These efforts may include, among other things, data from HHS Methamphetamine and Ecstasy infrastructure grant recipients and DOJ Weed and Seed sites, as well as data from NIDA/CEWG, DAWN, and DEA. The compilation and analyses can be used internally for policy and program development and could be made available in some form for community use from an existing Internet-accessed federal SAMHSA server using the Prevention Decision Support System query and needs assessment resources.
- ⁴⁸ SAMHSA's Substance Abuse Treatment Facility Locator, Treatment Improvement Exchange, and National Clearinghouse for Alcohol and Drug Information can be accessed via the internet at www.freatment.org, and www.freatment.org, and www.freatment.org, and <a href="https://wwww
- ⁴⁹ During the annual UN Commission on Narcotics and Drugs (CND) International Narcotics Control Board (INCB) meeting in Vienna, in March, 2001, the United States and the European Union (EU) passed a joint resolution on synthetic precursors:
 - Recommending creation of an early warning system to identify and advise industry on new chemicals used in illicit synthetic drug manufacture.
 - Urging countries to comprehensively test seized synthetic drugs and establish a network of collaborating laboratories to track new illicit drug manufacturing trends.
 - Specifically targeting the precursor PMK, a key chemical in MDMA production with limited legitimate commercial use.

The procedures used by DEA to administer the "letter of no objection" system have been challenged, with partially adverse results, in the U.S. District Court for the District of Columbia. <u>PDK Labs Inc.</u> v. <u>Ashcroft</u>, Civil Action Nos. 00-2894 and 00-2899 (HHK). PDK Labs Inc. is a manufacturer of drug products containing precursor chemicals, but is not registered to import such chemicals. PDK challenged DEA's denial of its right to request an administrative hearing after DEA failed to grant a letter of no objection to the firm importing chemicals for sale to PDK.

⁵⁰ 21 U.S.C. § 971.

Title VI, Subtitle A of Pub. L. 100-690 (part of the "Anti-Drug Abuse Act of 1988"), passed November 18, 1988.

⁵³ Title XXIII (Sec. 2301) of Pub. L. 101-647 ("Crime Control Act of 1990), November 21, 1990.

⁵⁴ Pub. L. 103-220, effective April 16, 1994.

- Pub. L. 104-237, signed October 3, 1996. DEA has finalized implementing regulations, with a transaction threshold of 0.4 kilograms (about 1 pound). In order to ensure that the federal government itself does not become a source for diverted chemical materials, the DEA, pursuant to 21 U.S.C. § 890 and procedures in recently published proposed regulations, monitors sales of crude iodine from the chemical stockpiles maintained by the Department of Defense. With respect to each known potential bidder, DEA certifies whether there is reasonable cause to believe that a sale would result in the illegal manufacture of a controlled substance. To make this determination, DEA examines the prospective bidder's and end-user's past experience in maintaining effective controls against diversion and other relevant factors. The system works satisfactorily, although it is difficult for DEA to generate the necessary certification correspondence within the 15 day bid "window" when a new firm appears as a bidder. Overall, diversion from this stockpile is unlikely because of the close government scrutiny, the very large volumes involved (5,000 pounds is the smallest quantity purchased under the program so far), the transportation logistics, and the extensive processing required to make the crude form of extracted iodine commercially useable.
- ⁵⁶ United States v. Lopez, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring), cited and quoted in Grutter v. Bollinger, 539 U.S. 306, 342 (2003).
- There have been reports of more frequent theft of anhydrous ammonia, a farm fertilizer used to manufacture methamphetamine. Theft of anhydrous ammonia is a federal crime, see 21 U.S.C. 864. Some states, such as North Dakota, have taken actions to improve security at ammonia distribution centers and to encourage farmers to buy locks for their anhydrous ammonia tanks. Some states have criminalized or enhanced penalties for the theft of anhydrous ammonia. Further efforts, such as federal assistance to develop a "best practices" manual, may be warranted.
- 58 See 21 C.F.R 1310.12 and 1310.13, as published at 68 Fed. Reg. 23195 (May 1, 2003).
- In addition to the above figures, 20,000 kilograms of ma huang, which contains ephedra, were voluntarily withdrawn by an importer in May 2003, due to new FDA action which effectively banned the marketing of ma huang in products marketed as dietary supplements.
- A public-private Suspicious Orders Task Force was established as a result of Sec. 504 of the Comprehensive Methamphetamine Control Act of 1996. The group consisted of federal and state regulators and law enforcement officials and the regulated business community; it met five times and, in a report to the Attorney General dated February 1999, agreed to several voluntary measures that, if widely implemented, will assist both industry and law enforcement. The Suspicious Orders Task Force identified indicators of suspicious transactions, recommended that manufacturers of retail over-the-counter drug products containing methamphetamine precursors limit package sizes and use only "blister" packaging, and recommended that all retail sales of elemental iodine and red phosphorous be reported to DEA. Many segments of industry have implemented these recommendations.
- Pfizer Pharmaceutical invested \$12 million over five years into the development of a new technology which would make it impossible for methamphetamine traffickers to use Sudafed and related products for illicit purposes. While initial attempts proved unsuccessful, research continues.
- ⁶² The final regulations were published in the Canada Gazette Part II, Vol. 136, No. 21 on October 9, 2002. A 1996 law, the "Controlled Drugs and Substances Act," was unable to stem the chemical flow until these implementing regulations were promulgated.
- The operations undertaken so far have been, in order, "Purple" for the cocaine oxidizing agent potassium permanganate, "Topaz" for the heroin chemical acetic anhydride, and "Prism" for the precursors to amphetamine-type stimulants.
- 64 The U.S. position is that such pharmaceutical preparations should be controlled pursuant to Article 12(14) of the 1988 UN Convention.
- ⁶⁵ Under the Methamphetamine Anti-Proliferation Act of 2000 (MAPA), DEA was directed to prepare a report to Congress on the blister pack exemption. DEA forwarded a report to Congress in November of 2001 recommending the removal of this exemption and the imposition of a strict 9 gram threshold, the limit allowed by Congress for non-blister pack product, and the current threshold for non-blister pack pseudoephedrine products. See Sec. 3642 of the Methamphetamine Anti-Proliferation Act of 2000, set forth at 21 U.S.C. § 802 (note), for more details. In October 2003, Sen. Feinstein introduced a bill (S.1784) proposing the removal of this exemption.
- ⁶⁶ See 21 U.S.C. § 971.
- ⁶⁷ Although DEA regulates imports of listed chemicals through a pre-notification/verification system and "letters of no objection" to governments in key chemical source countries, it effectively loses oversight once a shipment enters the United States. If the importer's sale to the declared customer is not consummated, the chemicals may be sold on the "spot market" without DEA oversight, which in effect circumvents the legal controls on chemical imports.

- ⁶⁸ See for example 21 U.S.C. 952 (import controls), 823 (registration requirements), and 826 (production quotas). For technical reasons, it is impractical under the current laws to designate bulk ephedrine and pseudoephedrine as "immediate precursors" of methamphetamine. See 21 U.S.C. 802(23), but see also 811(g).
- ⁶⁹ Because pharmacies are specifically exempt from registration to handle List I chemicals, by virtue of their registration to handle controlled substances (they would also be exempt as retail outlets under a separate provision of the DEA regulations), they do not receive pre-registration site visits by DEA and are not systematically made aware of the chemical diversion problem. Cases involving large-scale diversion from pharmacies have been reported nationwide and, in many cases, in regions not associated with methamphetamine production.
- The continued proliferation of thousands of small clandestine methamphetamine labs throughout much of the country is fueled by retail-level theft and "smurfing" (the purchase of small amounts of product at several locations to avoid attention). To curb these practices, it will be necessary to further control access to the most popular precursor in the most widely used form—pseudoephedrine in over-the-counter medications—without precluding access by law-abiding consumers. Some states have imposed stricter controls than apply under federal law. For example, they set purchasing limits on all pseudoephedrine and ephedrine products, regardless of the form of packaging. Several counties and municipalities in Missouri require the placement of these products behind the store counter, much like cigarettes.
- Shortly after his confirmation, former DEA Administrator Asa Hutchinson made methamphetamine one of five priority areas. In Spring 2002, he launched a tour with the theme "Meth in America, Not in Our Town," a nationwide campaign to raise awareness of the growing methamphetamine problem.
- The NMCI has created a secure, internal web site where law enforcement officials share ideas and information.
- ⁷³ The task force includes representatives from DEA, FBI, ICE, DCIS, EPA, US Attorneys' Offices, the California Department of Justice, the Kentucky State Police, the Oregon State Police, the Rocky Mountain HIDTA, the Arizona Attorney General's Office, the California Department of Toxic Substance Control, the Phoenix Police Department, the Mesa, Arizona Police Department, and the Arizona Department of Public Safety.
- ⁷⁴ The funds are provided to DEA through the Community-Oriented Policing Services (COPS) program.
- ⁷⁵ Two DEA components provide training on Internet-based investigations.
- ⁷⁶ Persons tracing their national and ethnic roots to the Middle East have been disproportionately represented among the ranks of "rogue" chemical company executives, brokers, and smugglers of illicit pseudoephedrine from Canada to the United States.
- $^{\scriptscriptstyle{77}}$ Median sentences in 2000 and 2001 were 30 months.
- ⁷⁸ Specifically, two large-scale traffickers were extradited from Israel on charges in Miami in July 2002 for conspiracy to import MDMA into the U.S. (the first extradition of any Israeli citizen to the U.S. for a drug crime); three Israelis, who were part of a sophisticated drug trafficking organization based in Israel, were arrested after an international controlled delivery of 1.4 million Ecstasy pills hidden in three diamond polishing tables; and Israeli citizen Oded Tuito, a designated "kingpin" under the Foreign Narcotics Kingpin Designation Act, was indicted and extradited from Spain to face charges in the Eastern District of New York (Brooklyn) stemming from his leadership of the world's largest MDMA smuggling ring.

- Labs that produce less than two ounces of methamphetamine per batch are considered small labs. See USSG § 2D1.1(c)(6), which responds to Sec. 3612 of MAPA. Career offender enhancements may also be available in these cases. See USSG §4B1.1.
- In 2000, only 31 federal methamphetamine defendants received this adjustment under Sentencing Guideline USSG § 2D1.1(b)(5). While not all 3,358 methamphetamine offenders were prosecuted for offenses related to manufacturing—as opposed to importation or distribution—the number of labs seized indicates that many were charged with manufacturing methamphetamine.
- These "fake" and "knock off" products add to the existing uncertainty and danger of the drug market, and in particular the club drug scene.
- Some of the approaches suggested in this outline for faster and more comprehensive data gathering and dissemination could require additional resources. As appropriate, options for additional funding should be considered.
- This data can be complemented by review of "Microgram," a publication compiled by the DEA Office of Forensic Sciences that tracks unusual drug seizures and means of concealment.

⁷⁹ 21 U.S.C. 856.

⁸⁵ Small cities and towns and rural areas must somehow be included—this will help avoid missing the "next" OxyContin or methamphetamine problem. It is acknowledged that it will be a challenge to select "representative" or "bellwether" towns.

The new equivalencies for MDMA and related substances were first set by emergency amendments to USSG § 2D1.1 (Amendment 609, effective May 1, 2001) and were repromulgated and made permanent by Amendment 621. See U.S. Sentencing Guidelines Manual, supp. to app. C. (2001).

⁸⁷ USSG § 2D1.1, Amendment 640 (2001).

For consistency and simplicity, references throughout this Action Plan are to Sentencing Guidelines ranges for "criminal history category I." Generally, offenders in this category have never been incarcerated or have been imprisoned on only one occasion for less than 60 days. Chapter 4 of the U.S. Sentencing Guidelines sets forth a point system of factors for assessing a defendant's criminal history. The higher the criminal history category, the longer the sentence.

The Commission's proposed changes, which will go into effect unless Congress revises them, were published at 69 Fed. Reg. 28994 (May 19, 2004).

This Action Plan includes only limited recommendations for changes to the federal sentencing guidelines. Rather than setting forth extensive proposals at this time, DOJ components will work to assure that, if necessary, legislative and guidelines changes occur so that sentences for particular offenses more appropriately reflect the harm suffered.

 $^{^{\}rm 91}$ U.S. Sentencing Guidelines Manual, supp. to app. C. (2001), Amendment 640.

⁹² Section 608 of Pub. L. 108-21 (passed as S. 151), signed April 30, 2003 (the "PROTECT Act").

⁹³ It should be noted that affirmative civil litigation seeking civil penalties and injunctions under the Controlled Substances Act against persons and firms that violate the chemical control system has increased in recent years. A small, informal cadre of federal affirmative civil enforcement litigators has developed— some focusing on chemical importers and over-the-counter drug manufacturers in judicial districts far from areas of methamphetamine production