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)

Recommendations: 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?")*

Discussion of "rapid analysis" stage: 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 drug-detection 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 main characteristics 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 scheduled? 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 precursor or essential chemicals 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:

1) 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.[1] 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.[2] 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

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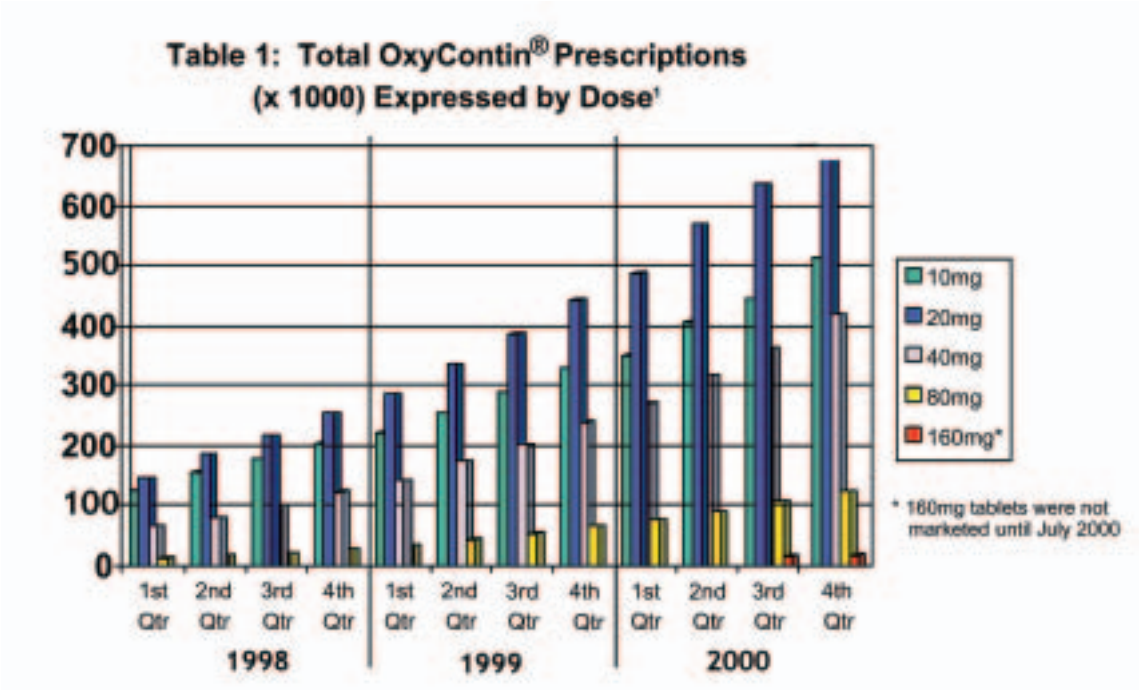
[1] Data from the Office of Diversion Control Quarterly Reports indicate that OxyContin® has risen dramatically in recent months in terms of mention by the field offices as a 'most abused' drug.

[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.

Table 1 shows the dramatic increase in the number of OxyContin® prescriptions from 1998 through 2000.



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: alpha-methyltryptamine (AMT) and 5-methoxy-N, N-diisopropytryptamine (5-Meo-DIPT—known as "Foxy").

The precursor chemicals used to manufacture MDMA—safrole, isosafrole, 3,4-methylenedioxyphenyl-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	II
Amphetamine	II
MDMA (“Ecstasy”)	I
GHB (except FDA-approved Xyrem)	I
PCP	II
LSD	I
Ketamine	III
Hydrocodone (including Vicodin)	III for drug products, bulk is II
Oxycodone (including OxyContin)	II
Flunitrazepam (Rohypnol)	IV

Appendix E:
Sentencing

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.[93]

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).