

Interim Report

from the Interagency Working Group on Synthetic Drugs

to the

Director of National Drug Control Policy

Attorney General

Secretary for Health and Human Services

May 23, 2005

Overview

In October 2004, the Federal government released the *National Synthetic Drugs Action Plan* (“*Action Plan*”), the first comprehensive national plan to address the problems of synthetic and pharmaceutical drug trafficking and abuse. The *Action Plan* outlined the problems, discussed current Federal and State efforts in the areas of prevention, treatment, regulation, and law enforcement, and made concrete recommendations toward a continuing effort by all Federal agencies with a role in reducing synthetic drug¹ abuse. A Synthetic Drugs Interagency Working Group (SD-IWG)², co-chaired by the White House Office of National Drug Control Policy (ONDCP) and the Department of Justice (DOJ), was directed to oversee implementation of the *Action Plan*, and to report to the Director of National Drug Control Policy, Attorney General, and Secretary for Health and Human Services³ six months after the document’s release. This interim report highlights the Administration’s efforts, outlines our future direction in leading the national effort to respond to the shifting nature of the synthetic drug threat, and describes the need for new Federal legislation. The Appendix contains a summary review of progress on each of the 46 recommendations.

Synthetic Drug Interagency Working Group

The SD-IWG met on four occasions between October 2004 and April 2005. The SD-IWG was divided into three subgroups: one dealing with methamphetamine and chemical control; one with the diversion of controlled substance pharmaceuticals; and one with treatment for, and prevention of, synthetic drug abuse. These subgroups met independently, and over the course of six months, divided the recommendations into three categories: those that will be, or are being, implemented by agencies participating in the SD-IWG; those that require action by Congress; and those that require further discussion and refinement through interagency discussion.

Current Situation and Trends

The market for illicit synthetic drugs and diverted pharmaceutical products is in transition. For most of the past several years, pseudoephedrine diverted from or through Canada fueled large domestic methamphetamine laboratories; now, large-scale production of the drug is shifting south of the border, being partially replaced by Mexican production (Fig. 1). Prescription

¹ For the purposes of this report, the term “Synthetic Drug” refers to a controlled substance of which the primary origin is not a plant or otherwise biological, but instead produced primarily through chemical or synthetic processes.

² Federal departments participating in the SD-IWG include agencies or offices within the Executive Office of the President, Departments of Health and Human Services, Homeland Security, Justice, State and Transportation, and United States Postal Service.

³ The *Action Plan* originally called for a report to be submitted to the Director of National Drug Control Policy and Attorney General. In recognition of the important role played by the Department of Health and Human Services in reducing the synthetic drug problem, the SD-IWG directed that the report also be submitted to the Secretary for Health and Human Services.

Figure 1: Methamphetamine Seizures at the Southwest Border (kg) (Source: DEA El Paso Intelligence Center)

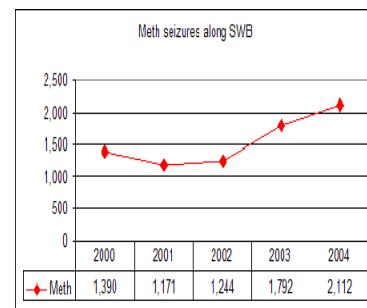
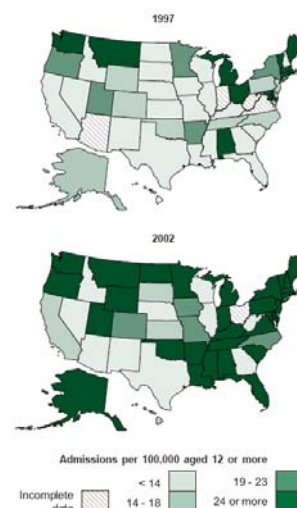


Figure 2. Narcotic Painkiller Admission Rates, by State: 1997 and 2002 (Source: Treatment Admissions Involving Narcotic Painkillers: 2002 Update, The DASIS Report, SAMHSA, July 2004)



drug abuse is increasing (Fig. 2), fueled in part by Internet sources acting in violation of Federal and State laws and accepted medical practice. On the positive side, the market for drugs such as MDMA and LSD has shrunk noticeably.⁴ These trends are due to the same factors that influence any market: pressures on, and variation in, supply and demand. Data released since the drafting of the *Action Plan* indicates some success. According to the *Monitoring the Future* study, an annual evaluation of teen drug use in America, current (past month) methamphetamine use among 8th, 10th and 12th graders is down by 25% over the past three years, and LSD and Ecstasy use has fallen dramatically (60% and 61%, since 2001, respectively).⁵ Meanwhile, Federal chemical control and enforcement pressures⁶ are probably responsible, at least in part, for a reduction in large-scale domestic production of methamphetamine and its shift to Mexico. Additionally, a growing number of states have imposed retail controls on pseudoephedrine products, with results that at this early stage appear promising.

Past Month Drug Use, Ages 12 and up (%)

	2002	2003
Marijuana	6.2	6.2
Prescription Drugs	2.6	2.7
Cocaine	0.9	1.0
Heroin	0.1	0.1
Methamphetamine	0.3	0.3

Source: Nat'l Survey Drug Use and Health, 2003.

Unique Aspects and Vulnerabilities

Prevention, treatment, and enforcement, including interdiction and eradication in source countries, are critical in order to disrupt the abuse and trafficking of illicit drugs of plant origin like cocaine, heroin, and marijuana. With synthetic drugs, crop eradication is not a possibility; instead, it is critical to control the most important precursor and essential chemicals in illicit drug production. Thus, the need for tight regulatory interventions is unique to synthetic drugs. At the same time, the SD-IWG recognizes the importance of balancing our anti-drug efforts with other important policy considerations, such as ensuring legitimate access to needed medications, avoiding needless regulatory intervention, preserving privacy, not interfering with the legitimate practice of medicine, and producing policies which serve patient needs and strengthen safety and physician freedom to prescribe as medically necessary.

In recognition of the importance of regulatory interventions, this report will first discuss regulatory interventions regarding methamphetamine precursors at both international and local levels, followed by an analysis of diversion of controlled substance pharmaceuticals, and finally treatment and prevention efforts. In addition to highlighting the ongoing efforts of SD-IWG agencies, this report highlights the need for Federal legislation and outlines the next steps Federal agencies must take to further disrupt the illicit market for synthetic drugs.

Methamphetamine Precursor and Chemical Control

The *Action Plan* contains a series of recommendations designed to make it more difficult for methamphetamine manufacturers to obtain ingredients – especially pseudoephedrine and

⁴ Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (2005). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2004* (NIH Publication No. 05-5726). Bethesda, MD: National Institute on Drug Abuse, 66 pp.

⁵ Lloyd Johnston, personal communication, unpublished analysis from Ibid.

⁶ For example, Operation Northern Star employed a comprehensive strategy targeting the entire methamphetamine trafficking process, and disrupted a major pipeline of pseudoephedrine from Canada into the United States.

ephedrine – used in the manufacturing process. These recommendations call for concurrently improving chemical control at two levels: in the international arena, where bulk pseudoephedrine is diverted to large laboratories; and in retail and wholesale markets, where smaller amounts of pseudoephedrine products purchased for making methamphetamine fuel thousands of domestic laboratories each year. On the international level, key recommendations of the *Action Plan* were to strengthen the international chemical control system by working with countries producing and importing chemicals to tighten controls on shipments of precursor chemicals; to enhance cooperation with Mexico, in light of its growing role as a methamphetamine supplier to the United States; and to support Federal legislation which would enable better controls on these chemicals. With respect to state and local chemical controls, the *Action Plan* recognized that one state in particular (Oklahoma) had recently adopted new legislation limiting retail access to pseudoephedrine, but due to the lack of long-term data, delayed evaluating Oklahoma’s approach until more data was available.

In reviewing our efforts to curb pseudoephedrine diversion at both international and local levels, the SD-IWG initiated a review of the structure of the methamphetamine market, inquiring what percentage of the methamphetamine consumed in America comes from the larger labs supplied by internationally diverted pseudoephedrine, and what percentage comes from smaller labs fueled by retail- or wholesale-level diversion. In recent years, some have described the market as a 80-20 ratio: namely, that at least 80% of the methamphetamine consumed in America came from “superlabs” in and outside of our borders, and no more than 20% came from smaller domestic laboratories with production capabilities of no more than a few pounds, but usually at most just a few ounces.⁷ The SD-IWG does not think that the 80-20 ratio is the best way to describe the methamphetamine market today. No precise breakdown is available, but current drug and lab seizure data suggest that a better description of the market stands at roughly 65-35, recognizing that approximately two-thirds of the methamphetamine used in the United States comes from larger labs, increasingly in Mexico, but that probably about one-third of the methamphetamine consumed in our Nation comes from medium-to-small domestic laboratories.⁸

The point of the analysis above is this: a precursor strategy focused only on international regulation, or alternatively only on local control, would be insufficiently comprehensive in nature. The fact that a significant percentage of methamphetamine comes from both categories highlights the importance of a bifurcated precursor strategy preventing chemical diversion at both the macro and the micro level.

⁷ Prior Administration statements describing a 80-20 ratio were also based on laboratory seizure and capacity numbers.

⁸ Although notoriously difficult to estimate precisely, lab seizure numbers and production capacity – the same model used for previously estimating the breakdown of the methamphetamine market at 80/20 – help provide a general picture of what percentage of the methamphetamine market comes from pseudoephedrine diverted in bulk from the international market to larger laboratories, and what percent is due to pseudoephedrine diverted at the retail or wholesale level. Labs with a production capacity of under one pound typically receive most of their pseudoephedrine at the retail level; in the one-to-nine pound range, both retail and wholesale diversion (the latter referring to illicit sales out the back door of retail establishments) are believed to play the major role, although some of these mid-range labs – a minority – receive pseudoephedrine through bulk diversion. Meanwhile, most of the labs with a more-than-ten pound production capacity in a 24-hour cycle (called “superlabs”) receive their pseudoephedrine through bulk diversion, as do most of the labs in Mexico. Using these figures, very roughly 65% of the methamphetamine seizures, including labs, in the United States and at the Southwest Border are believed to be sourced primarily, but not exclusively, from bulk pseudoephedrine diversion; approximately 35% is believed to be sourced primarily from domestic diversion at the retail and wholesale level.

2004 Laboratory Capacity Statistics⁹

Pseudo. source	Mainly retail/wholesale level diversion				Bulk/Int'l diversion		Total
	<2oz	2-8oz	9oz -1 lb	1-9.9 lbs	10 + lbs	SW Border	
Production capacity	<2oz	2-8oz	9oz -1 lb	1-9.9 lbs	10 + lbs	SW Border	Total
Total labs [L]	6593	1991	491	351	57	n/a	9483
Avg. capacity [C]	1 oz	4 oz	1 lb	5 lbs	20 lbs	n/a	n/a
Production [LxC]	412 lbs	498 lbs	491 lbs	1,755 lbs	1,140 lbs	4,840 lbs	9136 lbs
% of lbs produced	4.5 %	5.5 %	5.4 %	19.2 %	12.5 %	52.9 %	100 %

The Government's International Approach

The *Action Plan* specifically recognized that the move of large labs to Mexico requires that we offer assistance to help Mexico strengthen its anti-methamphetamine activities. This, in turn, requires working with other countries known to supply Mexican methamphetamine producers with illicit pseudoephedrine. The SD-IWG has responded to this:

- China (particularly Hong Kong) has been a significant source of pseudoephedrine tablets that have been diverted to methamphetamine labs in Mexico. The United States and Mexico recently obtained a commitment by Hong Kong not to ship chemicals to the United States, Mexico, or Panama until receiving an import permit or equivalent documentation and to pre-notify the receiving country before shipment.
- The United States has made significant progress in assisting Mexican authorities to improve their ability to respond to methamphetamine laboratories. Three times last year and once already this year, DEA provided diversion and clandestine lab cleanup training courses for Mexican officials (both Federal and State). More clandestine laboratory courses are planned for summer 2005 in furtherance of this objective.
- In conjunction with our joint efforts, Mexico this year began to impose stricter import quotas for pseudoephedrine, tied to estimates of national needs and based on extrapolations from a large population sample. Additionally, distributors have agreed to limit sales of pseudoephedrine to pharmacies, which in turn will sell no more than approximately nine grams per transaction to customers.

These developments stand as a model for the SD-IWG's next steps with the limited number of manufacturers which produce, in a limited number of countries, bulk ephedrine and pseudoephedrine. Our efforts are, and will continue to be, focused on the primary producing and exporting countries for bulk ephedrine and pseudoephedrine: China, the Czech Republic, Germany and India. Some of these efforts are not new, but involve a long-term commitment, using the tools at the Administration's disposal, to engage with foreign law enforcement and regulatory counterparts in these countries and to replicate the steps taken with Hong Kong and Panama: improving the sharing of information on pseudoephedrine shipments with other countries, thus preventing their diversion – especially to Mexico.

However, the SD-IWG believes that perfecting the ability of the Federal government to prevent large-scale pseudoephedrine diversion will likely require Federal legislation. Under existing Federal law, the DEA must be notified if an ephedrine or pseudoephedrine product is destined for, or will transit through, the United States. But the legal and regulatory tools to limit imports

⁹ Source: Clandestine Laboratory Seizure System, El Paso Intelligence Center. Some categories are listed as "n/a" because the numbers describe the numbers of laboratories seized by size. The methamphetamine seized at the SWB border is typically not found in a lab, but rather as a finished product

and after-import distribution are relatively crude. Moreover, an exemption in the 1988 UN Convention that controls chemicals allows most finished pharmaceutical products containing pseudoephedrine in combination with other ingredients to be shipped in international commerce without pre-notification – a wide-open loophole that drug traffickers have exploited.

The SD-IWG recommends that the Administration request Congress to enact legislation which:

- Enables import controls on bulk ephedrine and pseudoephedrine by treating the post-importation handling of bulk ephedrine and pseudoephedrine in a similar manner, for regulatory purposes, as Federal laws now treat the post-importation processing of Schedule I and II controlled substances.
- Regulates the chemical “spot market” via legislation which, as an extension of existing authority over imports, authorizes regulation of the first level of distribution after importation of bulk ephedrine and pseudoephedrine.
- Removes the so-called “blister pack exemption” and eliminates distinctions based on form of packaging.
- Lowers the threshold for single-purchases of products containing pseudoephedrine from nine grams to a lower amount.
- Does not unnecessarily impede upon the availability of these products for legitimate use.

While the Administration works with Congress to pass this legislation, the SD-IWG is committed to moving forward aggressively with the tools at the government’s disposal to stem the international flow of illicit precursors used to make methamphetamine and other drugs – and to ameliorate the impact of the drugs.

- The United States and Mexico are working to gain wider support for pre-notification of international shipments of tablets containing pseudoephedrine. As referenced above, these tablets fall under a loophole in the 1988 UN Convention, so cooperation would be voluntary under existing law. The DEA will seek cooperation through regional bodies, such as the Organization of American States’ drug-control commission, the Inter-American Drug Abuse Control Commission (CICAD), as well as the multilateral “Project Prism” initiative convened by the United Nations’ International Narcotics Control Board, to monitor international shipments of methamphetamine precursors.
- Over the last couple of years, DEA has elicited eBay’s assistance in preventing the diversion of precursor chemicals through their auction sites, requesting that eBay discontinue the auctioning of methamphetamine precursors such as ephedrine, pseudoephedrine, iodine, red phosphorus and the MDMA precursor, sassafras oil. As a result of DEA’s efforts, eBay has stopped brokering all ephedrine and red phosphorus products. eBay has also placed quantity limits on iodine sales while also developing “pop-up” announcements for the remaining chemicals advertised on eBay, which will inform eBay customers of federal laws and penalties regarding those chemicals. Our success with eBay serves as a model for next steps with other online sites such as Google and Yahoo.
- In order to assist State and local law enforcement agencies with information regarding methamphetamine laboratories and their consequences, DEA is working with the Environmental Protection Agency to revise the so-called “red book” of lab cleanup protocols. This should be complete by July of this year.

- Recognizing that children exposed to methamphetamine are uniquely vulnerable, the Administration began working with states during the President’s first term to help implement Drug Endangered Children (DEC) programs, which establish teams of specialists to respond to situations where minors are found in or near methamphetamine laboratories, and are not infrequently sickened or burned from exposure to toxic chemicals. Seventeen states now have DEC programs¹⁰; most or all of these were started with Federal support. Additional teams are being developed across the country, and DOJ and ONDCP will continue to work directly with states to expand the DEC program.

Promising State Approaches

Meanwhile, in recent years, state policymakers have wrestled with the question of how to reduce the local production of methamphetamine, usually by imposing limits on the amount of pseudoephedrine products that can be purchased in a single retail transaction. In April 2004, Oklahoma adopted the most far-reaching approach observed up to that time: limiting sales of both single-entity and combination pseudoephedrine products to pharmacies; requiring pseudoephedrine products to be kept behind the pharmacy counter; and requiring the purchaser to show identification and sign a logsheet.¹¹ When the *Action Plan* was published in October 2004, there was insufficient data to reach a conclusion as to the effectiveness of the Oklahoma model. However, the *Action Plan* noted Oklahoma’s approach, and the SD-IWG decided to review monthly data as it became available, in order to eventually determine whether that approach warrants reproduction in other states.

Since the release of the *Action Plan*, Oklahoma has released twelve months of data, and Oregon – which adopted a similar approach through temporary administrative rule in October 2004¹² – has four months of data as of this writing. Oregon’s approach had minor differences: Oregon, unlike Oklahoma, allowed combination pseudoephedrine products – those containing pseudoephedrine plus other active medical ingredients – to be sold at stores other than pharmacies, provided that the products were kept in a secure location.¹³ As of the date of this writing, Governors in five more states¹⁴ have recently signed legislation implementing an approach identical or similar to Oklahoma’s, and about twelve states appear to be proceeding with legislation which would adopt, more or less, the same approach.

OK lab seizures*
(Source: Ok. Bureau of Narcotics)

Month	2003	2004	2005
January	105	97	44
February	165	120	39
March	113	130	36
April	143	91	
May	90	48	
June	104	60	
July	86	62	
August	82	45	
September	71	50	
October	109	38	
November	69	29	
December	96	42	

* Months since new regulations were implemented are in red

OR lab seizures*
(Source: Oregon State Police)

Month	2003	2004	2005
January	34	40	21
February	38	42	18
March	36	49	
April	49	39	
May	51	59	
June	26	42	
July	37	42	
August	42	30	
September	52	28	
October	53	33	
November	33	18	
December	22	22	

* Months since new regulations were implemented are in red

¹⁰ Source: Department of Justice, Office of Crime Victims.

¹¹ Okla Stat Ann, §63-2-212.

¹² Oregon Administrative Rule (OAR) 855-050-0035. In April 2005, Oregon adopted a permanent rule nearly identical to Oklahoma’s statute: OAR 855-050-0037.

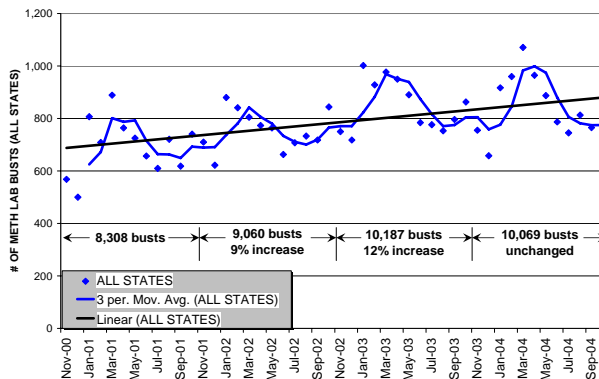
¹³ OAR 855-050-0035.

¹⁴ Arkansas (SB 109), Iowa (SB 169), Kansas (SB 27), Kentucky (SB 63), and Tennessee (SB 2318).

As state legislators have considered these policies, the larger question for Federal and State policymakers alike has been: Do these approaches work? Several subsidiary questions follow: Have the numbers of laboratories actually gone down? If so, are there alternative explanations or reasons? How much of the reduction in laboratory numbers can be directly attributed to the new regulations? And finally, which provisions appear to be the most meaningful in contributing to laboratory number reductions?

The tables on the preceding page indicate that Oklahoma and Oregon saw an immediate reduction in methamphetamine laboratory numbers upon the implementation of these new policies. In the year since Oklahoma’s approach has been implemented, methamphetamine lab numbers in that state are down by an average of 51% over the prior year¹⁵, and in the four months since Oregon’s approach was implemented, by about 42% from the same months in the prior year.¹⁶ Neither Oklahoma nor Oregon changed their method of counting methamphetamine laboratory numbers at the time of implementing new regulations, or since then.¹⁷ Both states say that they have had consistent definitions of what constitutes a methamphetamine lab, and law enforcement was not able to detect any significant inconsistency in reporting by state and local agencies.¹⁸ Both states have been able to supply up-to-date figures for lab seizures, without the lag time typical of reporting to the large national clandestine lab databases such as the El Paso Intelligence Center (EPIC). Therefore, at this point in time, the reductions seem to be real, and should not be attributed to reporting lag-time, less law enforcement focus on the problem, or inconsistent reporting.

With respect to alternative explanations for the reduction in laboratory numbers in these two states, we think the data supports a conclusion that the new regulations are the primary, but not sole, factor in reducing the number of labs. It is worth noting that overall, national methamphetamine laboratory numbers have been roughly stable over the past two years, rising in some states and falling in others. The figure at the right¹⁹ shows four periods



from November of one year through October of the following year. One can see that the number of methamphetamine lab seizures had been increasing by about 10% per twelve month period, but subsequently leveled-off. Part of this stabilization may have been due to the Administration’s successful efforts to stem the flow of pseudoephedrine diversion and trafficking at our northern border. For example, DEA’s Operation Northern Star was intended to drastically reduce the number of domestic methamphetamine “superlabs,” and in fact, domestic superlab numbers dramatically fell following the operation’s implementation.²⁰ Other factors, including improved treatment opportunities, traditional law enforcement efforts, and public education efforts are

¹⁵ Source: Oklahoma Bureau of Narcotics.

¹⁶ Source: Oregon State Police..

¹⁷ Source: Oklahoma Bureau of Narcotics and Oregon State Police.

¹⁸ Ibid. Both states report that they use definitions provided by the Clandestine Laboratory Seizure System (CLSS), El Paso Intelligence Center.

¹⁹ Clandestine Laboratory Seizure System (CLSS), El Paso Intelligence Center, Jan 2005.

²⁰ Ibid.

believed to have played a significant role in reducing the number of methamphetamine laboratories.

Nevertheless, the fact remains that even with the stabilization in methamphetamine laboratory numbers observed nationally, no states with consistently significant numbers of methamphetamine labs²¹ have seen the reductions in lab numbers that especially Oklahoma and, to a lesser but still significant extent, Oregon have seen. For example, during the twelve-month period from April 2004 to March 2005, California saw a reduction of 28%²², Missouri an increase of 8% and Tennessee an increase of 40%.²³ But nationally, while overall lab numbers were roughly stable – up in some states and down in others – the 51% reduction for Oklahoma over 12 months and 42% for Oregon in a four month time period stand out.

It is also worth noting that the reduction in Oregon's lab numbers has been impressive, but not as dramatic as Oklahoma's. As discussed earlier, there are two differences between the states' approaches: Oregon had allowed non-pharmacies to sell combination pseudoephedrine products from behind the counter, whereas Oklahoma requires both single- and combination-entity products to be sold from behind pharmacy counters. Law enforcement in Oregon reports that most of the laboratories they are now finding contain evidence that the methamphetamine was produced using the easier-to-procure combination pseudoephedrine products – and furthermore, that undercover investigations at both pharmacies and non-pharmacies indicated substantial compliance with the temporary rule in pharmacies, but less frequent (less than half of the time) compliance with the temporary rule in convenience stores.²⁴

Agencies participating in the SD-IWG will continue to monitor methamphetamine lab numbers in these two states, as well as in states like Iowa, Tennessee, Kentucky and Arkansas, which have recently adopted these approaches, but do not yet have at least three months of post-implementation data. At this point, the SD-IWG notes a significant data challenge: the lack of timely national data on methamphetamine laboratory numbers.²⁵ Although DEA's EPIC acts as the repository for methamphetamine lab numbers, DEA concedes that these figures do not tend to stabilize until after six months have passed. Moreover, although there does appear to be general consistency regarding which law enforcement agencies report their numbers, it seems clear that not all law enforcement agencies are necessarily reporting lab seizures to EPIC, making state-by-state comparison difficult.

²¹ States with a small number of methamphetamine laboratories in past years, even if posting significant decreases, were not necessarily statistically useful. For example, EPIC data at the time of this report indicated that in Rhode Island, there was only one methamphetamine lab in 2004 compared to four in 2003; although this is a 75% reduction, our focus was on states consistently reporting hundreds of methamphetamine labs annually.

²² As previously discussed, there has been a significant reduction in "superlabs," or laboratories with a production capacity exceeding 10 pounds in a 24-hour period. Clandestine Laboratory Seizure System (CLSS), El Paso Intelligence Center. Additionally, California authorities report that "(w)hile there is a recorded drop in the number of lab seizures in California from 2002 to 2004, the California Bureau of Narcotics Enforcement attributes this to staffing and budget re-allocation...rather than to a reduction in the number of labs operating in California." 2004 Pseudoephedrine OTCs and Methamphetamine Related Issues, A Briefing Report, California Bureau of Narcotic Enforcement, March 2005.

²³ Source: Clandestine Laboratory Seizure System (CLSS), El Paso Intelligence Center.

²⁴ Source: Oregon State Police.

²⁵ Oklahoma and Oregon state authorities directly provided laboratory data to the SD-IWG.

Nevertheless, the available data – a year’s worth of data from Oklahoma, four months of data from Oregon, and several years worth of national data – strongly suggest that Oklahoma’s and Oregon’s state-level approaches are probably primary reasons for a dramatic reduction in the number of small, toxic laboratories in Oklahoma as well as smaller reductions in Oregon. These promising data illustrate the importance of focusing both international and local anti-methamphetamine efforts on the most vulnerable area of the methamphetamine market: precursor controls.

Diversification of Controlled Substance Pharmaceuticals

During the last thirty-odd years, the United States’ anti-drug abuse efforts have traditionally been focused on illicit drugs like cocaine, heroin, or marijuana. The release of the President’s *2004 National Drug Control Strategy* marked the first occasion in which the abuse – sometimes called the non-medical use – of prescription drugs was formally addressed as a significant problem by the Executive Office of the President. This is because prescription drug abuse has surpassed methamphetamine, heroin and even cocaine as a drug category of abuse, and is now second only to marijuana.²⁶

Reducing prescription drug abuse requires understanding exactly how the otherwise-legal products are illicitly acquired. Existing data and research give only general outlines of how the illicit market for prescription drugs breaks down – and the SD-IWG considers better data on this critically important, so as to drive sound policy in this area over the upcoming years. Nevertheless, existing information, combined with anecdotal information from law enforcement, treatment providers and other abuse professionals, supports a conclusion that the illicit methods of procuring prescription drugs include the retail level, and can be roughly described as falling into three categories:

1. Prescription fraud and “doctor shopping,” the latter of which refers to the visit by an individual, who may or may not have a legitimate medical condition, to numerous practitioners within a short amount of time to obtain more prescription medication than is clinically necessary.
2. The Internet, by unscrupulous websites purporting to act as legitimate pharmacies. While some of these are linked to brick-and-mortar pharmacies that have expanded operations and started illegally distributing over the Internet, others operate completely outside the bounds of the law, and often outside the boundaries of our country, using the

Prescription Drug Abuse: Quick Facts

- In 2003, some 6.3 million Americans used psychotherapeutic drugs non-medically in the past month.
- About 1.9 million individuals were considered to have been dependent on, or to have abused, psychotherapeutic drugs over the past year.
- The number of people who had used pain relievers non-medically at least once during their lifetime increased 5 percent, from 29.6 million to 31.2 million Americans from 2002 to 2003.
- Also from 2002 to 2003, the non-medical use of any psychotherapeutics in the past month increased from 5.4 to 6.0 percent among young adults.
- And in 2003, 13.4 percent of youth between the ages of 12 and 17 had abused prescription drugs at least once in their lifetime.
- Again among young adults, past-month non-medical use of pain relievers increased by 15 percent, from 4.1 to 4.7 percent.
- From 1995 to 2002, emergency room visits resulting from the abuse of narcotic pain killers increased about 163 percent.

Sources: See footnote 26 below.

²⁶ Substance Abuse and Mental Health Services Administration. (2004). *Overview of Findings from the 2003 National Survey on Drug Use and Health* (Office of Applied Studies, NSDUH Series H-24, DHHS Publication No. SMA 04-3963). Rockville, MD; Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (2005). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2004* (NIH Publication No. 05-5726). Bethesda, MD: National Institute on Drug Abuse; Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995–2002*, DAWN Series: D-24, DHHS Publication No. (SMA) 03-3780, Rockville, MD, 2003.

international mail system to illegally dispatch controlled substances to those who would intentionally or unwittingly abuse them.

3. A broad third category which includes traditional acquisition methods of acquiring illicit drugs, such as theft, street-level dealing, and small-time distribution from acquaintances or friends (not unlike some local marijuana markets). Diversion from practitioners also plays a role.

The *Action Plan* called for increased attention in especially the first two categories²⁷, which are the most directly responsive to Federal measures and support. Specifically, the key diversion-related items in the *Action Plan* called for more support of State Prescription Drug Monitoring Programs (PDMPs), limiting illicit online sales of chemicals and pharmaceuticals, and responding to mail packages illegally containing drugs from entering the United States. As noted below, agencies participating in the SD-IWG are working hard toward these objectives using existing tools, but in the area of online diversion and the mail system, the SD-IWG believes that additional measures including Federal legislation should be considered.

Reducing Doctor Shopping

Disrupting opportunities to engage in “doctor shopping” requires, by definition, the cooperation of the medical community, the pharmaceutical community, and regulatory or enforcement agencies where appropriate. Simply put, the doctor shopper relies on a lack of communication between the prescriber and the dispenser. PDMPs are one tool that seek to bridge that gap, by tracking prescription drug sales at the pharmacy level, helping pharmacists ensure the validity of prescriptions, and helping physicians confirm that would-be abusers of prescriptions are not doctor shopping for controlled substances.

Toward the expansion of these programs, the Office of National Drug Control Policy, in coordination with the Department of Justice and National Alliance for Model State Drug Laws, has purposefully moved forward to convey the Administration’s support of PDMPs to state legislatures and other state policy makers. At the time of this writing, twenty-four states have in place, or are expected to implement this year, some type of PDMP. Another ten or so states have introduced legislation so far in 2005 which would implement these programs. Through testimony on several occasions already this year to state legislatures and other interactions, Administration officials have been working directly with state policymakers.

Although not under the direct control of the Federal government, continuing the expansion of these programs by encouraging their adoption at the State level will continue to be a priority of the Administration during the state legislative season. As legislatures begin to adjourn over the next few months, the Administration’s focus will move from advocacy to the gathering of more and better information about the impact of PDMPs. Specific questions pertain to which models are the most effective in reducing doctor shopping, and cost-effectiveness. To this end, both DOJ and the Department of Health and Human Services (HHS) will play key roles. The Administration hopes to see the current number of states operating or planning PDMPs increase this year, with the eventual goal of assisting all states in implementing these valuable programs

²⁷ The third category tends to fall within traditional local, rather than Federal, law enforcement; it is also impacted by treatment and prevention efforts, and is addressed in part in the “Prevention and Treatment” section of this document.

by the end of 2008. At present, the Federal government's primary role in this capacity is, and is expected to continue to be, an interagency strategy which provides support through grants²⁸, public policy advocacy, and providing State policymakers with relevant data and research.

Illegal Online Pharmacies

Any American who has filled a prescription at their local pharmacy is comfortably familiar with the routine: some form of consultation with a health care professional, which includes a personal diagnosis and discussion; and shortly afterward, a visit to a nearby pharmacy, which includes a brief explanation on the safe and most effective use of the pharmaceutical. These standard practices applicable to "brick-and-mortar" pharmacies have ensured that American patients, their doctors and their pharmacists have the maximum information available to ensure not only the best treatment of the patient's condition, but also that prescription drugs with addictive or abuse potential – such as those containing oxycodone, hydrocodone or alprazolam – are prescribed in the appropriate medical circumstances and in safe dosages.

Advances in information technology and communications have helped increase the access of patients, particularly those in rural or underserved areas, to such appropriate medical care. Toward that end, the Administration is supportive of legitimate online pharmacies operating within the bounds of accepted medical practice and Federal and State laws. However, certain unscrupulous individuals and organizations purporting to be online pharmacies have provided controlled substances and other pharmaceuticals without a prescription, flaunting the traditions described above which evolved to protect both doctor and patient. This is a violation of Federal law, and it should come as no surprise that many of these websites and businesses, when investigated, are found in far-flung regions in Asia, South America and the Caribbean, and operate without the protections that Americans take for granted. It should also not be surprising that when tested, many of the substances sent through the mail are not the medications they purport to be. It may be no coincidence that the advent of these online pharmacies has occurred in tandem with the aforementioned emergence of prescription drug abuse as a National drug control problem: uninhibited access to supply has coincided with a notable increase in prescription drug abuse.

The SD-IWG is pleased to report that since the drafting of the *Action Plan*, the efforts and accomplishments of the Federal government in this area, with the tools at the government's disposal, are not insignificant. To enhance focus in this area, DEA established an Internet investigation unit (OSI) at its Special Operations Division (SOD) to coordinate Internet cases. The DEA has issued immediate suspensions of numerous Internet pharmacies and DOJ has prosecuted doctors and pharmacies who illegally distribute via the Internet. Additionally, DEA, Immigration and Customs Enforcement (ICE), the United States Postal Service (USPS), Customs and Border Protection (CBP) and the Food and Drug Administration (FDA) participate in an interagency task force dedicated to addressing the illicit procurement of pharmaceuticals via the Internet. DEA has opened cases, in circumstances of clear illegality, involving drugs such as OxyContin and Vicodin, two of the major drugs-of-abuse in the prescription drug category. And

²⁸ The Harold Rogers Prescription Drug Monitoring Program provides grants to states for the planning, implementation, and/or enhancement of PDMPs, and were first provided in 2002 (FY 2002 U.S. Department of Justice Appropriations Act (Public Law 107-77)).

the FDA has brought cases against illegitimate Internet pharmacies with respect to various pharmaceutical products.

The explosion of illicit online pharmacies and their “spam” email advertisements, and the concomitant rise of prescription drug abuse in America, highlight the critical need for new legislation in this area. Although the basic Federal laws regulating pharmacies – brick-and-mortar as well as those operating online – are in place, the unique attributes of online pharmacies require special legislation to put online pharmacies on an equal footing with brick and mortar pharmacies. For instance, a consumer filling a prescription at a local community pharmacy knows where he or she obtained the medicine, can ask questions of the pharmacist if the consumer wants to discuss the proper dosage, drug interactions or expiration date issues, and can make an inquiry with the state pharmacy board or DEA if the consumer has a complaint. Unfortunately, consumers often lack these protections with online pharmacies, and as a result, illegal scams proliferate, and patients are taken advantage of.

The SD-IWG believes that legislation is necessary to ensure that online pharmacies adequately identify themselves to consumers. In addition, the law must be clarified to ensure that controlled substances are only dispensed for a legitimate medical purpose in the usual course of a doctor’s professional practice, and not on the basis of a suspect online questionnaire where the doctor never sets eye on the customer.²⁹

Some online pharmacies operate from websites in foreign countries, but the drugs are actually handled and shipped from U.S. distributors. In other cases, the controlled substances are illegally shipped from abroad. A critical need in this area is improving the tools available to prevent these packages from entering our country through the postal system. The FDA, USPS and CBP are the agencies primarily faced with this challenge. To illustrate the scope of the problem, the recent HHS Report on Prescription Drug Importation³⁰ estimated that 10 million shipments of non-controlled substance prescription drugs illegally enter the United States each year through the US Mail. We do not know the additional amount of packages which contain controlled substances, but it appears to be significant. The problem for the USPS and CBP is the administrative burden associated with seizing and forfeiting the hundreds of thousands of packages, as well as the strict notice and seizure procedures imposed by the Universal Postal Union (UPU) treaty.

Concerted action and better laws can help staunch this illicit commerce. DOJ and the USPS are developing better protocols to comply with the notice requirements under the UPU treaty. However, without legislation to authorize the summary forfeiture of illegally imported controlled substance pharmaceuticals, it is likely that they will continue to seep through our mail system. Moreover, under current procedures, which require law enforcement to notify the addressee that a package is being detained, it would be problematic for CBP to handle the flood of packages that would be seized under a stricter or zero-tolerance policy.

²⁹ In June 1999, the American Medical Association formally adopted the position that any health care practitioner who offers a prescription to a patient solely on the basis of an online questionnaire without ever physically examining the patient has not met the appropriate standard of medical care. *See* American Medical Association, *Guidance for Physicians on Internet Prescribing*, H-120.949 (1999).

³⁰ Task Force on Drug Importation pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173.

Protecting Americans from online rogue pharmacies will require new tools to keep pace with the criminals operating these websites. The SD-IWG recommends that the Administration's legislative package include language which:

- Requires that online pharmacies be registered with HHS and DEA and make certain disclosures on their Internet websites identifying, among other things, where they are located and what doctors and pharmacists are affiliated with the online pharmacy;
- Provides that no online pharmacy may dispense prescription drugs without a valid prescription issued for a legitimate medical purpose in the usual course of professional practice;
- Allows States to bring a civil action in federal court to enjoin the conduct of an online pharmacy that does not comply with the requirements of the bill and to enforce compliance.
- Enhances penalties for unlawfully dispensing controlled substances in schedules III through V. These enhanced penalties will apply equally to all unlawful distributors and dispensers of controlled substances; and
- Gives USPS and CBP the tools those agencies need to prevent packages with drugs from illegally entering the United States through the mail system, by authorizing the summary forfeiture of illegally imported controlled substance pharmaceuticals.

Treatment and Prevention

Most of the *Action Plan's* recommendations regarding treatment and prevention fall into three categories: increasing treatment capacity; improving the dissemination of "best practices" information regarding treatment and prevention; and implementing an early warning system that would notify Federal, State and local officials of emerging synthetic drug threats in a specific area.

Although many of the existing Federal prevention and treatment initiatives were initiated prior to the *Action Plan*, several of the most promising new initiatives were developed as a result of interagency coordination and discussion through the SD-IWG and directly respond to the recommendations of the *Action Plan*. This section focuses on three developments since the release of the *Action Plan*: (1) an overview of specific drug treatment programs and initiatives the Administration proposes to expand; (2) the formation of an Early Alert and Response Mechanism (EARM) for helping authorities identify and respond to emerging synthetic drug threats; and (3) the launch of an improved means of disseminating critical information about Federal grant support, new research, and best practices related to synthetics prevention and treatment – one of the *Action Plan's* key recommendations.

An Increased Commitment to Treatment

The Administration has requested significantly expanded support for treatment of drug abuse. This financial support, much of which is in the form of grants to states or local organizations, allows flexibility to respond to the region's particular drug threat.

Highlights of increased support requested for the next fiscal year (2006) for treatment and prevention include:

- A \$50.8 million increase for Access to Recovery, a voucher-based treatment grant program which can support individuals seeking treatment for methamphetamine and other drugs. The budget proposes a total of \$150 million for this program.
- An increase of \$30.6 million for the Drug Courts Program, for a total of \$70.1 million. This enhancement will increase the scope and quality of drug court services with the goal of improving retention in, and successful completion of, drug court programs, many or all of which are able to monitor persons before the court for possession of methamphetamine.
- A \$15.4 million increase for Student Drug Testing, for a total of \$25.4 million. This initiative provides competitive grants to support schools in the design and implementation of programs to randomly screen selected students and to intervene with assessment, referral, and intervention for students whose test results indicate they have used illicit drugs.
- An increase of \$5.8 million for the Screening, Brief Intervention, Referral and Treatment (SBIRT) program through SAMHSA, which intervenes early with users to stop drug use before it leads to abuse or dependence. This initiative will improve treatment delivery to achieve a sustained recovery for those who are dependent on drugs.

Early Alert and Response Mechanism

The SD-IWG is pleased to announce the creation of a coordinated Federal effort to quickly identify and deal with emerging synthetic drug threats in specific regions: the Early Alert and Response Mechanism, or EARM. While some drug threats have more or less existed uniformly across America – marijuana and cocaine come to mind – methamphetamine has not spread as uniformly across the country. Some areas, such as New England, post dramatically smaller indicators of methamphetamine use and production than, for example, the West Coast states – and methamphetamine’s sudden emergence can catch police, treatment professionals and parents by surprise. Even more striking in some rural cities, counties or demographic populations has been the sudden emergence of a specific synthetic drug abuse threat such as OxyContin. With the development of EARM, these indicators, at a relatively early state, should not go unnoticed. The abuse of methamphetamine and controlled substance pharmaceuticals depend on the diversion of legal substances which can be tracked, so the timely analysis of this information will better enable the quick identification of an emerging problem, and an appropriate response by Federal, State and local authorities, including prevention and treatment providers.

EARM will begin a pilot phase later this year, as a joint effort between SAMHSA, NIDA, DEA (including the National Drug Intelligence Center, or NDIC) and FDA, in cooperation with state and local law enforcement and public health agencies. The mechanism will differ from other data collection systems in that it will assimilate various types of available information (e.g. anecdotal, surveillance) on a flow basis – that is, without waiting for statistical confirmation. Experts will meet at least monthly to discuss current and potential threats and to share information from their data systems, augmented by their agencies’ respective knowledge. For example, DEA is able to track the numbers of nationwide, state and regional prescriptions for a given controlled substance (without patient identifying information), and can identify a sudden, otherwise-inexplicable rise

in prescriptions for a particular drug exceeding what would normally be expected. As another example, it is important to detect, as quickly as possible, phenomena such as one currently observed in some cities, where injected crystal methamphetamine is more frequently seen in some clubs, and is thought to be contributing to a rise in HIV and AIDS transmissions in the gay community. Or a sudden rise in pseudoephedrine sales in an area could indicate a brewing methamphetamine crisis. Once the mechanism of identifying threats has been pilot tested, the system will be refined to serve the needs of National, State and local decision makers.

One-Stop Shopping: www.methresources.gov

Several of the *Action Plan's* recommendations relate to acquiring the best scientific information available about prevention and treatment of synthetic drug abuse, and doing a better job of disseminating this information to treatment and prevention authorities. With respect to treatment methodologies, the SD-IWG notes that several studies are underway (the inception of most of these pre-date the *Action Plan*), and although there are some gaps to be filled – specific information about juvenile treatment methodologies for methamphetamine, for example – agencies like NIDA, SAMHSA and OJP collectively possess substantial scientific information about treatment methodologies for synthetic drugs. At this point, the more pressing challenge is how to best disseminate that information to those who need it.

A simple solution to the dissemination problem is expected by July: the launch of a new government website, www.methresources.gov, which will be administered by DOJ's Bureau of Justice Assistance. This website is important for two reasons. First, there is no single government website which brings together information about best practices for combating the spread of methamphetamine and other synthetic drugs, and also provides information about Federal resources (such as grants to treatment providers or police) related to synthetics. Wading through the labyrinth of Federal websites (SAMHSA, NIDA, OJP, ONDCP, and others, for Federal assistance including the Hal Rogers Prescription Drug Monitoring Program, the Community Oriented Policing Program, Access to Recovery, and Drug Courts, to name a few) to find Federal support for local efforts can be a daunting endeavor, and www.methresources.gov will aim to simplify the process of helping state and local authorities quickly identify opportunities for Federal help.

The second reason that this initiative is important is that good policy must be driven by good, rigorous scientific inquiry; in the case of drug policy, research must be put into effective practice. Recognizing this fact, HHS has developed the landmark "Science to Services" initiative, which facilitates the translation of research into both prevention and treatment practices. The goal of this initiative is to translate scientific findings into information that is easily understood by prevention and treatment professionals in order to facilitate their adoption and implementation. Many of the scientific studies regarding treatment and prevention evaluate what sort of approaches work, and which ones fail. The Administration aims to provide up-to-date information on best practices for treatment and prevention as directly and quickly as possible to those who can make use of it, and will use this website as one means to accomplish this objective.

Other examples of information which will be accessible through www.methresources.gov, and that have been, or are being developed by agencies participating in the SD-IWG, include:

- A National Registry of Effective Programs and Practices, for use as model programs;
- Model methamphetamine and synthetic state laws, from the National Alliance for Model State Drug Laws;
- Results of studies regarding innovative behavioral treatments for synthetic drug abuse; and
- Results of research on the Criminal Justice-Drug Abuse Treatment Studies, which collects data on treating synthetic drug abusers through the criminal justice system (e.g., probation or drug courts), and examines the effectiveness of various treatment approaches.

Conclusion

Over the last six months, the department and agencies participating in the SD-IWG have accomplished several of the critical objectives listed in the *Action Plan*; yet more remains to be accomplished. As noted above, however, several areas will require Federal legislation to provide Federal agencies with the tools necessary to further disrupt the illicit market for synthetic drugs. And there are a handful of *Action Plan* recommendations regarding which a healthy debate among SD-IWG agencies continues regarding the most effective approach.

The SD-IWG will continue to meet, and aims to recommend a legislative package this summer for the Administration to submit to Congress.

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Appendix A

Status of National Synthetic Drug Action Plan Recommendations

The SD-IWG reviewed the 46 recommendations of the *Action Plan* and separated the recommendations into three categories:

- **Category A:** those with which there is substantial agreement, and which already are, or will soon be, in progress;
- **Category B:** those with which there is substantial agreement in principle, but which will require Federal legislation; and
- **Category C:** those regarding which one or more Federal agencies participating in the SG-IWG determined merit further discussion or review.

The following lists briefly describe the status of the 46 recommendations. In most cases, those referenced in Category A and B are discussed in the body of the report, and only a few recommendations contain further discussion of their status. However, all recommendations in Category C are followed by a brief description of their status.

Category A: Recommendations with which there is substantial agreement, and which already are, or will soon be, in progress.

1. **Develop an Early Warning and Response Mechanism:** Establish a comprehensive, interagency early warning and response system to detect the emergence of new drugs and trends.
2. **Improve Data on Afflicted Geographic Areas.** 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.
 - Although treated as a separate recommendation in the *Action Plan*, this will be incorporated into the Early Alert and Response Mechanism discussed in the body of the report.
3. **Work with Manufacturers to Reformulate Abused Pharmaceutical Products.** 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.
 - Reformulation requires ongoing policy discussion and may raise questions related to the safety or efficacy of the drug for legitimate users; however, DEA has engaged in discussions with pharmaceutical manufacturers on this topic, and Pfizer, to list one example, is moving forward to market Sudafed PE, a non-pseudoephedrine decongestant. The Administration will continue to be supportive of industry efforts to reduce prescription drug abuse through reformulation, consistent with the requirement for FDA approval.
4. **Target Raves Where Drug Use is Facilitated.** 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.
5. **Increase Internet Investigations.** 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.
6. **Target Narcotic Analgesic Diversion.** 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 hydromorphone, such as Vicodin and Lorcet.
7. **Enhance Public Outreach Efforts Focusing on Synthetic Drugs:** 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.

- Upon review, there is no disagreement as to the value of this recommendation, but the precise nature of public outreach on synthetic drugs by SD-IWG agencies has changed somewhat. Although the Department of Education will have an important role, the Departments of Justice and Health and Human Services, in conjunction with the Office of National Drug Control Policy, are the primary government entities responsible for public outreach at this time. ONDCP anticipates devoting approximately one million dollars of the Media Campaign budget to outreach on Synthetic Drugs; discussion will continue among agencies regarding this recommendation.
8. **Develop Best Practices to Assist Drug-Endangered Children.** 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.
 - This recommendation is underway as it is described. Although not included in Category B within this Appendix, the SD-IWG intends to consider including, as part of a legislative package, language which strengthens protections of drug-endangered children.
 9. **Research and Develop Targeted Prevention Programs.** 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.
 10. **Increase Treatment Capacity.** 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.
 11. **Research Treatment for Synthetic Drug Abuse.** 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.
 12. **Develop Early Response Treatment Protocols.** Develop and disseminate early-response protocols addressing requests for treatment of dependency on emerging synthetic drugs and diverted pharmaceuticals.
 13. **Study Options for Criminal Justice System Treatment.** 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.
 14. **Expand Dissemination of Treatment Best Practices.** 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.
 15. **Support Stronger State Controls on Precursor Chemicals.** 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.
 16. **Strengthen Cooperation with Mexico.** 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 the drug intelligence center (CENAPI—Centro Nacional de Planeación y Información Para el Combate a la Delincuencia), the Federal Investigative Agency (AFI—Agencia Federal de Investigación), the Federal Commission for the Protection from Sanitary Risk (COFEPRIS—Comisión Federal de Protección contra Riesgos Sanitarios), and the Health Commission, as well as the Bilateral Interdiction Working Group, the Senior Law Enforcement Plenary, and the Binational Committee.
 17. **Enhance Coordination and Information Exchange with Canada.** 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.
 18. **Strengthen the Multilateral Chemical Control System.** 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 Boards 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.
19. **Exchange Information with Chemical Producing Countries.** 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.
 20. **Educate Store Employees.** 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.
 21. **Encourage Voluntary Controls by Retail Pharmacies and Stores.** 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.
 22. **Support State Prescription Monitoring Programs.** 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 cases 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.
 23. **Target Pseudoephedrine and Iodine Smuggling to and from Mexico.** 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.
 24. **Focus on Canadian Synthetics and Chemical Smugglers.** 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.
 25. **Investigate Ties between Canadian and Mexican Criminals.** 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.
 26. **Investigate Asian and European Sources of Synthetic Drugs.** 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 criminal where appropriate.
 27. **Apply Updated Clandestine Lab Cleanup Guidelines.** 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.
 28. **Share Law Enforcement Best Practices.** 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.
 29. **Increase Access to Civil Penalty Case Experts.** 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.
 - This list will be disseminated to US Attorneys offices nationwide, and relevant training is planned for inclusion in future Civil Enforcement conferences to increase the number of Federal prosecutors able to bring civil penalty cases in appropriate circumstances.
 30. **Enhance Methamphetamine Profiling Efforts.** 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.

31. **Increase Prosecutor and LEA Training.** 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.
32. **Make Full Use of Charging and Sentencing Options.** 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 hazardous waste.”
33. **Seek Updated Sentencing Guidelines for Club Drugs.** Work with the US 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.
 - In the PROTECT Act, Congress told the US Sentencing Commission last year to look into sentencing for GHB and as a result, the Commission increased the sentences and also clarified how analogue offenses are sentenced. Now that the Commission increased the guidelines, the SD-IWG will periodically monitor whether or not this is an item that requires further attention.

Category B: Recommendations with which there is substantial agreement in principle, but which will require Federal legislation to be fully effective.

34. **Remove the Blister Pack Exemption.** Support legislation that removes the blister pack exemption and eliminates distinctions based on the form of packaging.
35. **Regulate Chemical Spot Market.** 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.
36. **Enable Import Controls on Bulk Ephedrine and Pseudoephedrine.** 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.
37. **Strengthen Controls on Internet Sales.** 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.
38. **Limit Online Chemical Sales.** Continue ongoing efforts to advise the owners and operators of major online 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.
39. **Prevent Exploitation of Mail Services.** 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.
40. **Consider New Legislation on Club Drugs.** 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.
 - Some prosecutors indicate that club drug cases, including cases involving 1,4 butanediol and GBL cases, are cumbersome to litigate because the Government must establish beyond a reasonable doubt that the substances satisfy the definition of a controlled substance analogue. The SD-IWG will consider legislation to amend the Analogue Act. For example, a bill could specify that 1,4 BD and GBL are presumptive analogues and therefore are treated as Schedule I drugs when intended for human consumption, and could also authorize DEA to establish, through notice and comment, a list of presumptive analogues. These measures would facilitate the prosecution of cases involving emerging designer drugs.

Category C: Those regarding which one or more Federal agencies participating in the SG-IWG determined merit further discussion.

41. **Develop Guidelines for Juvenile Drug Treatment.** 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.
 - There is no disagreement about the value of guidelines and best practices for juvenile drug treatment, but the SD-IWG recognizes the need for better data as the basis for these guidelines. Toward this end, NIDA will continue to support research on juvenile drug treatment and, as better research becomes available, disseminate best practices information for juvenile drug treatment.
42. **Improve Education and Training on Pharmaceuticals:** 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.
 - The Food and Drug Administration has the responsibility for pharmaceutical product labeling, and SAMHSA engages in a variety of education and training activities concerning prescription drug abuse. The SD-IWG recommends further discussion and analysis of this recommendation.
43. **Examine the Use of Prescription Narcotics.** 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.
 - Some of this falls under Category A, as the National Survey on Drug Use and Health (NSDUH) has been recalibrated to ask more detailed questions about the scope of prescription drug abuse. However, further discussion and research are needed to improve data about the sources of diversion, e.g., what percentage of prescription drug abuse in the United States is enabled through the internet, through doctor shopping, through street-level drug dealing, et cetera.
44. **Determine Licit Chemical Needs.** 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.
 - SD-IWG agencies believe this to be a helpful recommendation, but the primary reason for this recommendation was in furtherance of the recommendation for better import controls (using licit chemical needs estimates to help determine legitimate import amounts). Although this recommendation does not technically require legislation, it will be pursued upon the implementation of legislation regarding import controls.
45. **Review Lab Cleanup Resources.** 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.
 - The first half of this recommendation should be considered accomplished, as both the current fiscal year budget and proposed budget for FY 2006 provide adequate funding to support state laboratory and dumpsite cleanups. Approximately \$24 million in COPS funds are available to state and local law enforcement this year for lab cleanup. With respect to the second half of the recommendation, the SD-IWG recognizes that expansion of the container program for seized materials – requiring about a \$40,000 initial outlay per jurisdiction -- could decrease the resources necessary for lab cleanup and, in particular, disposal of seized materials.
46. **Improve Intelligence Efforts Related to Synthetic Drugs.** 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.
 - Consensus is that our domestic intelligence is stronger than our international intelligence. The problem is also a lack of information sharing of, e.g., seized drug samples from Mexico, which presents problems under Mexican law and commercial information from India and China. The SD-IWG plans to convene a sub-group to review intelligence issues in more detail within the next three months.