Addressing Methamphetamine in the United States: A two part prescription to stop the methamphetamine epidemic

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Abstract

Methamphetamine abuse affects millions of Americans and is fueled by the diversion of the cold medicine pseudoephedrine internationally and within the United States. This paper seeks to evaluate the current regulatory system to prevent this diversion and proposes remedies to this system to end the threat of methamphetamines. This paper examines the international regime comprised of the International Narcotics Control Board (INCB) and the U.S. Drug Enforcement Administration (DEA). The INCB controls are very broad but do not sufficiently protect against diversion while the DEA controls are very strong but are limited to imports into the United States. This paper advocates for a DEA styled system to be implemented internationally while recognizing obstacles to its implementation. This paper examines domestic regulatory controls, including electronic tracking, but advocates for a national law requiring a prescription to obtain pseudoephedrine.

As former Deputy Director of the Office of National Drug Control Policy Tom McClellan said, "You know, we don't have a national drug problem; we have a series of regional problems." It is for this reason that identifying America's drug problem and writing a prescription to defeat it is difficult. The approach must be multifaceted and fitted to each drug and each region. In light of this, this paper seeks to explore the complex issues facing the control of methamphetamines (meth).

It is important to understand that meth is a dangerous drug that destroys the lives of millions of people in the United States. It is because meth has the ability to take over as our nation's most significant problem that a comprehensive strategy must be developed to deal with this drug. Supply reduction is at the center of this strategy because of how effective it can be against meth. The best way to defeat meth is to target its precursor chemicals, namely pseudoephedrine.

Currently, there are two international regulatory regimes to monitor precursor chemicals.

The first is a broad but very weak system that is controlled by the International Narcotics Control

Board. The second is very strong but narrow, and is controlled by the United States Drug

¹Tom Risen. "Drug Czar Looks South Of The Border." *National Journal Insider Interviews*. May 4, 2010. http://insiderinterviews.nationaljournal.com/2010/05/drug-czar-looks-south.php.

Enforcement Administration. Given that neither of these current systems can fully protect us against the meth epidemic, I will propose an alternative that combines these systems. I will discuss the obstacles this proposal would face and why there is sufficient political will to enact it. Domestically in the United States, there are also insufficient controls on precursor chemicals. Currently, there is an on-going debate on whether to implement electronic tracking programs or to make pseudoephedrine "prescription-only." The prescription-only method would greatly reduce the availability of meth's major precursor chemical. While there would be opposition to this proposal, there is sufficient political will to implement it. Together, by implementing a stronger international system of regulation along with making pseudoephedrine prescriptiononly, we can end the meth epidemic and significantly curtail use of meth in the United States.

What is Meth?

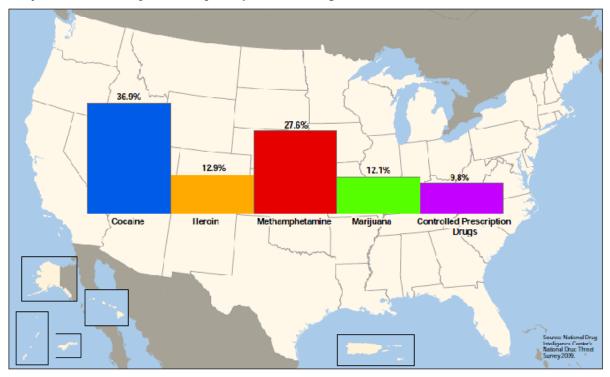
The U.S. Director of National Drug Control Policy, Gil Kerlikowske, once said in an interview, "When I've been in New York City in a Midtown precinct, I could have put meth on the table in the precinct and I don't think there would have been an officer that would have known it or recognized it," indicating that meth is not an urban drug.² Meth is a peculiar drug and has a number of characteristics that differentiate it from other drugs like crack and heroin.

Meth is not a national problem. Each year, the National Drug Intelligence Center (NDIC) conducts the National Drug Threat Survey (NDTS), a "probability-based sample of thousands of state and local law enforcement agencies designed to represent all national, regional, and state agencies."³ Agencies are asked to identify the drug that poses the greatest threat to the community. In 2009, 36.9% of state and local law enforcement agencies identified cocaine as

² Risen. "Drug Czar Looks South Of The Border."

³ National Drug Intelligence Center. "National Prescription Drug Threat Assessment 2009." U.S. Department of Justice. April 2009.
⁴ Ibid.

the most significant problem and 27.6% identified methamphetamines as the most significant problem.⁵



Map A6. 2009 Greatest Drug Threat, as Reported by State and Local Agencies

This data would lead us to believe that meth is the second most important drug in the eyes of law enforcement. However, further analysis of the survey, as it is broken down by the NDIC, reveals that in some parts of the United States meth is by far the most important drug.

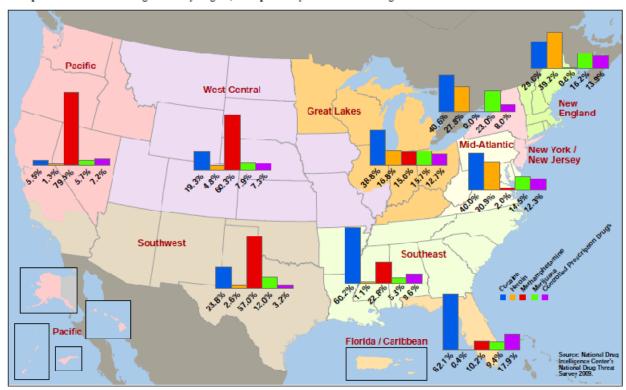
The NDIC divides the results by the nine Organized Crime and Drug Enforcement Task Force regions (OCDETF) and finds that in the West, meth is seen as a much more severe problem. In the Pacific region, 79.5% of respondents indentified meth as the most significant drug problem.⁶ The West Central and Southwest regions replied similarly with 60.3% and 57% indentifying meth respectively.⁷ The Great Lakes, Southeast, and Florida/Caribbean regions

⁵ National Drug Intelligence Center. "National Drug Threat Assessment 2010." *Department of Justice*. May 25, 2010. http://www.justice.gov/ndic/pubs38/38661/38661p.pdf>. 60.

⁶ Ibid., 59.

⁷ Ibid.

reported meth as a somewhat important drug but not the most important, with 15%, 22.8%, and 10.2% respectively. The Mid-Atlantic, New England, and New York/New Jersey regions each had 2%, .8%, and 0% of respondents identify meth as the most significant problem respectively. This analysis demonstrates that meth dominates the West and Midwest of the United States and causes a substantial problem for law enforcement in those areas. This reveals how meth is different than its counterparts, cocaine and heroin, which have greater impact in the East. Realizing this aspect of meth helps us to understand why there is not a national consensus on what to do about meth and its precursors because the effects of the drug are unevenly distributed across the United States.



Map A5, 2009 Greatest Drug Threat by Region, as Reported by State and Local Agencies

^{8 8} National Drug Intelligence Center. "National Drug Threat Assessment 2010."

⁹ Ibid.

Unlike its major competitors, heroin and cocaine, meth is a synthetic drug that is made, not grown and refined.¹⁰ There are several "recipes" for meth, each involving different chemicals and requiring different levels of expertise.¹¹ Three main types of meth are made through these processes, each characterized by its active precursor element. They include ephedrine, pseudoephedrine, and Phenyl-2-Propanone (P2P) based meth.¹² Pseudoephedrine, which is the active ingredient in many common cold medicines, is the most commonly used method because it produces the purest meth and is easiest to work with. The other precursors are seen as outdated and are only used when pseudoephedrine is not available.

Meth's real danger comes in how easy it is to make. It is hard to imagine individuals growing poppy plants in their backyard and then refining them into heroin. One would require sufficient knowledge, space, and chemicals that are not available to the average person. Everything you need to make meth however, can be found at your local pharmacy. One needs pseudoephedrine, found in cough medicine, camping fuel, and lithium from a battery.¹³ The process is so easy in fact, that teenagers in Iowa were cooking meth in soda bottles attached to their bikes that they rode around to avoid being caught.¹⁴

Like cocaine, meth is a stimulant, and the effects of both drugs are similar. Meth creates an intense feeling of euphoria called, "the rush," where the drug triggers an extreme release of dopamine in the brain. Dopamine is the pleasure causing chemical in the brain and meth floods the brain with it, releasing all available dopamine. This changes the way the brain operates so

¹⁰ Washington/Baltimore HIDTA Futures Unit. "Methamphetamine: A Unique Threat to Law Enforcement."

¹¹ Ibid.

¹² Ibid.

¹³ Ibid

¹⁴ Reding, Nick. *Methland*. New York: Bloomsbury USA, 2009.34.

¹⁵ National Institute on Drug Abuse (NIDA). "Methamphetamine Abuse and Addiction." *National Institute on Drug Abuse Research Report*, January, 2002.

¹⁶ Reding. *Methland*. 48.

the user never feels the same again and has trouble living without meth. ¹⁷ This change is known as addiction, "a chronic, relapsing disease, characterized by compulsive drug-seeking and drug use which is accompanied by functional and molecular changes in the brain." Meth use is also associated with the overall deterioration of the body as well as the development of paranoia, which can continue long after use has stopped.¹⁹

Meth use has spread so that there no longer is a typical user. 20 The traditional user was always an adult male with lower-than-average income.²¹ Meth was seen as a rural drug that was used by unemployed, blue-collar workers who were looking for something to help them work long hours or just to get through life. Now meth is beginning to be used by people of all races and economic statuses.²² The complete spread of meth to all communities has yet to take place however, and meth remains stigmatized as the "poor man's cocaine."²³

Why is Meth significant?

It can be difficult to gauge the significance of meth in American society. Meth is by far not the most abused drug. In 2008, approximately 15.2 million persons (6.1% of United States) aged 12 or older had used marijuana in the past month. ²⁴ Only 314,000 persons (.1%) had used meth in the past month, or about one fiftieth of marijuana users.²⁵ Comparing meth to other hard

¹⁷ Byker, Carl. "The Meth Epidemic." *PBS Frontline*, February 14, 2006.

¹⁸ NIDA. "Methamphetamine Abuse and Addiction." 4.

¹⁹ Prah. "Methamphetamine." 591.

²⁰ National Drug Intelligence Center. "Methamphetamine: Fast Facts." U.S. Department of Justice. April 2003. http://www.justice.gov/ndic/pubs3/3981/index.htm#Who%20uses.

²¹ Prah. "Methamphetamine." 591.

²² National Drug Intelligence Center. "Methamphetamine: Fast Facts."

²³ Washington/Baltimore HIDTA Futures Unit. "Methamphetamine: A Unique Threat to Law Enforcement." 3. ²⁴ Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). "Results from the 2008 National Survey on Drug Use and Health: National Findings." U.S. Department of Health and Human Services (HHS), September, 2009. 264. ²⁵ Ibid.

drugs, there were approximately 1.86 million persons (.7%) who had used cocaine or crack in the past month in 2008 and 213,000 persons (.1%) who had used heroin.²⁶

Why, if meth is not the most used drug, should we be concerned about drafting a strategy to combat meth use? The answer has two parts. First, 314,000 regular users is still 314,000 lives consumed by substance abuse. Add to that the lives of families and friends who are affected by meth and the toll is even larger. Meth users often steal to support their habit and an increase in crime is demonstrated where meth use is high. This is part of the reason why law enforcement officials in areas where meth is prevalent view it as the most significant problem. To each person whose life is touched by meth, the drug is significant. Because of meth's destructive power, a comprehensive solution is necessary.

Second, the meth problem needs to be solved because of the potential it has to be much larger. Consider that as of now, meth is almost exclusively present in the Western and Midwestern parts of the United States. That means that there are 314,000 users in only approximately half of the country. While is it impossible to estimate how many users there would be if meth further expanded, it remains that there are still untapped markets for meth to reach.

Does meth have the ability to compete with other drugs? Meth is a stimulant like cocaine. However, meth is more powerful than cocaine and produces a longer high. When a user takes a hit of cocaine, 50% of the drug has metabolized or absorbed into the body after an hour whereas for meth, it takes 12 hours for 50% to metabolize.²⁷ The effect of this is that meth

²⁶ SAMHSA. "Results from the 2008 National Survey on Drug Use and Health: National Findings." 264.
²⁷ Prah. "Methamphetamine." 591.

creates an almost 24 hour high, while cocaine's high only lasts for 30 minutes.²⁸ In economic terms, for consumers, meth is a better product.

Then why hasn't meth already taken over the east coast? There are several possible obstacles that may have prevented meth's expansion and acceptance in drug using communities. The first is that meth is a relatively new drug. Meth has been around for the past 50 years but it was mostly made by individuals and outlaw motorcycle gangs. In 1989, this all changed when the Amezcua brothers in Mexico industrialized the meth trade.²⁹ Small-time operations were able to churn out a couple of grams for personal use and small-time dealing, but the Mexican cartels took production to a new level, where so-called "super labs," could make up to ten pounds of meth in a 24 hour period.³⁰ Cocaine and heroin addicts already have their preferred products. It could be that these goods are not that instantly interchangeable and that it takes time for addicts to develop a new preference.

Another explanation is that the stigma that surrounds meth, that it is a poor, white person's drug, has limited its expansion into major cities in the east. Meth has peculiar roots and populations with which it is associated. On the one hand, meth was used as a way to stay up while working; the "blue-collar working drug that allows you to provide for your family." From this meth moved into lower class white social networks. On the other hand, meth acts like a club drug like ecstasy. It is favored on the club scene because it allows individuals to stay awake and party for days without sleep, and it is particularly popular in the gay community. Between these two populations and associations, meth has so far missed a large portion of users.

Prah. "Methamphetamine." 591.
 Byker, Carl. "The Meth Epidemic." *PBS Frontline*, February 14, 2006.

³⁰ Prah. "Methamphetamine." 592.

A third explanation could be what some law enforcement officials believe, that meth yields lower profits than cocaine.³¹ This point is disputed however, and some officials believe that in the long run, "meth's affordability and ease of production, along with its long lasting effect, will pave the way for its acceptance in almost any community."³²

Ultimately though, because it is a superior product, meth is likely to beat out cocaine and heroin. Social and economic factors may limit its spread today, but as users look for greater highs and as competing drug traffickers look for ways to edge into an established market, meth will likely spread east and increase its market share. Former Executive Director of the United Nations Office on Drugs and Crime (UNODC), Antonio Costa, has said that, "in the period ahead, the use of synthetic drugs may become the most serious problem ever faced." Sandro Calvini, the former head of the U.N. anti-narcotics program in Colombia, agrees:

Cocaine has no future. Wherever amphetamines and synthetic drugs have arrived onto the market, such as China, Southeast Asia, Mexico, then there is always a big boom and it replaces everything, cocaine, heroin, the lot. It is a pill that looks like an aspirin and is much more user-friendly, it works fast and doesn't involve the paraphernalia of injecting or sniffing, a much better kind of drug- more dangerous but it works.³⁴

Because meth is so dangerous and because it has the potential to get much worse, a strategy must be developed and implemented to stop an epidemic.

Why Supply Reduction?

If an effective strategy is necessary, what should that strategy include? In order to limit the availability of methamphetamines in the U.S. and ultimately reduce use, a supply reduction approach must be taken. Demand reduction is an important part of a complete solution.

Prevention, through the education of children and young adults, and treatment, through

³¹ Washington/Baltimore HIDTA Futures Unit. "Methamphetamine: A Unique Threat to Law Enforcement." 3.

³³ Gary Roberts. "The Emergence of ATS." UNODC Global Youth Network.

³⁴ Misha Glenny. McMafia: A Journey through the Global Criminal Underworld (New York, Knopf, 2008). 262.

medically proven programs, are both necessary to truly solve the drug problem in the United States. Prevention and treatment are generally cheaper and more cost effective than supply reduction strategies but they cannot entirely remove the problem. If the United States government spent all of its money on treating addiction and educating children to stay away from drugs but did not attempt any supply reduction, we would still have drug addicts in this country. Drugs would be cheaper and more available than ever and the temptation and ease of access would be too great. However, it should be noted that even if we could eliminate 99% of the supply of drugs, drug addicts would still seek the now more expensive drug. Demand reduction and supply reduction must go hand in hand and must be included in a comprehensive strategy. One without the other does not solve the problem.

Supply reduction is the focus of this paper because of how effective it can be against meth, even though the track record of supply reduction efforts executed by the United States government is dismal. Despite the U.S. spending billions of dollars each year, in addition to the contributions of other countries, the price of drugs (except for marijuana) fell from 1981 to 2007, and in most cases, the purity of drugs rose during that same time period. This indicates a greater availability of drugs in the U.S. While there have been recent successes in Colombia, the effort has taken decades and includes a "state-building" approach that is not feasible for the United States to implement in every country, nor timely given the nature of the problem.

Despite this, the strategy against meth recommended in this paper is a supply reduction of a different kind. The majority of the funding for supply reduction in the U.S. goes towards eradication programs, building law enforcement capacity in other countries, and supplying our allies with the equipment to catch and bring down drug traffickers. The strategy outlined in this paper focuses on the implementation of regulations. Beyond the need to hire government

³⁵ Fries. 2.

officials to collect forms from legitimate business persons and investigators to verify registration and compliance, regulations carry little cost. Meth's characteristics make it uniquely susceptible to supply reduction in the form of regulations. Unlike many supply reduction strategies which aim to reduce the supply of drugs by small margins and simply end up pushing production of trafficking to other regions, the strategy outlined against meth in this paper has the ability to severely limit the supply to the point where it is implausible for the drug to exist as a part of normal society. By implementing regulations, we could almost completely eliminate the supply of meth and so deserves significant attention.

An International Approach

Methamphetamines pose a significantly different problem to law enforcement and policymakers than cocaine and heroin because it is a synthetic drug. Cocaine is derived from the coca plant, which is grown only in Colombia, Peru, and Bolivia. We can send in the military to eradicate coca fields, we can set up investigations of the criminal organizations based in the Andean Region, and we can track shipments leaving this area because geography plays a major role in the production of cocaine. Heroin is similar although not as limited. We know it is produced in Afghanistan, Burma, Mexico, and much of South America.

Meth is not dependent on a geographic area, but it is dependent on specific precursor chemicals.³⁷ These chemicals include phenylpropanolamine (P2P), ephedrine, and pseudoephedrine. P2P has been identified as a dangerous drug which can cause hemorrhagic stroke.³⁸ In light of this fact, the U.S. Food and Drug Administration (FDA) issued a public health advisory in November 2000 requesting all drug companies to discontinue products with

³⁶ United Nations Office on Drugs and Crime. World Drug Report 2010. United Nations Publication, 2010. 161.

³⁷ United Nations Office on Drugs and Crime. *World Drug Report 2010*. United Nations Publication, 2010.

³⁸ Drug Enforcement Administration. "Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine." *Federal Register* 75 (7 March, 2010): p. 38916.

P2P.³⁹ Most companies complied but the FDA codified their recommendation in December 2005 when they categorized P2P as Category II, nonmonograph, "not generally recognized as being safe for human consumption".⁴⁰ As a result, P2P is only used in the U.S. for rare veterinary purposes.⁴¹ Likewise, the wide-spread use of ephedrine has declined due to the introduction of pseudoephedrine in over-the-counter medicines. Ephedrine can be used by anesthesiologists in hospitals and as prescription and non-prescription medicine to treat asthma.⁴²

While these two drugs, P2P and ephedrine, still pose a potential risk for diversion for the production of meth, the main source of the problem comes from pseudoephedrine (PSE). PSE is a widely used and very popular decongestant found in over-the-counter cold medicines such as Sudafed. PSE's danger comes from its wide availability. Virtually anyone can go into a local pharmacy and purchase PSE.

Because PSE is at the crux of methamphetamine production, it presents an opportunity for law enforcement and policymakers to limit the availability of meth by regulating PSE.

Limiting the availability of PSE for meth producers (also called batchers) requires two types of regulations, at the international level and at the U.S. domestic level. Meth has two main sources, from super labs found in Mexico and from small time batchers found through the U.S. The percentage that comes from each source varies from year to year. In 2007, it was estimated that 80% of the meth in the U.S. came from the Mexican super labs. Between 2007 and 2009, production shifted to small-time batchers in the U.S. as the Mexico moved to limit the

³⁹ Drug Enforcement Administration. "Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine." p. 38916.

⁴⁰ Ibid.

⁴¹ Ibid.

⁴² Ibid.

⁴³Celinda Franco. "Methamphetamine: Background, Prevalence, and Federal Drug Control Policies." *Congressional Research Service*. January 27, 2007.

availability of PSE.⁴⁴ However, in 2010, another shift was noticed. Mexican traffickers have found ways to subvert domestic controls on PSE and small-time batchers have been thwarted by increased efforts by American law enforcement agencies.⁴⁵ This balance could easily change so any comprehensive strategy that seeks to substantially limit the availability of meth in the U.S. must address both sources of the drug in order to have an impact.

The International Narcotics Control Board

The international drug control system is made up of three organizations, the Commission on Narcotic Drugs (CND), the United Nations Office on Drugs and Crime (UNODC), and the International Narcotics Control Board (INCB). These institutions are housed in the United Nations under the Economic and Social Council and receive their mandate from three international conventions, the 1962 Single Convention, the 1971 Psychotropics Convention, and the 1988 Trafficking Convention. The CND is the "central policy-making body" for the drug control system and is responsible for policies at the international level. The CND analyses the world drug situation, monitors the UNODC, and develops proposals for the UN Economic and Social Council in regards to drugs. The UNODC coordinates and assists the efforts of national governments in international drug control. The UNODC seeks input from Member States and publishes a strategy each year to direct the drug control efforts of national governments. The INCB is an "independent, quasi-judicial expert body" and is responsible for monitoring the implementation of the three conventions by national governments.

⁴⁴ National Drug Intelligence Center. "National Methamphetamine Threat Assessment." U.S. Department of Justice.

⁴⁶ International Drug Policy Consortium. "Global Drug Control System." 2011.

⁴⁷ Ibid.

⁴⁸ International Drug Policy Consortium. "Commission on Narcotic Drugs (CND)." 2011.

⁴⁹ United Nations Office on Drugs and Crime. "The Commission on Narcotic Drugs: its mandate and functions."

⁵⁰ International Drug Policy Consortium. "UN Office on Drugs and Crime (UNODC)." 2011.

³¹ Ibid

⁵² International Drug Policy Consortium. "International Narcotics Control Board (INCB)." 2011.

The INCB is made up of 13 individual members who serve independent of the interests of national governments or the U.N.⁵³ Three of the members are chosen from a list proposed by the World Health Organization (WHO) and the rest are nominated and elected by the Member States on the Economic and Social Council.⁵⁴ The INCB is really only an information collecting agency and has no real power that it has ever exercised. The INCB's greatest tool has been the reports it produces each year. The INCB names parties that have not fulfilled treaty obligations.⁵⁵ Technically speaking, the INCB can recommend the sanction of nations to the CND and Economic and Social Council for not complying with the treaties.⁵⁶ These sanctions have never been issued but could include orders to stop importing from or exporting to a particular nation.⁵⁷ While unwilling to impose sanctions on nations, the INCB does use its role as the information collector to engage in long-term monitoring of precursor chemicals and to assist short-term tracking and enforcement.

Long-term Monitoring

In order to track long-term trends in the diversion of precursor chemicals, the CND passed a resolution in March 2006 that requests Member States to provide annual estimates of "their legitimate requirements for ephedrine, pseudoephedrine, 3,4-methylenedioxyphenyl-2-propanone (3,4-MDP-2-P) and 1-phenyl-2-propanone (P-2-P)". The purpose of this exercise is to provide an indicator to exporters of these precursor chemicals what quantity each country should be receiving. Member States calculate their legitimate needs by adding their medical

⁵³ International Drug Policy Consortium. "International Narcotics Control Board (INCB)." 2011.

⁵⁴ Ibid.

⁵⁵ Ibid.

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ International Narcotics Control Board. "Annual legitimate requirements for substances frequently used in the manufacture of amphetamine-type stimulants (ATS)." 2011.

needs, scientific and research needs, industrial needs, imports and re-exports, and reserve stocks. ⁵⁹

As of January 28, 2011, there were 125 participating governments reporting their legitimate requirements of the three precursor chemicals. ⁶⁰ The two nations with the largest reported legitimate requirement of pseudoephedrine were the United States and China with 390,000 kilograms and 160,000 kilograms respectively. 61 The next largest reported amount required for legitimate use was the Republic of Korea with 66,000 kilograms. 62 The amounts required by each country are posted online and updated if there are any changes. The list of legitimate requirements allows exporters to identify suspicious transactions. For instance, if an exporter rarely receives requests from Portugal but over the course of several weeks receives requests that amount to 50 kilograms, the exporter can check the INCB reported requirement list. The exporter would see that Portugal only requires 15 kilograms annually and that in all likelihood, the amount that has been requested will be diverted for illicit purposes. 63 The exporter can then alert the authorities and the INCB and further action can be taken. Exporters have an incentive to notify the INCB because they do not want to be labeled as a source for the diversion of pseudoephedrine. For instance, if the INCB, through its annual report, labels India as a source for pseudoephedrine and blames the pharmaceutical industry there for not checking exports well enough to prevent diversion, India could face international repercussions. While it is unlikely to face fines, this label could affect the aid India receives or the business transactions

⁵⁹ International Narcotics Control Board. "Issues that Governments may consider when determining annual legitimate requirements for ephedrine and pseudoephedrine."

⁶⁰ International Narcotics Control Board. "Annual legitimate requirements reported by Governments for ephedrine, pseudoephedrine, 3,4-methylenedioxyphenyl-2-propanone, 1-phenyl-2-propanone and their preparations." January 18, 2011.

⁶¹ Ibid.

⁶² Ibid.

⁶³ Ibid.

conducted with Indian companies. Even though Indian companies would still make a profit from illicit sales, they still have an interest in making legal sales whenever possible.

Additionally, this system helps the INCB monitor worldwide trends in diversion. If at the end of the year, the INCB realizes significantly more has been shipped to Chile than Chile says it requires, the INCB can focus its efforts. The INCB can help Chile increase its customs enforcements and it can let exporting nations know they should be cautious about receiving requests from Chile.

Short-term Tracking and Enforcement

In addition to monitoring long-term trends, the INCB facilitates a system of Pre-Export Notifications (PEN). The INCB has created an online system whereby exporter nations can submit notifications of shipments to the governments of the destinations of precursor chemicals. Governments of importing countries are asked to submit notification regardless of suspicious activity and regardless of whether the importing nation has requested documentation. The purpose of PEN is to identify suspicious activity, such as when there are particularly large shipments requested by an individual importer, and to establish the identities of importers. Creating this record facilitates the operations of law enforcement.

One of the most useful products of the INCB PEN system has been Project Prism. In June 2002, the INCB called together the U.S. Government and the European Commission to discuss precursors of Amphetamine-Type Stimulants (ATS).⁶⁶ Out of this meeting of representatives of 38 countries, Project Prism began by creating a network of national authorities

⁶⁴ United Nations Information Service. "PEN Online (Pre-Export Notification)." 2011.

⁶⁵ International Narcotics Control Board. "Measures to Enhance the Control and Monitoring of Precursors Frequently Used in the Manufacture of Illicit Drugs." Recommendations by the International Narcotics Control Board. 1998.

⁶⁶ World Customs Organizations. "Enforcement and Compliance- Responsibilities: Drugs and Chemical Precursors." 2011.

on this issue.⁶⁷ Project Prism has focused on the "five major stimulant precursors (ephedrine and pseudoephedrine for methamphetamine, P-2-P for amphetamine, 3,4-MDP-2-P and safrole for Ecstasy)."⁶⁸ Project Prism provides a method for law enforcement to collaborate on the diversion of precursor chemicals⁶⁹ and relies directly on the use of information received from PEN.⁷⁰

In 2010, the INCB coordinated Operation PILA through Project Prism, which focused on ephedrine and pseudoephedrine and tracked shipments "to the Americas, Africa, Oceania, and West Asia" that were diverted for the production of amphetamine-type stimulants. Under Operation PILA, authorities learned that the leading source of precursor chemicals that are diverted is India, giving the strong indication that China's efforts to crack down on diversion have worked. This operation also revealed that Mexico remains the primary destination of diverted pseudoephedrine despite the ban on importation that the Mexican government has imposed.

Limitations of the INCB System

The INCB system should be applauded for its efforts. The INCB tracks long term trends which allow Member State governments to address issues in diversion patterns. The INCB also facilitates the efforts of law enforcement and brings together different national law enforcement agencies that might not otherwise collaborate on diversion investigations. However, the INCB is the only worldwide precursor chemical control regulatory body and has significant flaws that

⁶⁷ World Customs Organizations. "Enforcement and Compliance- Responsibilities: Drugs and Chemical Precursors."

⁶⁸ Ibid.

⁶⁹ International Narcotics Control Board. "Annual Report of the International Narcotics Control Board Focuses on Relationship between Drug Abuse, Crime and Violence at Community Level." March 3, 2004.

⁷⁰ United States Department of State Bureau for International Narcotics and Law Enforcement Affairs.

[&]quot;International Narcotics Control Strategy Report" Volume I Drug and Chemical Control. March 2011.

⁷¹ Ibid.

⁷² Ibid.

⁷³ Ibid.

allow diversion to occur. Despite the successes of the INCB, more must be done to effectively limit the availability of precursors for diversion.

The inherent flaw of the INCB system is that it depends on the capability of cooperating Member States. No state participating in the INCB wants to be labeled as corrupt or as a significant source of diverted pseudoephedrine. This could have dire foreign policy implications. While the intentions of states may be to control the pseudoephedrine trade, in many cases, this might not be possible. For countries like India, the flow of exports may be too great to accurately notify importers and for other nations, the resources may not exist to handle the flow of precursor chemicals. The real problem is not with exporter nations. Pseudoephedrine is only produced in India, Germany, the Czech Republic, and China in only a small number of labs. Pseudoephedrine is a complicated chemical to make and it requires significant knowledge and vast infrastructure to successfully make it. These nations and small number of producers have an interest in complying with current regulations. They do not want to be seen as the supplier of meth to the world.

Poorer nations and their inability to effectively manage the pseudoephedrine trade pose the most significant threat to the INCB system. These poorer states are the ones criminal organizations use to divert precursor chemicals. India may send a PEN to Panama, but when the diverters ship the chemicals from Panama to Costa Rica, a PEN may not be sent, and if not at this stage of the process, then at several shipments down the line. At each stage, diverters can change the company name so that the PEN does not track the same person or company. Intermediaries create the greatest problem for the INCB system. While major exporter and importer nations have the capability, the will, and the resources to track these shipments, smaller,

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⁷⁴Steve Suo. "Clamp down on shipments of raw ingredients." *The Oregonian*. October 6, 2004.

poorer countries do not. Add to that the corruption that exists in much of the world, and suddenly the system can easily be subverted.

But, isn't the INCB system designed to detect subversion and diversion patterns? The legitimate requirement reporting system tracks long term trends but it is slow. It may be an entire year before the picture of which country is receiving too much pseudoephedrine becomes clear. By this time, the diverters will have changed their pattern and law enforcement will be at a loss to stop their actions.

The short-term tracking found in the PEN system works better to prevent diversion. This system can show law enforcement a pattern quickly so that they can act. However, this system can be subverted by changing the name of the importer/exporter between countries. This system is still voluntary and not all transactions may be recorded in poorer, more corrupt nations.

The chink in the armor of the INCB system is that when one nation fails, the system can be infiltrated. One nation that inconsistently uses the PEN system can allow diverters to act with impunity. Add to this the constant threat of traffickers changing the name or description of their product between ports, and the problem intensifies. Suddenly the shipment of pseudoephedrine that arrived in Panama from India becomes cough drops destined for Mexico. With this gap in the system, international regulations can easily be exploited.

Drug Enforcement Administration registration for U.S. bound imports

An alternative system of regulation has been set up by the DEA. The DEA receives its authority from the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substance Act (CSA).⁷⁶ The DEA has the responsibility of regulating a closed

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⁷⁶ Drug Enforcement Administration. "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine." *Federal Register* 75 (5 March, 2010): p. 10168.

system for controlled substances.⁷⁷ This means that any person manufacturing, distributing, dispensing, importing, exporting, or conducting research with controlled substances must obtain a DEA registration and "comply with the applicable requirements of the activity." The CSA establishes the well-known schedules of drugs. Under the scheduling system, drugs such as meth, heroin and other illicit drugs⁷⁹ are classified as Schedule I for having a high potential for abuse and no accepted medical use. Pseudoephedrine, ephedrine, and P2P are authorized for legal use and are instead considered listed chemicals, governed by the Chemical Diversion and Trafficking Act (CCDTA) of 1988.80

The Combat Methamphetamine Epidemic Act of 2005 (CMEA), signed into law on March 9, 2006 as Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 establishes the most current version of the regulatory system. 81 Regulations state that importers must provide DEA with advance notification of any import of listed chemicals. 82 The requirement for notification is satisfied when the importer submits DEA Form 486 A to the Import/Export Unit of the DEA, "not later than 15 days prior to the importation." The importer must provide information on "the chemical (name, size and weight of the container, number of containers, total weight of chemical), importation (date, foreign port of shipment, United States port of entry) and the foreign supplier (name, address, contact information)."84 The purpose of this regulation is to document each transaction so that the DEA can establish patterns and

⁷⁷ Drug Enforcement Administration. "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine." p. 10168.

⁷⁹ Cocaine is currently listed as a Schedule II drug for its limited medical use.

⁸⁰ Drug Enforcement Administration Office of Diversion Control. "List I and List II Chemicals."

⁸¹ Drug Enforcement Administration. "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine." p. 10168.

⁸³ Drug Enforcement Administration. "Section 1313.12 Requirement of authorization to import." Federal Register 75 (9 March, 2010): p.10683

⁸⁴ Drug Enforcement Administration. "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine." p. 10168.

information about trading parties and recognize when diversion occurs. This regulation also gives the DEA notice so it can stop a shipment that it believes is likely to be diverted. For importers who meet DEA criteria of being a "regular importer of listed chemicals," notification is only due by the date of importation. ⁸⁵ This is to help ease the trade of these chemicals for importers who have earned the trust of the DEA, while still establishing information to help with investigations.

The CMEA also establishes specific guidelines for the transfer of pseudoephedrine, ephedrine, and P2P. In addition to notification prior to importation, an importer must provide personal information as well as transfer specific information from whomever the importer is transferring the chemicals. ⁸⁶ If the person transferring chemicals is not a regular customer of the importer, the importer must notify the DEA no less than 15 days prior to the transaction. ⁸⁷ If after this notification the quantity changes, or if the transferring party changes, the importer is required to notify the DEA and wait another 15 days. ⁸⁸ These regulations give the DEA time to investigate unknown brokers and traders and establish information about who is handling these chemicals. These same requirements are also placed on exporters of these chemicals that are based in the U.S. ⁸⁹

In addition to requiring registration and notifying the DEA, the regulations set forth under the CMEA grant the DEA broad powers to investigate the "chain of distribution" of pseudoephedrine, ephedrine, and P2P. The CMEA requires that the importer "shall include all information known to the importer on the chain of distribution of such chemical from the

⁸⁵ Drug Enforcement Administration. "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine." p. 10168.

⁸⁶ Ibid.

⁸⁷ Ibid.

⁸⁸ Ibid.

⁸⁹ Ibid.

manufacturer to the importer."90 Further, the Attorney General may ask foreign manufacturers and distributors to "provide information known to them on distribution of the chemical, including sales." If the foreign distributor or manufacturer fails to comply, the Attorney General can prohibit the importation of pseudoephedrine, ephedrine, and P2P from these entities. 92 The prohibition takes 60 days to be implemented but effectively makes it illegal for U.S. importers to import from these persons or companies.

Benefits and limitations of the DEA system

The DEA system of regulation is very strong. It effectively tracks the transfer of any pseudoephedrine, ephedrine, or P2P in or out of the United States. The system establishes known information about the handlers of the drugs and requires them to register. This means that if investigations of diversion need to take place, details and whereabouts of the parties involved are immediately known. The system also bars the entry of unknown or fly-by brokers or dealers. This means that criminal organizations entering the market looking for a quick way to divert pseudoephedrine cannot effectively do so. The company must be established, apply for a DEA registration and report to the DEA when shipping, and would still face greater scrutiny until it passes the threshold of a "regular customer" for the importer or exporter. For most criminal organizations looking to divert chemicals, allowing the DEA to investigate the workings of your fake or illicit company does not seem like the best way to avoid attention. Further, the newest provisions of the system allow the DEA to back track through transfers of these chemicals. The DEA can better establish patterns and dealers and begin to get a hold on the diversion of precursor chemicals.

⁹⁰ Drug Enforcement Administration. "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine." p. 10169.

⁹² Ibid.

However, the brilliance of the DEA system stops when we realize that the U.S. is only half (sometimes more, sometimes less) of the problem. In the U.S., the problem is not when the chemicals enter the ports, but when they are sold over the counter.

Most transfers of these precursor chemicals involving the U.S. are probably licit because of these stringent procedures and so, when the DEA investigates the distribution channels, it is most likely seeing legal transfers of these chemicals. The DEA system is limited because a significant amount of the problem comes from the transfer of the precursor chemicals to other countries. Brokers and dealers can subvert the power of the DEA by never dealing directly with the U.S. A trader can buy from India shipping to Chile and smuggle to Mexico, rather than subjecting himself to the DEA.

Finally, like all trade regulations, the DEA system falls prey to false identification of cargo. If a trader buys from India intending to sell to another country, but ships to the U.S. stating that his goods are Viagra, the criminal has avoided the U.S. system while shipping his goods. The practice of falsifying records surely has a greater risk and probably increases the pay for the illicit broker, but, is still an effective way of transferring pseudoephedrine, ephedrine, and P2P while avoiding the threat of the DEA.

A past attempt and a disconnected comparison

Gene Haislip, former head of the DEA's Office of Diversion Control, pioneered precursor chemical controls in the 1980s and was on the forefront of the initial effort against methamphetamines. Haislip compares the meth problem to the Quaalude epidemic the DEA eliminated during the 1980s. Quaaludes, methaqualone by its medical name, are a depressant that was legally manufactured in the United States but began to be abused by teenagers in the

1970s. 93 By 1981, Quaalude abuse was second only to marijuana and an estimated eighty to ninety percent of methaqualone production went into the illicit market. 94 Haislip believed that the solution to the problem was approaching manufacturers. 95 Haislip went to South America, where he found that most of the supply was coming from factories in Germany, Austria, Hungary, and China. 96 Haislip gathered evidence of how the drugs were diverted and the consequences of their use and met with the manufacturers individually. 97 In fear of being held culpable, manufacturers began decreasing production. 98 At this time, doctors quit prescribing methaqualone because of its addictive properties and within a few years, Quaaludes had no legitimate use and ceased to be produced.⁹⁹

Haislip believed that the same tactic could be used against meth by approaching the manufacturers of pseudoephedrine. 100 He had some success with producers who sold the precursor chemical in powder form. ¹⁰¹ These companies realized that accidentally selling huge quantities of raw pseudoephedrine could endanger their image and they restricted their sales at the request of the DEA. The challenge to Haislip's request came from the producers of the pill form of pseudoephedrine. Meth batchers switched from using the raw powder form of the drug they bought from wholesalers to buying the individual packets of Sudafed and other drugs. The individuals who go around, buy the drugs and pop out the pills are called "smurfers" because they are doing such a monotonous task. The major producers of these drugs in the

⁹³ PBS Frontline. "The Quaalude Lesson." February 14, 2006.

⁹⁴ Ibid.

⁹⁵ Ibid.

⁹⁶ Ibid.

⁹⁷ Ibid.

⁹⁸ Ibid.

¹⁰⁰ PBS Frontline. "Interview Gene Haislip." February 14, 2006.

¹⁰¹ Ibid.

pharmaceutical industry resisted new regulations because the evidence against them was much more indirect.

Haislip's concept for the solution to the meth problem is well-intentioned but perhaps naïve. There are some key differences between the Quaalude example and pseudoephedrine (PSE). PSE is a vastly more popular drug that is used in over-the-counter medicines worldwide. It is a brand name and is one of the biggest advances in the cold and flu industry in years. It is not a drug that can be scared away. It is too much of a cash cow for the pharmaceutical industry. Quaaludes were never as widely used. They had to be prescribed by a doctor and evidence was emerging that they were addictive anyway. It is inconceivable to imagine a total elimination of the use of pseudoephedrine. The United States and the world seem too dependent on the drug and would not stand for its removal.

The need for a new system

The current regulatory regime in place has two arms. The first, operated by the International Narcotics Control Board (INCB), is wide reaching, but very weak. The INCB does not have the mandate to enforce; it is an information collecting agency. The INCB system provides a mechanism for national law enforcement but it can easily be subverted by brokers between nations and by targeting nations with weak customs enforcement. The second arm, operated by the DEA, is strong and incorporates much of what a truly effective system needs. However, it is focused only on goods to and from the United States. The DEA lacks a mandate to expand abroad and without that, it cannot be an effective regulatory system.

Unfortunately, wishing away pseudoephedrine or scaring its producers into limited use is not an option. Instead, a middle ground must be found that allows for the trade of these necessary chemicals while preventing diversion. Without changes to the system, the current

state of diversion will remain or worsen, as criminal organizations find new ways to exploit the current regime.

The most effective way to achieve this would be to implement a DEA-style system on a worldwide scale. Implementing a stronger system globally would solve the current deficiencies in the regulatory system. While there would be obstacles to implementation of this new system, there is sufficient political will to create it.

Information and transparency are the keys to a successful regulatory system. A new approach should be able to identify all handlers of the precursor chemicals, including producers, exporters, brokers, traders, shippers, importers, and recipients. The new system should be able to track the shipment of the dangerous goods, so that if it is diverted, the point at which this happens is known and the parties responsible identified.

A system of international registration

To achieve this, there would need to be an international registration of all parties. Like the DEA system where all importers and exporters are required to register, international actors would have to do the same. This would enable law enforcement collaborative efforts, like Project Prism, to have access to information on the parties involved in transactions. Registration would rid the market of criminals looking for a quick diversion scheme. The process would have to be extensive enough to establish that the trading entity was legitimate.

Ideally, the process of verification would be executed by an international body, such as the INCB. Since this function is not within the mandate of the INCB, new legislation would have to be drafted and ratified; this obstacle will be discussed later. Like nation states, this regulatory authority coming from an international body would be subject to corruption. However, unlike the leaving the responsibility of monitoring pseudoephedrine exports to the

national governments, less corrupt nations, such as the United States, would have a greater involvement in the international body than they would influence over national governments. Because the U.S. would have an interest in making this system work, it could demand greater accountability from the organization. Unlike other international organizations, which support the goals of the U.S. abroad, this organization would directly affect U.S. national security. This would give the United States incentive to keep this organization as corruption free as possible.

The purpose of registration would be to create a closed system, so that no independent trader could operate outside of it. By doing so, there would be no unknown information. If diversion occurred, information would be immediately on hand to assess the situation.

Notification

Similar to the DEA system, exporters, importers, and brokers would need to notify the governing international body 15 days prior to all transactions. This would give the regulating body time to verify the legitimacy of all transactions while maintaining enough timeliness for the trade of the precursor chemicals to occur. Like the DEA system, actors who established trust by meeting certain criteria of being a regular user would be exempt and allowed to give short notification.

Notification would especially benefit the international system because if a database were established that tracked all international transactions, then the list of government reported legitimate requirements of precursor chemicals would become incredibly useful. An up to date system would allow the INCB to effectively identify where pseudoephedrine is imported legally but diverted after reaching the port. The INCB would immediately recognize whether a country has imported a significant amount more than it officially requires, indicating that that nation could be diverting precursor chemicals after the point of sale.

An international notification system could improve upon the DEA model by requiring notice of when shipments of precursor chemicals are exported and when they are received. This would establish accountability at every step of the process. A container full of pseudoephedrine could be followed from the manufacturer to the exporter, from the exporter to the broker, from the broker to the importer, and from the importer to the end user. This way law enforcement would know immediately when the chemicals were diverted. This would help to stop the mislabeling of precursor chemicals because if a shipment arrived at a port and did not contain the specified chemical, law enforcement would be able to identify where in the chain it would have been switched.

This idea is comparable to the use of end-user certificates (EUC), which are required in the trade of small arms and light weapons. ¹⁰² In many countries, including the United States, a company exporting weapons must obtain a license from the government before it exports any goods. ¹⁰³ When this license is issued, it usually includes an EUC instructing the receiving party not to re-export the good. ¹⁰⁴ Governments use this mechanism to protect national security and stop certain technology from ending up in embargoed states. Like EUCs and the arms trade, the international system to control pseudoephedrine would attempt to track the movement of the good at each step of the way.

Penalties

The DEA regulations are so powerful because of the penalties non-compliance can create. The DEA has the ability to block an importer from trading with the U.S. if it fails to

¹⁰² Bromley, Mark and Hugh Griffiths. "End-User Certificates: Improving Standards to Prevent Diversion." Stockholm International Peace Research Institute. March 2010. 1.

¹⁰⁴ Ibid.

provide specific information. Additionally, criminal and civil penalties can be imposed if the trader knowingly diverts these precursor chemicals. .

In order to be effective, an international system would have to carry the same weight. An international regulatory body would need the ability to block nations or individuals who fail to comply. This would be a strong incentive to cooperate with the regulatory regime. The prospect of being excommunicated from the trade of these chemicals would compel nations and individuals to follow the rules and report correctly. This would mean that any legitimate business person would not risk working with criminals or face losing his entire livelihood and business. Nations would be compelled to cooperate if further penalties could be imposed on them. Nations defying the regime could be blocked out of the trade of these precursor chemicals. If investigators of the international body repeatedly found that Panama was not in compliance and that the Panamanian government was not open to increasing its efforts with the help of the international community, this regime could effectively shut them out of the market. The weight of this penalty would force nations to comply. This would also force them to reduce corruption or risk being barred from this trade.

Obstacles to implementation

If the just described system of regulations would benefit the international community so much, then why wouldn't nations come together and implement it? There are a number of reasons this solution has not occurred. First and perhaps most prominently, is the structural nature of the drug problem. Drugs, like crime and disease, tend to fade into the background of problems that people face, unless there is a crisis. Drugs can easily become a part of everyday life. People know that there are a set of individuals who use drugs. People are unaware that

37,777 people died from drug-induced causes in 2008.¹⁰⁵ As long as the numbers of drug abuse and deaths stays consistent from year to year and there is no sharp increase, there is no crisis to rally people. When people aren't rallied behind a cause, there is usually little political capital. When this happens, major reforms like the system described are unlikely to happen, even though they could essentially eliminate the problem.

More than lack of call for reform, the system described contains many fundamental issues that inhibit its implementation. The first is the question of funding. Where are the funds expected to come from for this regulatory system? How much will this cost and how will that cost be divided? Should the U.S. pay more because it has the worst meth problem? These are all very valid, specific questions that complicate the implementation of this proposal.

Another logistical complication this system would face would be the size and breadth of exporters, traders, broker, and importers, that registration would have to cover. The international body governing this regulatory system could receive so many requests that it would be difficult to fully implement the regime at once. Conducting background checks on each registrant could become cumbersome; the entire process may have trouble getting off of the ground. This issue is directly related to funding. How many agents would be employed by this international unit? The size of the regulatory body would determine how effective it is. As experts in the field of U.S. export compliance often state, if you triple the number of compliance officers, you'd triple the number of fines issued. The amount of funding and the size of the organization would determine how effective regulations could be from the start.

In addition to handling the registration of legitimate businesses, the international system would surely receive false registrations for "straw companies" set up by organized criminal

¹⁰⁵Arialdi Miniño, Jiaquan Xu, and Kenneth Kochanek. "Deaths: Preliminary Data for 2008." *National Vital Statistics Report*. December 9, 2010. http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_02.pdf>. 45.

groups to legally obtain pseudoephedrine for the purposes of diversion. This is a serious concern and initially the flood of registration requests could be so large that organized criminal groups slip through the system as the international regulatory body attempts to register all companies while maintaining the supply of pseudoephedrine. However, the hope would be that after all legitimate companies are registered, the number of requests for registration would decrease. This would then give investigators registering companies the time to look into new requests. While straw companies still might be a problem after this point, organized criminal groups are probably less likely to allow themselves to be investigated by anyone. With a few small measures, such as visiting the actual company, investigators could determine if the business is real or a front. The investigators could request tax returns and monitor the actions of the trader or broker until them have established themselves as a legitimate company. This process would help weed out the presence of organized crime.

Who would run this new regulatory body? There are several options. The first is the U.S. DEA. The problem with this is that the DEA has no international authority and while in some cases countries are willing to cede sovereignty for America's "War on Drugs," there are too many actors in this system that would need to give up sovereignty to the DEA to allow them to stage investigations and so this is an unlikely scenario.

A more likely option is the INCB or another international agency created in the same vein as the UNODC and the CND. The system would need a new treaty as there is currently not one that gives a mandate to direct these described powers. The INCB seems like a likely candidate for control of this system. First, it already commands the current international system, however weak it is. Second, while it serves in the interest of all Member States, it is run by a set of individuals who are supposed to support the interest of the international organization rather

than his or her home state. This makes the INCB a more neutral institution. This is vital for a regulatory regime with such power. While it would be impossible for this body to be completely void of the interest of national interest, an organization like the INCB would work better than a single nation controlling the regulatory framework.

In addition to these practical problems, there exists the pushback that this proposal would almost certainly receive from the pharmaceutical industry and from sovereign nations. The pharmaceutical industry is against almost any regulation of its operations. In the United States, the pharmaceutical industry contributes more to political campaigns than any other industry. ¹⁰⁶

According to Center for Responsive Politics, they gave \$240,385,934 in 2010; the second highest was the electric utilities industry at \$191,304,085. ¹⁰⁷ The pharmaceutical industry is led by PhRMA (Pharmaceutical Research and Manufacturers of America), a lobbying organization that pulls together the interests of the top pharmaceutical companies in the U.S. ¹⁰⁸ PhRMA was always associated with the Republican Party in the United States but in recent years has contributed heavily to Democrats as well. ¹⁰⁹ This makes the pharmaceutical industry a powerful player in Washington politics and a significant obstacle to the implementation of an international regulatory system.

Nation-states would likely oppose this proposal to some degree given the imposition on their national sovereignty. The current system under the INCB is voluntary and no real penalty can be used. Why would nations enter into an agreement where they could be held more accountable?

¹⁰⁶ Center for Responsive Politics. "Top Industries." January 31, 2011.

¹⁰⁷ Ibid.

¹⁰⁸ Silverman, Ed. "Pharma: 'The Most Effective Lobby On Capitol Hill." *Pharmalot*. March 12, 2008.

¹⁰⁹ Ibid.

Leverage to make it possible

With these obstacles to implementation standing in the way of this proposed system, it would seem that a strong international regulatory system would never be able to exist. Despite these substantial problems, the conditions are right for a system to be implemented and these problems can be mitigated.

The view that drugs are a background issue that can never be addressed is cynical and would mean that drug control policy would never be implemented. However, we see that new measures are constantly adopted despite a lack of overwhelming political will. Instead of drugs just being a background issue, the meth problem is still a significant problem. While the public may not necessarily see it this way, more education is necessary to convince them that this is a vital issue.

In general, public consensus is not needed for every issue. Take for instance, the European Union (EU). This institution developed initially without the consent of the people of Europe, but it touched their lives in very profound ways through the regulations it imposed. Today, the EU has more democratic elements, but this demonstrates that a regulatory regime can exist without the express consensus of the public. As long as the regulatory system proposed does not severely impact the availability of these chemicals to everyday citizens, there will be enough permissive consent from the public for it to be implemented.

The final issue standing in the way of the implementation of a system such as this is whether there exists the political will to force an international treaty to create this system.

Pharmaceutical companies would oppose this new measure and they have incredible influence because of the money they contribute to political campaigns. However, they could be persuaded by demonstrating to them that this is a middle ground solution. Far more oppressive steps could

be taken by individual governments, such as banning the use of these chemicals entirely, which would severely hurt these companies. Political support for this proposal would need to be established throughout the United States. If this system was sold as a complete solution to such a severe problem, the American people could be brought along to support such a program. Together, if the politicians see that people support this and the pharmaceutical industry believes this is a small concession to stop even greater consequences, this proposal could pass in the United States.

If the United States supports this plan, the rest of the world will follow because the U.S. has leverage to implement this system. The U.S. represents 31.3% of the pseudoephedrine market share according the list of reported legitimate requirements. This means that if the United States demanded a more comprehensive system and threatened to restrict their use of pseudoephedrine, pharmaceutical companies would have to comply.

As for the concern that would surely be expressed by nations worried about their sovereignty, they would need to understand that diversion and the meth epidemic is a serious problem. Meth has the ability to enter every country and devastates its population through addiction and its negative effects. This is a preventative measure to stop the expansion of meth into other parts of the world. While selling nations on this idea may be difficult, demonstrating the struggle the United States has had with meth so far is evidence in support of why a comprehensive solution needs to happen now.

A domestic approach

Even if international regulations were fully implemented and effectively closed the supply of pseudoephedrine diverted to Mexico, a large enough supply would still be available in

¹¹⁰ International Narcotics Control Board. "Annual legitimate requirements reported by Governments for ephedrine, pseudoephedrine, 3,4-methylenedioxyphenyl-2-propanone, 1-phenyl-2-propanone and their preparations."

the United States over-the-counter that would allow meth to be produced. In 2009, there were 9,187 meth labs discovered by law enforcement in the United States.¹¹¹ Incidents range from a superlab, defined as labs that are capable of producing ten or more pounds in a single production cycle¹¹², to a house that burns downs while producing meth, to a large trash bag left on the side of the road containing the toxic materials the batcher has used to make the meth while driving. Domestic labs incidents appear to be on the rise at a significant rate; in March 2009, there were 966 meth lab incidents nationwide, compared to 756 incidents in March 2008 and 596 incidents in March 2007.¹¹³ The reason for the increase is likely the improved measures by the Mexican government to control pseudoephedrine. In 2007 Mexico announced a ban on the importation of pseudoephedrine and ephedrine for 2008 and a complete ban on use by 2009 of both chemicals.¹¹⁴

Across the country, methamphetamine production is conducted by outlaw motorcycle gangs and individuals who produce their own supply of meth for limited distribution. The majority of meth that is produced in the United States is produced in superlabs that are based in California. These large scale operations are supported by organized "smurfing" organizations, when individuals go into retail stores, buy the maximum amount of pseudoephedrine they can in the form of pills, and then proceed to pop the pills out of the blister packs. 116

Smurfing represents a significant problem for law enforcement and is the major source of pseudoephedrine for meth traffickers. The practice is so rampant in fact, that pseudoephedrine is

¹¹¹ Office of National Drug Control Policy. "Methamphetamine Trends in the United States." *Fact Sheet.* May 2010.

<sup>2.
&</sup>lt;sup>112</sup> National Drug Intelligence Center. "Situation Report: Pseudoephedrine Smurfing Fuels Surge in Large-Scale Methamphetamine Production in California." *U.S. Department of Justice*. June 2009.

¹¹³ Office of National Drug Control Policy. "Methamphetamine Trends in the United States." 1.

¹¹⁴ National Drug Intelligence Center. "Situation Report: Pseudoephedrine Smurfing Fuels Surge in Large-Scale Methamphetamine Production in California."¹¹⁵ Ibid.

¹¹⁶ Ibid.

smuggled south into Mexico to be used in the superlabs located there.¹¹⁷ The California Bureau of Narcotics Enforcement estimates that at least 50 percent of the pseudoephedrine sold in California is diverted for the illicit production of methamphetamine.¹¹⁸ Individuals are paid \$30 to \$35 for each box of pseudoephedrine they purchase for \$6.¹¹⁹

Past legislation

Law enforcement and policymakers fully recognized the consequences smurfing had on the meth epidemic and moved to end operations in 2005 with the Combat Methamphetamine Epidemic Act (CMEA) by placing requirement on retailers of pseudoephedrine, ephedrine, and P2P. 120 Under the new law, retailers are required to check the identity of each purchaser, including name, address, and signature, and maintain a logbook of sales, and limit the quantity sold to an individual to 3.6 grams per day and 9 grams over a 30 day period. The CMEA was certainly a step in the right direction; however, it did not go far enough to effectively control the diversion of pseudoephedrine. An individual is still able to go to multiple stores in a day. Organized smurfers can travel in packs, sending each person in one at a time to buy pseudoephedrine at a store, and then will move on to the retailer down the road. The CMEA requires a logbook be kept, but not that it is electronically accessible. In most cases, logbooks are on paper or are confined to the store's computer and so an organized group could easily travel from store to store and never be recognized as diverting the chemicals. Finally, where electronic records are kept and where diverters have reached their monthly allotment of pseudoephedrine, they use false identification.

¹¹⁷ National Drug Intelligence Center. "Situation Report: Pseudoephedrine Smurfing Fuels Surge in Large-Scale Methamphetamine Production in California."

¹¹⁸ Senator Diane Feinstein. "Senate Caucus on International Narcotics Control Holds Hearing on Methamphetamine and Making Pseudoephedrine Prescription Only." April 13, 2010. ¹¹⁹ Ibid.

¹²⁰ Ibid.

¹²¹ Drug Enforcement Administration. "Rules- 2006." Federal Register 71 (26 September, 2006): p. 56008-56027.

The CMEA left major loopholes for organized criminals involved in diversion to abuse. To correct these, many states have adopted their own measures. The two most popular methods have been electronic tracking systems and classifying pseudoephedrine as prescription-only. It is the opinion of this author that the prescription-only method is more beneficial and needs to be implemented nationwide.

The electronic tracking solution

The implementation of the CMEA and the failure of paper logbooks led directly to the idea of implementing an electronic system to track pseudoephedrine purchases. 122 Law enforcement reasoned that if the information were located in one place, it could be used as a powerful tool against diverters. 123 Oklahoma was the first state to implement an electronic tracking system in 2006, followed by Arkansas and Kentucky. 124 Despite the implementation of this system in these states, the production of methamphetamine continued with little disruption. Kentucky deployed its system in 2008. The year before its introduction, there were 309 lab incidents in Kentucky. In 2008, there were 427 lab incidents and in 2009 there were 716. 126

The electronic tracking system is ineffective for a number of reasons. First, there is inconsistency among retailers that provide substantial discord in the system. Some retailers require approval from their central office and the inconsistent implementation of the system has stymied its ability to function. Second, the system can be subverted by traveling to multiple states. In the case of Kentucky, which borders seven states, this can present a real problem. If the other states do not have comparable system or if the systems do not integrate to show when

¹²²Kent Shaw. "The Status of Meth: Oregon's Experience Making Pseudoephedrine Prescription Only." April 13, 2010.5.

¹²⁴ Senator Diane Feinstein. "Senate Caucus on International Narcotics Control Holds Hearing on Methamphetamine and Making Pseudoephedrine Prescription Only." ¹²⁵ Ibid.

¹²⁶ Ibid.

an individual is going between borders, then diverters can easily obtain the pseudoephedrine they need. Additionally, similar to the logbook, false identification is a serious concern for electronic tracking. California implemented a limited electronic tracking system in part of the state. After collecting the information and reviewing it as part of an investigation, law enforcement officials determined that 70 to 80 percent of identifications they received were false. This reality renders the electronic tracking system completely ineffective at stopping the diversion of pseudoephedrine.

But, even if these deficiencies were overcome and the system fully implemented as planned, it would only be retroactive and wouldn't prevent diversion. The electronic tracking system is meant to develop a database for law enforcement to use for investigations. When they see that an individual has purchased above the monthly allotment, they can arrest him. They can also investigate individuals who have purchased just under the limit but tend to do so each month. The problem with this is that it does not stop that individual from purchasing and diverting the pseudoephedrine. In general, the pharmaceutical industry has problem with acting as law enforcement. They do not believe it is the responsibility of their employees to limit the amount of pseudoephedrine an individual can buy based on information in an electronic system. Because of this, the electronic tracking system is relegated to being a source of information for law enforcement. The other problem with this is that it places additional burdens on law enforcement. Now, officers have to sift through records to determine who could be diverting pseudoephedrine. This requires additional officers, training, and man-hours to stage investigations. Overall, the electronic tracking system has many deficiencies, wouldn't prevent diversion, and would cost more, so it is an imperfect solution.

¹²⁷ Senator Diane Feinstein. "Senate Caucus on International Narcotics Control Holds Hearing on Methamphetamine and Making Pseudoephedrine Prescription Only."

The prescription-only solution

An alternative to the electronic tracking system has developed in Oregon and Mississippi: making pseudoephedrine available by prescription only. This system adds another layer of security. Diverters must visit a doctor to obtain a prescription for pseudoephedrine, delaying the time they can receive the drug and adding a person they must convince it is for a legitimate need. Providing a cashier at a pharmacy with a false identification is fairly easy and they will most likely accept a reasonable fake. But a doctor requires insurance or at least a higher cost to obtain a prescription. This cuts into the profit margin of the diverter and makes obtaining pseudoephedrine not cost effective.

The results of this method have been astounding. Oregon made pseudoephedrine available by prescription only in 2006. 128 The Oregon legislature passed a law which required the Oregon Board of Pharmacy, the state agency which, "regulates the Practice of Pharmacy and enforces laws regarding pharmacists, drug outlets and the sale of drugs in Oregon," 129 to make all pseudoephedrine products Schedule III, prescription only. ¹³⁰ In 2004, Oregon had 472 meth lab incidents. ¹³¹ In 2007, they only had 22 and in 2009 they only had 10, which were only dump sites near the border where meth producers from other states came to dump their leftover toxic chemicals. 132 Washington State had 186 lab incidents in 2009. 133 The effect of the law has gone beyond meth labs and is attributed to a decline in property crime rates which had been on the rise

¹²⁸ Senator Diane Feinstein. "Senate Caucus on International Narcotics Control Holds Hearing on Methamphetamine and Making Pseudoephedrine Prescription Only."

¹²⁹ Oregon Board of Pharmacy. "About Us." Last updated October 7, 2010.

¹³⁰ Meth Lab Homes. "Should products containing pseudoephedrine be available only by prescription?" January 13,

¹³¹John Kroger. "Oregon's Methamphetamine Control Strategy United States Senate Caucus on International Narcotics Control." April 13, 2010. 132 Ibid.

¹³³ Ibid.

but dropped 17% in 2006 after the passage of the law. The drop was the largest in the nation. Oregon also recorded the largest overall drop in crime in 2008 with a decrease of 10.6%.

The prescription-only law has made a huge dent into the number of labs found in Oregon, but it hasn't eliminated meth in Oregon. The drug still flows from California, Mexico, and other states, but domestic production in Oregon has virtually ceased. Proponents of the law contend that if the measure were adopted nationwide, meth labs would virtually cease to exist and the benefits seen in Oregon would be extended. Based on the comparison between the electronic tracking and prescription-only solutions, it is clear that prescription-only would be more effective. There are however, some potential drawbacks to implementation of this strategy

Preventing prescription abuse

One of the major arguments against the use of prescription-only laws is that current measures to prevent prescription drug abuse are insufficient. If this system were implemented, it would do little to really stop the diversion of pseudoephedrine. The first answer to this claim is that a significant amount of pseudoephedrine is necessary to create large quantities of meth while prescription drug abuse is of a different nature. Prescription drug abuse stems from over prescribing which develops a dependence or addiction in individuals. That individual then seeks more prescription drugs to feed his or her habit. Pseudoephedrine on the other hand is collected by the bucket full for the production of meth. Doctors would know not to prescribe more than a certain amount because it would just be unnecessary.

¹³⁴ Kroger. "Oregon's Methamphetamine Control Strategy United States Senate Caucus on International Narcotics Control."

¹³⁵ Ibid.

¹³⁶ Senator Diane Feinstein. "Senate Caucus on International Narcotics Control Holds Hearing on Methamphetamine and Making Pseudoephedrine Prescription Only."

Prescription drugs do carry with them the obstacle of "doctor shopping," when an individual goes to multiple doctors seeking the same prescription. To prevent this, the implementation of a nationwide prescription-only law should be accompanied by increased efforts to establish Prescription Drug Monitoring Programs (PDMP). A PDMP is an electronic database regulated by the state that tracks each prescription made by doctors to patients. 137 As of July 2010, 34 states have operational PDMPs and seven have enacted legislation to establish a PDMP but are not operational. 138 PDMPs allow regulators to identify doctors who are overprescribing, individuals who are doctor shopping, and combinations of medicine prescribed to individuals that could be deadly. There are currently plans to integrate PDMPs so that doctor shopping between states does not occur.

PDMPs would complement a prescription-only law and could eliminate any diversion of pseudoephedrine domestically. Every transaction would be recorded for law enforcement to view and use to investigate.

Obstacles to implementation

The only other major argument against the implementation of a nation-wide prescriptiononly law that the pharmaceutical industry holds onto dearly is that it would restrict access to care for patients. They argue that pseudoephedrine is a vital drug for millions of Americans. To limit access to pseudoephedrine would require families to go to the doctor every time they have a cold. Visits to the doctor are expensive and too many of them would raise premiums for everyone, so implementing this law would cost everyone more.

Oregon Attorney General John R. Kroger, one of the major proponents of the prescription-only law, contends that these accusations are untrue, that the access to care provided

¹³⁷ Drug Enforcement Administration. "Questions and Answers State Prescription Drug Monitoring Programs." July 2010. ¹³⁸ Ibid.

to patients has not changed.¹³⁹ He has toured his state and has not received a single complaint from a citizen.¹⁴⁰ Further, he contends that citizens are so elated with the decrease in crime and meth use that they would not care if costs increased.

One question that opponents raise about the prescription-only law for pseudoephedrine is whether there is a suitable alternative. In response to the Control Methamphetamine Epidemic Act of 2005, Pfizer, Inc. introduced replacement cold medicines containing phenylephrine. ¹⁴¹ However, phenylephrine, at the currently approved 10-mg for adults, is "unlikely to provide relief of nasal congestion." ¹⁴² For phenylephrine, only 38% of the dose reaches the systemic circulation, while 90% of the dose of pseudoephedrine does this. ¹⁴³ In a randomized double blind, placebo-controlled crossover study of 20 patients with nasal stuffiness, phenylephrine was no more effective than placebo. ¹⁴⁴ This indicates that there is no suitable alternative to pseudoephedrine and that it is possible that care will be diminished for patients because they have lost access to pseudoephedrine. However, given that this study was so small, we can determine that the results are inconclusive. Subsequent studies should be conducted to determine whether phenylephrine is a viable alternative. While this study casts doubt on its role as a substitute for pseudoepdrine, it cannot be ruled out.

Conclusion

Both the international and domestic solutions proposed in this paper place costs on consumers and producers. For the supplier and shipper, more forms must be filled out and more employees hired to comply with regulations. For the tax payers, more money must be paid to

¹³⁹ Kroger. "Oregon's Methamphetamine Control Strategy United States Senate Caucus on International Narcotics Control."

¹⁴⁰ Ibid.

¹⁴¹Leslie Hendeles and Randy Hatton. "Oral phenylephrine: An ineffective replacement for pseudoephedrine?" *The Journal of Allergy and Clinical Immunology*. May 1, 2006.

¹⁴² Ibid.

¹⁴³ Ibid.

¹⁴⁴ Ibid.

run a new regulatory system. For the customer, more money will have to be paid to get the same drugs as before. But despite these costs and despite these inconveniences, these measures are necessary and worth every sacrifice. As outlined in the beginning of this paper, meth is a terrible drug that touches millions of lives, whether through abuse, the loss of a loved one, or the crime associated with the drug. In order to stop this drug and its effects, strong measures must be taken.

The solution proposed in this paper to fight the meth problem in the United States has the ability to effectively end the epidemic and rid the U.S. of one drug problem. The steps will control an international supply, cutting off Mexico's ability to produce meth and transport it into the U.S. The plan will place more levels of security at the domestic level, which will significantly curtail domestic meth labs. The strategy outlined does not insist on securing every inch of the border or burning down every farm where illicit drugs are grown. Instead it is a sensible approach to a serious problem. The regulations make life more difficult for some individuals but they make life possible for even more.

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