

# METH EPIDEMIC SOLUTIONS

*Never doubt that a small group of  
thoughtful, committed citizens can change the world.  
Indeed, it's the only thing that ever has.*

—Margaret Mead

ROB BOVETT\*

## I. INTRODUCTION

An epidemic of methamphetamine abuse and addiction has swept across our nation and the world.<sup>1</sup> Its wake has destroyed families, devastated communities, caused property crimes to surge, and caused severe neglect of children. Tragically, the meth epidemic is unnecessary.

In 1976, the key ingredient necessary to make the most potent form of meth was approved by the federal government for over-the-counter sale. Over the course of the next thirty years, in eerie ten-year segments, the government repeatedly bowed to pressure from the pharmaceutical industry, choosing corporate profits over public health and safety. However, recent efforts have begun to turn the tide and bring the meth epidemic to an end.<sup>2</sup> There is still much work to be done, but we now have an opportunity—a golden opportunity—to address the underlying issue of addiction.

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\*Rob Bovett, J.D., Northwestern School of Law of Lewis & Clark College (1990); B.A., English and Political Science at the University of La Verne (1987). Mr. Bovett is legal counsel for the Oregon Narcotics Enforcement Association and the Lincoln Interagency Narcotics Team, and is co-founder and President of the Oregon Alliance for Drug Endangered Children. Mr. Bovett is the author of Oregon's meth lab chemical control laws, and helped author the international precursor controls contained in the federal Combat Methamphetamine Epidemic Act enacted by Congress in 2006. This article is dedicated to Oklahoma State Trooper Nikky Joe Green.

1. *See generally* REP. OF THE INT'L NARCOTICS CONTROL BD. FOR 2005 (2006) [hereinafter 2005 INT'L NARCOTICS REPORT]. In addition to the United States, many other areas of the world are suffering the ill effects of a meth epidemic, including, but not limited to, Southeast Asia, East Asia, Southern Africa, parts of Eastern Europe, Canada, New Zealand, and Australia. *See generally id.*

2. *See infra* note 3. This article will focus on only one part of the solution, namely control of the key ingredient necessary to make *d*-methamphetamine. The full solution requires strong support for science-based prevention, enforcement, and treatment.

## A. TYPES OF METHAMPHETAMINE

There are two major kinds of methamphetamine: Dextrorotatory methamphetamine (“*d*-meth”) and levorotatory methamphetamine (“*l*-meth”).<sup>3</sup> These two meth molecules are essentially mirror images of each other.<sup>4</sup> The *d*-meth variety is a strong central nervous system stimulant with powerful addictive properties. The *l*-meth variety is a topical nasal decongestant used as the active ingredient in a popular over-the-counter inhaler.<sup>5</sup>

There is also a third variety of methamphetamine, racemic meth (“*dl*-meth”), which is essentially a fifty-fifty mixture of *d*-meth and *l*-meth. As a result, *dl*-meth is a much less potent stimulant. This is the type of meth that was typically manufactured (and on the streets of America) throughout the 1960s and 1970s.<sup>6</sup>

## B. EPHEDRINE AND PSEUDOEPHEDRINE

There are two primary methods for illicitly manufacturing *d*-meth, and many variations of each method. On the street, they are commonly referred to as the “Red P”<sup>7</sup> and “Nazi”<sup>8</sup> methods. Both require the use of ephedrine or pseudoephedrine as the essential precursor.<sup>9</sup>

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3. NAT’L DRUG INTELLIGENCE CTR., NAT’L DRUG THREAT ASSESSMENT 14 (2003); see PHYSICIAN’S DESK REFERENCE 2482, 2678 (2006) (providing for the terms “desoxy,” i.e., *d*-meth and “levmetamphetamine,” i.e., *l*-meth, respectively). The two isomers of meth are named *d*- and *l*- by the direction in which they rotate a plane of polarized light. An isomer that rotates the light clockwise carries the *d*- prefix, and an isomer that rotates the light counterclockwise carries an *l*- prefix. A better method of labeling optical isomers, for reasons that go beyond the scope of this article, is (+) and (–), rather than *d*- and *l*-, respectively. There is also a better method of naming isomers based on their molecular structure. However, for reasons of historical usage and ease, throughout this article, I will use the *d*- and *l*-nomenclature.

4. For a further explanation in the context of pharmaceuticals, see Michael Strong, *FDA Policy and Regulation of Stereoisomers: Paradigm Shift and the Future of Safer, More Effective Drugs*, 54 FOOD & DRUG L.J. 463 (1999). One way to think of these two stereoisomers of meth is to imagine the meth molecule as a human hand. Your right hand and your left hand both have four fingers, a thumb, and a palm. But they are not the same. They are mirror images of each other. The two mirror-image meth molecules have different pharmacological effects on the human body. Although fascinating to the author, a full exploration of stereoisomerism and chirality in organic chemistry is well beyond the scope of this article.

5. Rules & Regulations Dep’t of Health & Human Services, 61 Fed. Reg. 9,570 (Mar. 8, 1996) (codified at 21 C.F.R. pt. 321). Vicks® Vapor Inhaler uses this active ingredient. For a time, the active ingredient was labeled “*l*-desoxyephedrine,” which is simply another name for *l*-meth. *Id.* The FDA later changed the labeling requirement to “levmetamphetamine.” Rules & Regulations Dep’t of Health & Human Services, 63 Fed. Reg. 40,647 (July 30, 1998) (codified at 21 C.F.R. pts. 310 and 321).

6. The various processes for illicitly manufacturing racemic meth typically involve a synthesis of phenylacetone and methylamine. Another name for phenylacetone is 1-phenyl-2-propanone, or “P2P,” which gives these types of meth labs their street name.

7. This process involves reducing ephedrine or pseudoephedrine to *d*-meth using phosphorus and hydriodic acid. Although there are many variations, the most commonly used reducing agents (or “reagents”) are iodine and red phosphorus. The use of red phosphorus gives this method its street name “Red P.” Among chemists, this process is more commonly referred to as “Ogata

Small amounts of ephedrine and trace amounts of pseudoephedrine are found in the plant *ephedra sinica*, also known as the Chinese herb *ma huang*.<sup>10</sup> However, nearly all of the world's supply of ephedrine and pseudoephedrine is mass produced in nine factories in three countries.<sup>11</sup>

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reduction," named for the original variation of the process developed in 1919 by the Japanese organic chemist Akira Ogata. This method is easily scalable, so it is used in small toxic labs, as well as the "superlabs" of drug trafficking organizations.

8. This process involves reducing ephedrine or pseudoephedrine to *d*-meth using anhydrous ammonia and lithium or sodium metal. The street name "Nazi" meth lab is believed to have derived from a German patent issued for a variation of this reduction methodology in 1936. See German Patent No. 639,126 (I.G. Farben) (filed May 16, 1935) (issued Nov. 28, 1936). The header of the patent features the seal and swastika used on all German patents during the time of Hitler's Deutsches Reich, thus giving the method its street name. Among chemists, this process is more commonly referred to as "Birch reduction," named for a variation of this reduction process developed by the Australian organic chemist Arthur J. Birch. This method is not easily scalable, so it is typically only used in small toxic labs.

9. The difference between the methamphetamine molecule (C<sub>10</sub>H<sub>15</sub>N) and the ephedrine or pseudoephedrine molecule (C<sub>10</sub>H<sub>15</sub>NO) is a single oxygen atom. Therefore, as described in notes 7 and 8, *supra*, the two primary methods for illicitly manufacturing meth essentially involve removing the oxygen atom from ephedrine or pseudoephedrine. Another decongestant, phenylpropanolamine (PPA), is very similar in molecular structure to ephedrine and pseudoephedrine. However, PPA has one less methyl group (a carbon atom and three hydrogen atoms). Thus, reducing PPA in a "Red P" or "Nazi" meth lab results in amphetamine, a much weaker stimulant drug than methamphetamine (amphetamine is methamphetamine minus a methyl group). After the disclosure of data questioning the safety of PPA, it was voluntarily removed from the market by the pharmaceutical industry following the issuance of an FDA notice in 2001, and is therefore seldom seen any longer in clandestine drug labs. Phenylpropanolamine: Proposal to Withdraw Approval of New Drug Applications and Abbreviated Drug Applications, 66 Fed. Reg. 42,665 (proposed Aug. 14, 2001).

10. Unlike methamphetamine, which has one chiral center, thus providing the two optical isomers *d*-meth and *l*-meth (i.e., one set of mirror image molecules), the ephedrine molecule has two chiral centers, which provides four optical isomers (i.e., two sets of mirror image molecules). They are *d*-ephedrine, *l*-ephedrine, *d*-pseudoephedrine, and *l*-pseudoephedrine. The naturally occurring varieties in *ephedra sinica* are *l*-ephedrine and *d*-pseudoephedrine, both of which reduce to *d*-meth. The other two varieties, *d*-ephedrine and *l*-pseudoephedrine, reduce to *l*-meth, a topical nasal decongestant. See Strong, *supra* note 4, at 463. Interestingly, at least one pharmaceutical company pursued *l*-pseudoephedrine as a possible substitute decongestant for *d*-pseudoephedrine, not just because it does not reduce to *d*-meth, but for its apparent safer qualities. See (-)-Pseudoephedrine as a Sympathomimetic Drug, U.S. Patent No. 6,495,529 (Booth, et al.) (Warner-Lambert, aka Pfizer) (filed Apr. 16, 2001) (issued Dec. 17, 2002). In addition to abuse and use to make *d*-meth, the patent itself noted that *d*-pseudoephedrine has "undesirable side effects, including central nervous system stimulation, lightheadedness, nervousness, anxiety, paranoia, heart arrhythmia, atrial fibrillations and premature ventricular contractions." 529 Patent col.1 1.57-60 (citing 95 AM. HOSP. FORMULATORY SERV. 847-48). See also Carlos Cantu et al., *Stroke Associated with Sympathomimetics Contained in Over-the-Counter Cough and Cold Drugs*, 34 STROKE: J. AM. HEART ASS'N 1667 (2003). Unfortunately, *l*-pseudoephedrine appears not to have been further pursued.

11. Steve Suo, *Unnecessary Epidemic*, THE OREGONIAN, Oct. 3, 2004, at A1. The ephedrine and pseudoephedrine producing nations are India, China, and Germany, although India and China are the primary sources of the diverted ephedrine and pseudoephedrine feeding the meth "super labs" of the drug cartels. Although not currently a significant source of ephedrine and pseudoephedrine for mass production of meth, *ephedra sinica* is not internationally regulated, and thus has the potential to become a significant precursor for meth if authorities in China should elect to no longer closely monitor the export of bulk *ephedra*. See INT'L NARCOTICS CONTROL BD., 2005 ANNUAL REPORT ON PRECURSORS & CHEMICALS FREQUENTLY USED IN THE ILLICIT

## II. THE EVOLUTION OF METH EPIDEMIC SOLUTIONS

Over the course of the past thirty years, there have been a number of attempts to stop the spread of the meth epidemic by controlling the key ingredients ephedrine and pseudoephedrine. For most of those years, the efforts were stymied or watered down and rendered ineffective. However, in recent years, there have been strong actions taken at state, national, and international levels. The results are dramatic, and have provided a window of opportunity for taking the next steps to deal with the underlying issue of addiction.

### A. 1976 TO 1985: ROOTS OF THE EPIDEMIC

On September 9, 1976, the Food and Drug Administration (FDA) effectively approved ephedrine and pseudoephedrine for over-the-counter sale as decongestants.<sup>12</sup> This action was the culmination of a lengthy process initiated by Congress in 1962 to determine what pharmaceutical products should be sold over-the-counter.<sup>13</sup> The FDA ultimately approved eight decongestants as safe and effective for over-the-counter sale, including ephedrine and pseudoephedrine.<sup>14</sup>

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MANUFACTURE OF NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES 3, 71 (2006), available at [http://www.incb.org/incb/annual\\_report.html](http://www.incb.org/incb/annual_report.html) [hereinafter INT'L NARCOTICS CONTROL BD., PRECURSORS & CHEMS.].

12. Establishment of a Monograph for OTC Cold, Cough, Allergy, Bronchodilator, and Asthmatic Products, 41 Fed. Reg. 38,312 (Sept. 9, 1976) (codified at 21 C.F.R. pt. 341).

A nasal decongestant is an agent which reduces nasal congestion in patients with acute or chronic rhinitis. These agents may be administered topically as drops, sprays or inhaled vapors or orally in a solid or liquid dosage form. The drug effect is brought about by constriction of dilated blood vessels (vasoconstriction) within the nasal mucosa, thus temporarily reducing the swelling associated with inflammation of the mucous membrane lining the nasal passage.

*Id.* (citing I.R. Innes & M.N. Nickerson, *Drugs Acting on the Postganglionic Adrenergic Nerve Endings and Structures Innervated by Them (Sympathomimetic Drugs)*, in THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 507 (Goodman & Gilman eds., 4th ed. 1970)).

In general, side effects associated with recommended oral doses of OTC nasal decongestants are minimal, but at higher doses may include nervousness, dizziness, and sleeplessness. Individuals with disease conditions which can be aggravated by sympathomimetic drug action, e.g., high blood pressure, heart disease, diabetes mellitus and hyperthyroidism, should not use decongestants orally except under the advice and supervision of a physician.

Establishment of a Monograph, 41 Fed. Reg. at 38,397.

13. For a thorough explanation of the history of this process, see Judge Sirica's decision in *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979).

14. As relevant to this article, those included ephedrine (topical only), pseudoephedrine (oral), phenylephrine, and phenylpropanolamine (oral). Establishment of a Monograph, 41 Fed. Reg. at 38,397. The panel rejected ephedrine (oral), phenylpropanolamine (topical), and *l*-methamphetamine (inhalant) because of insufficient data to support a finding of efficacy and safety. *Id.*

## B. 1986 TO 1995: MISSED OPPORTUNITIES

By 1986, concern over the use of ephedrine and pseudoephedrine to manufacture meth made its way to Congress. That year, Congress was preparing to pass an omnibus anti-drug abuse bill. A number of versions were developed in the Senate and House of Representatives. The House version included provisions relating to the diversion of precursor chemicals, including ephedrine and pseudoephedrine, but those provisions merely directed the Attorney General to study the issue and report back to Congress.<sup>15</sup> However, on September 23, 1986, Senator Bob Dole introduced a new omnibus bill at the request of the Reagan Administration.<sup>16</sup> The new bill was a bipartisan effort to combine the “very best” provisions offered in earlier partisan versions, plus additional improvements and provisions worked out through bipartisan efforts.<sup>17</sup>

Part six of the new bill contained the “Chemical Diversion and Trafficking Act of 1986.”<sup>18</sup> That part of the bill required all manufacturers, distributors, importers, and exporters to maintain records concerning the distribution, sale, importation, and exportation of certain listed chemicals within quantity thresholds set by the Attorney General.<sup>19</sup> The listed chemicals included ephedrine and pseudoephedrine.<sup>20</sup> The record-keeping provisions required logging the name, address, and identification for each individual or entity receiving the listed chemical.<sup>21</sup>

Part six also required all importers and exporters of the listed precursors to obtain a permit from the Drug Enforcement Administration (DEA).<sup>22</sup> It also directed the United States Attorney General to maintain an active domestic and international program to prevent the diversion of these listed chemicals, including the development of cooperative efforts with foreign drug control authorities.<sup>23</sup>

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15. H.R. 5484, 98th Cong. § 623 (as introduced by House, Sept. 8, 1986).

16. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986), 132 Cong. Rec. 25,633 (1986).

17. 132 Cong. Rec. 25,633 (1986) (statement of Sen. Dole).

18. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986) §§ 1561-64, 132 Cong. Rec. 25,650 (1986).

19. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986) § 1562, 132 Cong. Rec. 25,650.

20. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986) § 1562(d)(1) (F), (G), 132 Cong. Rec. 25,651.

21. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986) § 1562(a)(1), 132 Cong. Rec. 25,650.

22. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986) § 1562(b), 132 Cong. Rec. 25,651.

23. Drug Enforcement Act of 1986, S. 2850, 98th Cong. (1986) § 1564, 132 Cong. Rec. 25,652.

Part six of Senator Dole's omnibus bill was nothing short of revolutionary.<sup>24</sup> Any doubt about the intent of these new provisions was answered in the summary provided by the sponsors<sup>25</sup>:

This section establishes a new system of control over the sales of certain precursor and essential chemicals in the manufacture of illegal drugs through new record keeping, reporting, and identification requirements designed to keep these chemicals out of the hands of illegal drug manufacturers. The House package only provides for a study to determine the need for legislation or regulation to control the diversion of legitimate precursor and essential chemicals to the illegal manufacture of drugs. The Senate Democrat package does not include any like provision.<sup>26</sup>

Although caught by surprise, the pharmaceutical industry lobbyists immediately realized the implications of this new proposal.<sup>27</sup> They quickly mobilized and were successful in defeating this first serious attempt to strongly control ephedrine and pseudoephedrine.<sup>28</sup> The new provisions did not make it into the final bill. Instead, the enacted legislation settled for the weaker provisions directing the United States Attorney General to study the issue and report back to Congress.<sup>29</sup>

The pharmaceutical industry then successfully applied pressure on the Administration to back down when it reported back to Congress.<sup>30</sup> In April of 1987, the United States Attorney General Edwin Meese dutifully reported back to Congress, as directed in the 1986 legislation.<sup>31</sup> The report

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24. Interview by PBS Frontline with Gene Haislip, Former Head of DEA Diversion Control (Sept. 20, 2005), available at <http://www.pbs.org/wgbh/pages/frontline/meth/interviews/haislip.html>. Mr. Haislip stated,

[w]e had extremely good reception on the part of this proposal, both from the president, the Justice Department and the Congress. However, it did soon surface that legitimate industry had concerns, and I suppose most especially the proprietary associations that represent the manufacturers of the pharmaceutical preparations with ephedrine and pseudoephedrine in them.

*Id.*

25. "Final Summary—Drug Control Act of 1986," 132 Cong. Rec. 25,671 (1986).

26. *Id.*; 132 Cong. Rec. 25,673.

27. Interview by PBS Frontline with Allan Rexinger, former pharmaceutical lobbyist (Nov. 5, 2005), available at <http://www.pbs.org/wgbh/pages/frontline/meth/interviews/rexinger.html>. "I found out about it by reading in the Congressional Record. It was a total surprise." *Id.*

28. Steve Suo, *Lobbyists and Loopholes*, THE OREGONIAN, Oct. 4, 2004, at A1.

29. Anti-Drug Abuse Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207 (1986). The weaker study and report back to Congress provisions were contained in Title I, Subtitle R, § 1901 of the Act. *Id.*

30. Suo, *Lobbyists and Loopholes*, *supra* note 28, at A1.

31. "A communication from the Attorney General of the U.S. transmitting, pursuant to law, and report on a legislative proposal relative to methods to control diversion of legitimate and

proposed the same regulatory scheme from Senator Dole's bill, but with one major difference: The new proposal exempted any regulated chemical contained in a legal pharmaceutical product.

Nevertheless, a variety of bills were introduced in 1987 to strongly regulate ephedrine and pseudoephedrine.<sup>32</sup> The bills ranged from the strong controls contained in Senator Dole's original 1986 bill, to variations of those controls.<sup>33</sup> On October 15, 1987, a hearing was held by the United States House Judiciary Committee to consider the Attorney General's report and the various bills.<sup>34</sup> Unfortunately, the end result was the passage of a bill in 1988 that included the exception for legal pharmaceutical products.<sup>35</sup>

On an international level, world concern over the development and spread of illicit synthetic drugs manufactured through diversion of legitimate chemicals resulted in the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The 1988 Convention has been ratified by ninety percent of all nations, including all of the key ephedrine and pseudoephedrine manufacturing and importing nations.<sup>36</sup>

Article Twelve of the 1988 Convention, entitled "Substances Frequently Used in the Illicit Manufacture of Narcotic Drugs or Psychotropic Drugs," specifically provided for the tracking and reporting of critical precursor chemicals, including ephedrine and pseudoephedrine. Unfortunately, Section Fourteen of Article Twelve included essentially the same

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essential chemicals to the illegal production of drugs; to the Committee on the Judiciary." 133 Cong. Rec. 9,771 (daily ed. Apr. 27, 1987) (statement of Sen. Meese).

32. See H.R. 2585, 100th Cong. (introduced June 3, 1987) (containing the original strong controls from Senator Dole's bill); H.R. 2846, 100th Cong. (introduced June 30, 1987) (proposing to regulate ephedrine, but not pseudoephedrine); H.R. 3062, 100th Cong. (introduced July 30, 1987) (containing a variation of the original proposal); H.R. 3268, 100th Cong. (introduced Sept. 15, 1987) (containing another variation of the original proposal).

33. H.R. 2585, 100th Cong. (introduced June 3, 1987); H.R. 2846, 100th Cong. (introduced June 30, 1987); H.R. 3062, 100th Cong. (introduced July 30, 1987); H.R. 3268, 100th Cong. (introduced Sept. 15, 1987).

34. 133 Cong. Rec. D725 (daily ed. Oct. 15, 1987).

35. Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, 102 Stat. 4181, 4312-20 (1988). Title VI, Subtitle A, of the Act was entitled the Chemical Diversion and Trafficking Act of 1988. 102 Stat. 4312-20. The infamous "31 word exception" appeared in 6054 of the Act, 102 Stat. 4317, which amended the definition § 102 of the Controlled Substances Act, 21 U.S.C. § 802(39), by defining "regulated transaction" to exclude "any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetics Act." Section 6054 of the 1988 Act also inserted subsection (34) into 21 U.S.C. § 802, which added both ephedrine and pseudoephedrine as a "listed precursor chemical" subject to regulation under the Controlled Substances Act.

36. United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Opened for Signature Dec. 20, 1988, [http://www.unodc.org/pdf/treaty\\_adherence\\_convention\\_1988.pdf](http://www.unodc.org/pdf/treaty_adherence_convention_1988.pdf) (Canada, July 5, 1993; China, Oct. 25, 1989; Czech Republic, Dec. 30, 1993 (Czechoslovakia ratified June 4, 1991); Germany, Nov. 30, 1993; India, Mar. 27, 1990; Mexico Apr. 11, 1990; United States, Feb. 20, 1990).

exception for the benefit of the pharmaceutical industry: “The provisions of this article shall not apply to pharmaceutical preparations.”<sup>37</sup>

Thus, in 1988, the pharmaceutical industry successfully avoided effective domestic and international control of ephedrine and pseudoephedrine. Over the next few years, the meth epidemic began to proliferate across the United States, through organized drug cartels, as well as through small toxic home meth labs.<sup>38</sup>

By 1993, it had become clear that the pharmaceutical industry would need to make further concessions to avoid strong control of ephedrine and pseudoephedrine. The industry chose to sacrifice ephedrine. A 1993 compromise required sellers of ephedrine tablets to keep records of customers, report suspicious sales, and register with the DEA.<sup>39</sup>

As a result of these new controls, ephedrine became scarce and meth purity began to drop as the drug cartels were forced to cut their meth with diluents in order to meet demand.<sup>40</sup> Average meth purity in the United States plummeted from seventy percent pure in the middle of 1995 to just over forty percent pure in the middle of 1996.<sup>41</sup> When meth supply is short

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37. 2005 INT’L NARCOTICS REP., *supra* note 1, at 28. By 2005, the tragic consequences of this loophole were crystal clear:

Pseudoephedrine is the key precursor used for the illicit manufacture of methamphetamine, which is abused mainly in the United States and in countries in Southeast Asia. While pseudoephedrine is listed in Table I of the 1988 Convention, the control measures provided for in article 12 of that convention do not apply to pharmaceutical preparations containing the substance. As a result, and as more and more countries have strengthened their controls over the raw material, traffickers are increasingly taking advantage of that loophole in the international drug control regime.

*Id.*

38. Suo, *Unnecessary Epidemic*, *supra* note 11, at A01.

39. Domestic Chemical Diversion Control Act of 1993, Pub. L. No. 103-200, 107 Stat. 2333 (1993). The controls were phased in from April of 1994 through August 1995. 21 C.F.R. pts. 1307, 1309, 1310, 1313, 1316. Effective November 10, 1994, the DEA eliminated the quantity threshold for ephedrine. Elimination of Threshold for Ephedrine, 59 Fed. Reg. 51,365 (Oct. 11, 1994) (codified at 21 C.F.R. pts. 1310 and 1313). Later, due to safety concerns, ephedrine was effectively banned by the FDA. *See* Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk; Final Rule, 69 Fed. Reg. 6,788 (Feb. 11, 2004) (codified at 21 C.F.R. pt. 119); Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use, 70 Fed. Reg. 40,232 (July 13, 2005) (codified at 21 C.F.R. pts. 310 and 341).

40. Suo, *Unnecessary Epidemic*, *supra* note 11, at A1. The most common diluent, or cut, for methamphetamine is methylsulfonylmethane (“MSM”), also known as dimethylsulfone (DMSO<sub>2</sub>). MSM is a dietary supplement for both human and livestock consumption, and is the preferred diluent for meth because it easily blends and crystallizes with meth. NAT’L DRUG INTELLIGENCE CTR., CRYSTAL METHAMPHETAMINE 3 (2002). When the supply of meth is short, “cutting” meth with a diluent, such as MSM, enables the illicit drug dealers to provide enough meth to meet demand.

41. *Id.* Average purity levels were calculated and tabulated by *The Oregonian* and the RAND Corporation using data derived from the DEA’s System to Retrieve Information from Drug Evidence, commonly known by its acronym STRIDE.

and meth purity declines as a result of cutting, prices generally increase; and with reduced purity and increased price, less people become addicted and the collateral damage to society is reduced.<sup>42</sup> Unfortunately, it did not take long for the drug cartels to begin making the switch to pseudoephedrine.<sup>43</sup> By mid-1997, the average purity of meth in the United States was back up to sixty percent.<sup>44</sup>

On Halloween in 1995, the DEA proposed new regulations pursuant to their discretionary authority in the 1993 legislation.<sup>45</sup> The new proposed regulations would require manufacturers and wholesale distributors of pseudoephedrine to get a license from the DEA and keep a record of every sale of more than 400 tablets of pseudoephedrine.<sup>46</sup> For another brief moment in time, it appeared that the federal government would get serious about comprehensively controlling both ephedrine and pseudoephedrine. But it was not to be.

### C. 1996 TO 2005: AN EPIDEMIC IN FULL BLOOM

In March of 1996, California Senator Diane Feinstein introduced a bill that would have allowed the DEA to clamp down on companies whose products were repeatedly found in meth labs.<sup>47</sup> The DEA would be required to first issue a warning notice, but subsequent offenses could lead to civil penalties of as much as \$250,000 or revocation of the license to manufacture or sell the products.<sup>48</sup> An identical bill was introduced in the House of Representatives.<sup>49</sup>

In August of 1996, the DEA adopted the proposed pseudoephedrine control rules published on Halloween in 1995.<sup>50</sup> The new rules were scheduled to go into effect on October 7, 1996.<sup>51</sup> In the face of these new strong controls, and this aggressive proposed legislation, the pharmaceutical industry scrambled. Senator Orrin Hatch intervened on behalf of the industry,

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42. *Id.*; see generally Office of Nat'l Drug Control Pol'y and RAND CORP., *The Price and Purity of Illicit Drugs: 1981 Through the Second Quarter of 2003* (Nov. 2004).

43. See *supra* note 42; Suo, *Lobbyists and Loopholes*, *supra* note 28, at A1.

44. Suo, *Lobbyists and Loopholes*, *supra* note 28, at A1.

45. 21 U.S.C. § 814(a) (1993).

46. Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act, 60 Fed. Reg. 55,348 (Oct. 31, 1995) (codified at 21 C.F.R. pts. 1309, 1310, and 1313).

47. S. 1607, 104th Cong. (introduced Mar. 12, 1996).

48. *Id.*

49. H.R. 3067, 104th Cong. (introduced Mar. 12, 1996).

50. Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Federal Food, Drug, and Cosmetic Act, 61 Fed. Reg. at 40,981.

51. *Id.*

worked a deal with Senator Feinstein, and introduced a bill that included an amazing provision:

SEC. 210. WITHDRAWAL OF REGULATIONS.

The final rule concerning removal of exemption for certain pseudoephedrine products marketed under the Federal Food, Drug, and Cosmetic Act published in the *Federal Register* of August 7, 1996 is null and void and of no force or effect.<sup>52</sup>

Ironically named the Methamphetamine Control Act (MCA), the bill passed both the Senate and House, and was signed by the President on October 3, 1996, four days before the new DEA regulations were scheduled to go into effect.<sup>53</sup> Congress had effectively nullified the new DEA rules. The industry had yet again successfully evaded comprehensive control of pseudoephedrine.

In lieu of the DEA rules to control pseudoephedrine, the MCA instead provided for a reporting threshold of twenty-four grams per transaction.<sup>54</sup> However, that reporting requirement came with a huge exception: Products containing no more than three grams of pseudoephedrine tablets packaged in a blister pack were exempt.<sup>55</sup>

Despite exempting pseudoephedrine pills in blister packs, the MCA did implement the first strong controls on bulk pseudoephedrine.<sup>56</sup> As a result, the average purity of meth fell again, to just above thirty percent by the middle of 1999.<sup>57</sup> Unfortunately, the drug cartels simply switched to the unregulated pseudoephedrine pills.

By 2000, the continuing march of the meth epidemic across America caused Congress to again turn its attention to the control of pseudoephedrine. In that year, Congress enacted an omnibus bill designed to improve services and protections for children.<sup>58</sup> Included as title 36 of the legislation was the Methamphetamine Anti-Proliferation Act (MAPA).<sup>59</sup>

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52. S. 1965, 104th Cong. (1996) (internal citations omitted) (italics not in original).

53. Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104-237, 110 Stat. 3099 (Oct. 3, 1996) (codified as amended in scattered sections of 21 U.S.C.).

54. Comprehensive Methamphetamine Control Act of 1996, 21 U.S.C. § 401 (1996).

55. *Id.* This so-called “blister pack” exemption was premised on the notion that illicit meth manufacturers would not spend the time and energy to pop large amounts of pseudoephedrine pills out of foil covered blister packs; an absurd and ridiculous assumption to anyone familiar with the habits of small-scale meth manufacturers and their meth-addicted associates, or the manual labor resources that could be utilized by the drug cartels. *Id.*

56. Comprehensive Methamphetamine Control Act of 1996, 21 U.S.C. § 401 (1996), 110 Stat. 3106.

57. Suo, *Unnecessary Epidemic*, supra note 11, at A1.

58. Children’s Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000).

59. Methamphetamine Anti-Proliferation Act of 2000, § 3601, 114 Stat. 1227.

MAPA reduced the reporting threshold for pseudoephedrine from twenty-four grams to nine grams, but retained the unfortunate “blister pack” exemption.<sup>60</sup> The purity of meth began to rise yet again, and continued to rise until mid-2005, where it reached seventy-seven percent average purity.<sup>61</sup>

Another disturbing trend also rose to epidemic proportions during this same time period: the proliferation of small toxic home meth labs. In addition to the damage done by addiction and addiction-driven crimes, these small toxic home meth labs do additional damage by generating toxic by-products and posing a high risk of catching fire or exploding.<sup>62</sup> Most tragically, they also pose severe dangers to drug-endangered children forced to live in meth lab environments.<sup>63</sup>

By 2004, the annual number of meth lab incidents reported by law enforcement authorities in the United States had risen to over 17,500.<sup>64</sup> In 2005, the federal government increased its estimate of the percentage of meth on the street being produced in local toxic home meth labs from twenty percent to thirty-five percent.<sup>65</sup> Also in 2005, a majority of counties in the United States identified methamphetamine as their number one drug problem.<sup>66</sup>

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60. 21 U.S.C. § 3622, 114 Stat. 1230.

61. Steve Suo, *Crackdown Puts Meth Trade in a Bind*, THE OREGONIAN, Nov. 5, 2006, at A1.

62. See generally JOHN MARTYNY ET AL., NAT’L JEWISH MED. & RES. CTR., CHEMICAL EXPOSURES ASSOCIATED WITH CLANDESTINE METHAMPHETAMINE LABORATORIES (2004); *Public Health Consequences Among First Responders to Emergency Events Associated with Illicit Methamphetamine Laboratories—Selected States, 1996-1999*, 49 MORBID & MORTALITY WKLY. REP. 1021 (2000).

63. See NAT’L ALLIANCE FOR DRUG ENDANGERED CHILDREN, NATIONAL PROTOCOL FOR MEDICAL EVALUATION OF CHILDREN FOUND IN DRUG LABS (2004), available at <http://www.nationaldec.org/medical%protocol/DECNationalProtocal.pdf>; OFFICE FOR VICTIMS OF CRIME, U.S. DEP’T OF JUSTICE, CHILDREN AT CLANDESTINE METHAMPHETAMINE LABS: HELPING METH’S YOUNGEST VICTIMS, OVC BULLETIN 1 (2003), available at <http://ojp.usdoj/ovc/publications/bulletins/children/197590.pdf>; ORE. DEP’T OF HUMAN SERVS. CHILDREN IN METH-AMPHETAMINE “LABS” IN OREGON (2003), available at <http://egov.oregon.gov/DHS.ph/cdsummary/2003/ohd5219.pdf>; NAT’L DRUG INTELLIGENCE CTR., CHILDREN AT RISK (2002), available at <http://www.usdoj.gov/rdic/pubs/1/1466/index.htm>.

64. OFFICE OF NAT’L DRUG CONTROL POL’Y, SYNTHETIC DRUG CONTROL STRATEGY 4 (2006), available at [www.whitehousedrugpolicy.gov/publications/synthetic\\_drug\\_control\\_strat/synth\\_strat.pdf](http://www.whitehousedrugpolicy.gov/publications/synthetic_drug_control_strat/synth_strat.pdf).

65. INTERAGENCY WORKING GROUP ON SYNTHETIC DRUGS, INTERIM REPORT FROM THE INTERAGENCY WORKING GROUP ON SYNTHETIC DRUGS TO THE DIRECTOR OF NATIONAL DRUG CONTROL POLICY, ATTORNEY GEN., SECRETARY FOR HEALTH AND HUMAN SERVICES, 3 n.8 (May 23, 2005), available at [http://www.whitehousedrugpolicy.gov/publications/pdf/interim\\_rpt.pdf](http://www.whitehousedrugpolicy.gov/publications/pdf/interim_rpt.pdf) [hereinafter INTERIM REP.].

66. NAT’L ASS’N OF COUNTIES, THE METH EPIDEMIC IN AMERICA 2 (July 5, 2005), available at [http://www.naco.org/content/contentgroups/publications/1/press\\_releases/documents/Naco-methsurvey.pdf](http://www.naco.org/content/contentgroups/publications/1/press_releases/documents/Naco-methsurvey.pdf).

Faced with an ever increasing incidence of small toxic meth labs, rising meth purity, and the failure of the federal government to effectively deal with the growing meth epidemic, law enforcement authorities began turning to state legislatures and local governments for relief.

For example, in 2001, the author prepared a bill for the Oregon legislature to clamp down on the precursors, reagents, and diluents commonly used to make meth.<sup>67</sup> The author was instructed to have a meeting with the pharmaceutical lobbyists, and told to work it out.<sup>68</sup> After extensive negotiations, the lobbyists agreed to allow the bill to proceed with some of our nation's first strong controls on key reagents and diluents. But, when it came time to control the key precursor, pseudoephedrine, the lobbyists would only agree to limit individual sales to nine grams per transaction.<sup>69</sup> The author took what he could get, and hoped it would make a difference.<sup>70</sup> It did not.<sup>71</sup>

In 2003, the author was assigned to have another meeting with the pharmaceutical lobbyists and told to work it out.<sup>72</sup> Knowing that that strategy had failed in 2001, the author and his colleague, Craig Durbin,<sup>73</sup> decided to fight the pharmaceutical industry. Unfortunately, that new strategy likewise failed.<sup>74</sup>

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67. H.B. 3661, 71st Leg. Sess. (Or. 2001).

68. Interview by PBS Frontline with Rob Bovett, Legal Counsel for the Or. Narcotics Enforcement Ass'n (July 22, 2005), available at <http://www.pbs.org/wgbh/pages/frontline/meth/interviews/bovett.html>.

Basically the legislative approach that year was to stick me in a room with 12 lobbyists. And I can say this because I'm a lawyer: There is something worse than being stuck in a room with a dozen lawyers, and that's being stuck in a room with a dozen lobbyists. You can't take a shower long enough to wipe off the grime from that type of experience.

*Id.*

69. *Id.* "My first experience with them was in 2001, here at the Oregon [State] Legislature, where I tried to work cooperatively with them to get effective controls on pseudoephedrine. That didn't work. They gave a lot of issues on other ingredients, but not pseudoephedrine." *Id.*

70. 2001 Or. Laws, ch. 615 (Enacting 2001 Or. H.B. 3661).

71. In 2001, the number of meth lab incidents reported by law enforcement authorities in Oregon was 522. H.B. 3661 went into effect on January 1, 2002. In 2002, the number of meth lab incidents reported by law enforcement authorities in Oregon was 466.

72. The Oregon legislature meets every other year. OR. CONST. art. IV, § 10.

73. Then Lt. (now Capt.) Craig Durbin, Oregon State Police.

74. The bill Mr. Bovett prepared in 2003 was Oregon H.B. 2034. We attempted to include a provision that would have required all pseudoephedrine products be kept behind-the-counter. 2003 Or. H.B. 2034, Dash-2 amendments. The pharmaceutical lobby fought our efforts to include that provision during multiple committee hearings. The bill passed, but without the behind-the-counter provision. 2003 Or. Laws, ch. 448 (Enrolled 2003 Or. H.B. 2034).

The day after Christmas in 2003, a tragic event occurred that would forever change the landscape of pseudoephedrine control.<sup>75</sup> On that day, Trooper Nikky Joe Green of the Oklahoma State Police was nearing the end of his shift and stopped to check on a possible disabled vehicle on the side of the road which had its trunk and hood open.<sup>76</sup> What Trooper Green discovered was a meth lab.<sup>77</sup> When Trooper Green attempted to arrest the suspect, a struggle ensued and the suspect shot and killed the trooper.<sup>78</sup>

Coupled together with an onslaught of local toxic meth labs, this tragic event galvanized political will in Oklahoma. In 2004, Oklahoma passed the first state law effectively controlling pseudoephedrine, by requiring that pseudoephedrine products be placed behind the pharmacy counter and that all sales be logged, including photo identification for each customer.<sup>79</sup> This was the first of two watershed events in 2004.

The State of Oregon quickly seized the opportunity to follow suit.<sup>80</sup> However, Oregon initially did not go quite as far as Oklahoma. The initial control adopted in Oregon included all elements of the new Oklahoma rule, except there was no logging for each sale, and “combination” pseudoephedrine products were allowed to remain behind the counter in both pharmacies and grocery stores or convenience stores.<sup>81</sup>

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75. The Officer Down Memorial Page, <http://odmp.org/officer.php?oid=17073> (last visited Jan. 26, 2007).

76. *Id.*

77. *Id.*

78. *Id.*

79. Okla. H.B. 2176 (2004) (codified, as amended, OKLA. STAT. ANN. § 63-2-212 (2004)). This set of requirements is sometimes referred to as “Schedule V,” a reference to Schedule V of the Controlled Substances Act in many states, which contain requirements that are effectively the same as the Oklahoma pseudoephedrine control legislation. *Id.* However, there is currently no uniformity among states as to the existence of Schedule V, and the requirements contained in Schedule V. Therefore, I will refer to this set of controls as the “Oklahoma rule.”

80. At one point in the summer of 2004, the author was warned by the lobbyist for Pfizer, then the world’s largest manufacturer of pseudoephedrine products, that if we continued to pursue legislation to pull pseudoephedrine products from over-the-counter sales, Pfizer might very well get out of the pseudoephedrine business. It was meant as a threat, but the author treated it as an opportunity. After it became clear that the Oklahoma and Oregon pseudoephedrine controls had successfully reduced the incidence of meth labs in those states and that other states would likely follow suit, Pfizer read the handwriting on the wall and beat out their competition by quietly reformulating their key pseudoephedrine products with another decongestant, phenylephrine, and announced their new products to the *Wall Street Journal*. Heather Won Tesoriero, *Pfizer-Backed Move to Curb Cold Pills May Boost Company*, WALL ST. J., Apr. 13, 2005, at B1.

81. OR. ADMIN. R. 855-050-0035 (2004). “Combination” product refers to a pharmaceutical product that contains more than one active ingredient, for example pseudoephedrine (a decongestant) together with an antihistamine. This action was the direct result of a request by Oregon Governor Ted Kulongoski to the Oregon Board of Pharmacy on behalf of the Governor’s Meth Task Force. Our request was for the full Oklahoma rule. Public Safety Review Task Force Recommendations, <http://159.121.112.123/PSReview/viewtfrec.php?tf=MTF> (last visited Jan. 19, 2007). However, the Oregon Board of Pharmacy initially chose to implement the weaker version.

Thus, in 2004, two experiments began in two different states: Oregon and Oklahoma. A few months later, the results were clear. The Oregon rule was effective at reducing the incidence of local toxic meth labs, but not nearly as effective as the Oklahoma rule.<sup>82</sup> So in early 2005, Oregon adopted the full Oklahoma rule.<sup>83</sup>

In May of 2005, a report from the federal government recognized the significant progress being made in Oklahoma and Oregon.<sup>84</sup> Although the report refrained from endorsing the Oklahoma and Oregon pseudoephedrine controls, the report did label them as promising approaches and found that the results “strongly suggest that Oklahoma’s and Oregon’s state-level approaches are probably primary reasons” for the dramatic reduction in the number of small toxic meth labs.<sup>85</sup>

Coupled together with a migration of Oklahoma and Oregon meth “cooks” and “smurfers”<sup>86</sup> into neighboring states,<sup>87</sup> the successful results in Oklahoma and Oregon led to a domino effect in other states. By the end of 2005, a majority of states had adopted some variation of strong controls on pseudoephedrine, and the annual number of meth lab incidents reported by law enforcement authorities in the United States plummeted from over 17,500 in 2004 to 12,500 in 2005.<sup>88</sup>

Another watershed event occurred in 2004. On October 4, 2004, *The Oregonian* began publishing a series of articles with an international focus aimed at the drug cartel “super labs” responsible for producing most of the world’s meth.<sup>89</sup> This series brought much needed public and political

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82. INTERIM REP., *supra* note 65, at 6-9.

83. OR. ADMIN. R. 855-050-0037, 0043 (2005) (repealed 2006).

84. INTERIM REP., *supra* note 65, at 6-9.

85. *Id.* at 9.

86. A person who illicitly manufactures meth is commonly referred to as a meth “cook.” A person who busily goes from store to store acquiring pseudoephedrine pills for a meth cook, usually in exchange for finished product, is commonly referred to as a “smurf,” an oblique reference to the social structure and behaviorisms of small blue characters in a popular children’s animated television series by that same name.

87. See Steve Painter, *Meth Makers Flock Here for Ingredients*, WICHITA EAGLE (Kansas), Dec. 14, 2004; *Oregon Law Drives Meth Makers to Washington* (King 5 News, Seattle, Washington, television broadcast Feb. 15, 2005).

88. OFFICE OF NAT’L DRUG CONTROL POL’Y, PUSHING BACK AGAINST METH: A PROGRESS REPORT ON THE FIGHT AGAINST METHAMPHETAMINE IN THE UNITED STATES 6-9 (Nov. 30, 2006); NAT’L ALLIANCE FOR MODEL STATE DRUG LAWS, RESTRICTIONS ON OVER-THE-COUNTER SALES/PURCHASES OF PRODUCTS CONTAINING PSEUDOEPHEDRINE—STATE LEGISLATIVE/REGULATORY RESTRICTIONS (Nov. 3, 2006).

89. OregonLive.com, Unnecessary Epidemic: A Five-Part Series, <http://www.oregonlive.com/special/oregonian/meth/> (last visited June 27, 2007). As a result of this ground breaking investigative journalism, reporters Steve Suo and Erin Hoover Barnett were finalists for the 2005 Pulitzer Prize for national reporting. The Pulitzer Prize Winners 2005, <http://www.pulitzer.org/year/2005/national-reporting/> (last visited June 27, 2007).

attention to the need for strong domestic and international control of ephedrine and pseudoephedrine as a means of controlling the meth epidemic.<sup>90</sup>

Also in October of 2004, the federal government issued its own report.<sup>91</sup> Although lacking the thorough examination of the underlying facts and history as provided by *The Oregonian*, the report identified the need for stronger state, federal, and international control of ephedrine and pseudoephedrine.<sup>92</sup> The stage had been set for taking strong action to control both domestic and international pseudoephedrine.

With a dramatic reduction in the incidence of small toxic meth labs in Oklahoma, Oregon, and many other states,<sup>93</sup> two questions arose: (1) How to eradicate the remaining local toxic meth labs, as a matter of public safety and community protection; and (2) how to eradicate the “super labs” producing most of the meth.

Answering the first question required an analysis of the source of pseudoephedrine feeding the remaining small toxic meth labs in those states that had already taken strong action to control pseudoephedrine, such as Oklahoma and Oregon. Not surprisingly, the primary sources of pseudoephedrine for the remaining small toxic meth labs in those states were group smurfing and interstate smurfing.<sup>94</sup>

To eliminate group smurfing, in 2005 the Oregon legislature enacted a bill to classify pseudoephedrine as a prescription drug.<sup>95</sup> In order to prove

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90. The series also led to the production of a national broadcast by PBS's Frontline. *The Meth Epidemic* (PBS Frontline Film 2006), available at <http://www.pbs.org/wgbh/pages/frontline/meth> (last visited July 10, 2007).

91. See generally OFFICE OF NAT'L DRUG CONTROL POLICY, NAT'L SYNTHETIC DRUGS ACTION PLAN (2004).

92. *Id.*

93. OFFICE OF NAT'L DRUG CONTROL POL'Y, *supra* note 64, at 11. By 2006, the federal government estimated that the percentage of meth on the street being produced in local toxic home meth labs had decreased from thirty-five percent to twenty percent. *Id.*

94. Interstate smurfing refers to the practice of traveling to a state where pseudoephedrine is not as heavily regulated, in order to smurf the pseudoephedrine. See *supra* note 86 (providing the meaning of the term “smurf”). Group smurfing refers to the practice of having a group of smurfers, each of whom goes to a pharmacy or two and acquires a small amount of pseudoephedrine at each pharmacy, thus effectively evading the Oklahoma rule by acting as a group.

95. 2005 Or. Laws, ch. 706 (Enrolled House Bill 2485), § 11; OR. REV. STAT. § 475.973 (2005). For a time, the Oregon legislature seriously considered banning pseudoephedrine altogether. Jeff Mapes, *State Lawmakers Draft Ban on All Cold Pills Used to Make Meth*, THE OREGONIAN, May 25, 2005, at A1. House Bill 2485 was half of the 2005 Oregon anti-meth package. The other half was Enrolled Senate Bill 907, focusing on drug endangered children. 2005 Or. Laws, ch. 708. Interestingly enough, there was only one Oregon legislator who voted against the entire 2005 Oregon anti-meth package. Tragically, in a bizarre turn of events, a few months later, that legislator was charged with possession of meth, and later resigned. Janie Har, *Lawmaker Faces Arrest in Salem on Meth Charge*, THE OREGONIAN, Oct. 13, 2005, at A1; Jeff Mapes & Janie Har, *Private Troubles, Public Downfall*, THE OREGONIAN, Oct. 16, 2005, at A1.

the point, the bipartisan Oregon legislative meth caucus themselves became group smurfers (the author served as their pretend meth “cook”), and over the course of an hour they lawfully purchased enough pseudoephedrine to produce 180 doses of meth.<sup>96</sup> The prescription requirement went into effect on July 1, 2006.<sup>97</sup> As a result, Oregon has now experienced the largest reduction in small toxic meth labs.<sup>98</sup> To address interstate smurfing, we urged Congress to pass legislation that, at a minimum, would nationalize the highly successful Oklahoma rule. Entitled the Combat Methamphetamine Act (CMA), it was introduced in the Senate.<sup>99</sup>

Finally, to address cutting off the supply of pseudoephedrine feeding the “super labs” producing most of the world’s meth, we urged Congress to pass legislation requiring the tracking of international pseudoephedrine shipments to ensure they were not diverted, setting international quotas on legitimate imports of pseudoephedrine, and empowering the federal government to cut United States foreign aid from countries that failed to comply. Entitled the Methamphetamine Epidemic Elimination Act (MEEA), it was introduced in the House.<sup>100</sup>

### III. 2006 AND BEYOND: A GOLDEN OPPORTUNITY

By the end of 2005, it was clear that the pharmaceutical industry was not happy with the CMA, and the Administration was not happy with the MEEA.<sup>101</sup> As a result, Congressional leaders decided they needed to consolidate the CMA and the MEEA into a single piece of legislation, and stuff

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96. Jeff Mapes, *Lawmakers Score Pills to Cook Up Support for Prescription Bill*, THE OREGONIAN, July 20, 2005, at A1.

97. OR. ADMIN. R. 855-080-0023 (2006).

98. See generally OFFICE OF NAT’L DRUG CONTROL POL’Y, PUSHING BACK AGAINST METH, *supra* note 88; see generally Pre and Post Pseudoephedrine Control Oregon Meth Lab Stats, <http://www.oregondec.org/OregonMethLabStats.pdf> (last visited Apr. 17, 2007).

99. S. 103, 109th Cong. (introduced Jan. 24, 2005).

100. H.R. 3889, 109th Cong. (introduced Sept. 22, 2005). The bill was assembled by Congressman Mark Souder (R-In) and combined key provisions from earlier legislation: specifically H.R. 1056, introduced on March 2, 2005, by Congresswoman Darlene Hooley (D-Or); H. Amdt. 460 to H.R. 2601 as offered by Congressman Mark Kennedy (R-Mn) and passed by the House on July 19, 2005; and H. Amdt. 461 to H.R. 2601 as offered by Congresswoman Hooley and passed by the House on July 19, 2005.

101. However, unlike past attempts in Congress, the pharmaceutical industry was no longer entirely united. For example, Pfizer, which had already reformulated many of its products, see *supra* note 71, was not as actively opposed to the CMA as Schering-Plough, which could not yet reformulate one of its most popular pseudoephedrine products. Ironically, only a few years before, Schering-Plough had fought efforts by the insurance industry to move that same product from prescription to over-the-counter, fearing that a lack of insurance coverage for the drug product would reduce sales. See Holley M. Spencer, *The Rx-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health*, 51 AM. U. L. REV. 999, 1023 (2002).

the result into a bill that was destined for passage. The result was the Combat Methamphetamine Epidemic Act (CMEA), inserted into the “USA PATRIOT Improvement and Reauthorization Act” as Title VII, and signed into law by President George W. Bush on March 9, 2006.<sup>102</sup>

Subtitle A of the CMEA contains domestic controls on pseudoephedrine.<sup>103</sup> It essentially nationalizes the highly successful Oklahoma rule by moving all pseudoephedrine products behind the counter, but with a big difference: It does not confine the products to behind the pharmacy counter (in other words, convenience stores, grocery stores, mobile cart vendors, and others can keep selling pseudoephedrine products).<sup>104</sup> It went into effect on September 30, 2006.<sup>105</sup>

Subtitle B of the CMEA contains the international controls from the MEEA.<sup>106</sup> Unlike the Subtitle A domestic controls, the Subtitle B international controls were not watered down.<sup>107</sup>

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102. U.S.A. PATRIOT Improvement and Reauthorization Act of 2005, Pub. L. No. 109-177, 120 Stat. 192, 256 (2006). Some of us were not very excited to see the CMEA inserted into that controversial bill. However, the argument on the flip side was that the CMEA did not have the votes in Congress to pass on its own.

103. *Id.* § 711 (e)(1)(A).

104. Our efforts to fight this unfortunate watering down of Subtitle A of the CMEA failed. It is particularly troublesome that these products have been left in convenience stores. While sales of these products in convenience stores represent less than one percent of the overall legitimate sales of the products; retaining the products in convenience stores leaves a huge hole in overall control. See GENE M. LUTZ & JAIME MAYFIELD, CTR. FOR SOC. & BEHAV. RES., IOWA ADULT PSEUDOEPHEDRINE PRODUCTS PURCHASING SURVEY, CENTER FOR SOCIAL AND BEHAVIORAL RESEARCH, UNIVERSITY OF NORTHERN IOWA 12 (2003), available at [http://www.csbs.uni.edu/dept/csbr/pdf\\_ODCP\\_Pseudoephedrine-2003.pdf](http://www.csbs.uni.edu/dept/csbr/pdf_ODCP_Pseudoephedrine-2003.pdf) (sales in convenience stores represents less than one percent of the legitimate product sales); JONATHAN E. ROBBIN, DRUG ENFORCEMENT ADMIN., ESTIMATION OF SIZE OF SALES OF PSEUDOEPHEDRINE PRODUCTS BY CONVENIENCE STORES IN OREGON, RICERCAR, INC. 9-10 (2001) (almost all convenience stores were selling pseudoephedrine “wildly in excess” of legitimate consumer demand; most convenience stores were “extreme outliers” for what they should have been selling; product sales expected to be in the thirty to forty dollar range per month per store, based on national studies, were instead in the \$500-\$1,000 range per month per store).

105. Despite our failure to prevent the watering down of Subtitle A of the CMEA, see *supra* note 78, we were successful in preventing the pharmaceutical industry from inserting a preemption clause inserted into Subtitle A. A preemption clause would have gutted the stronger and more effective controls enacted by a number of states, such as Oklahoma and Oregon.

106. U.S.A. PATRIOT Improvement and Reauthorization Act, Pub. L. No. 109-177, §§ 721-23, 120 Stat. 267-70 (2005).

107. However, the President added a so-called “signing statement” to the bill. The signing statement purports to reserve to the “unitary executive branch” the authority to withhold from Congress certain information, and recommendations for legislation. *Id.*; see President’s Statement on H.R. 3199, the “USA PATRIOT Improvement and Reauthorization Act of 2005,” (Mar. 9, 2006), <http://www.whitehouse.gov/news/releases/2006/03/20060309-8.html>. It remains to be seen whether this purported reservation of “unitary executive branch” authority will be exercised to withhold information or recommendations relating to the international pseudoephedrine control provisions of the CMEA.

In addition to the international controls provided in the CMEA, a few recent events have significantly furthered the cause of international control of ephedrine and pseudoephedrine. In March of 2006, the United Nations passed a resolution calling on all nations to establish strict control and monitoring of precursor chemicals,<sup>108</sup> as well as actively cooperate in the backtracking of illegal diversions of precursor chemicals to their source.<sup>109</sup>

In Mexico, the location where most of the “super labs” supply most of the meth in America,<sup>110</sup> the government recently took aggressive action to significantly reduce importation of pseudoephedrine to levels supported by legitimate consumer need.<sup>111</sup> This strong action has significantly impaired

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108. The Resolution encourages all nations to establish or strengthen mechanisms and procedures to ensure strict control of substances used to manufacture illicit drugs, to support international operations aimed at preventing their diversion, including thorough coordination and cooperation between regulatory and enforcement services involved in precursor control, in cooperation with the International Narcotics Control Board, and to counter smuggling networks effectively, particularly in source and transit countries, by conducting, inter alia, backtracking law enforcement investigations.

G.A. Res. 60/178, ¶ 13, U.N. GAOR, 60th Sess., U.N. Doc. A/RES/60/178 (Mar. 22, 2006); see United Nations Commission on Narcotic Drugs Resolution, G.A. Res. 48/11, U.N. GAOR, 48th Sess. (Feb. 28, 2003) (“Strengthening international cooperation to prevent the illicit manufacture of and trafficking in narcotic drugs and psychotropic substances by preventing the diversion and smuggling of precursors and essential equipment in the context of Project Prism, Operation Purple and Operation Topaz.”). Project Prism is an ongoing effort of the International Narcotics Control Board to monitor and prevent the international illicit diversion of key precursor chemicals, including ephedrine and pseudoephedrine. See generally INT’L NARCOTICS CONTROL BD., PRECURSORS AND CHEMICALS, *supra* note 11.

109. The Resolution urges all nations and relevant international organizations to cooperate closely with the International Narcotics Control Board in order to enhance the success of “international initiatives and to initiate, where appropriate, investigations by their law enforcement authorities into seizures and cases involving the diversion or smuggling of precursors and essential equipment, with a view to tracking them back to the source of diversion in order to prevent continuing illicit activity.” G.A. Res. 60/178, ¶ 13, U.N. GAOR, 60th Sess., U.N. Doc. A/RES/60/178 (Mar. 22, 2006).

110. In the 1990s, most of the “super labs” were set up in remote farm areas of central California. Interview by PBS Frontline with Bob Pennal, Commander, Fresno Meth Task Force (2005), available at <http://www.pbs.org/wgbh/pages/frontline/meth/interviews/pennal.html>. However, strong action by United States authorities effectively chased the “super labs” to Mexico. See Richard Marosi, *U.S. Crackdown Sends Meth Labs South of the Border, Mexico Inherits a Problem that Was Long California’s*, L.A. TIMES, Nov. 26, 2006, at A1; see also 2005 INT’L NARCOTICS REP., *supra* note 1, at 58.

111. After the “super labs” migrated to Mexico in the late 1990s and early 2000s, Mexico’s importation of pseudoephedrine skyrocketed from a legitimate need of roughly 70 metric tons per year to 224 metric tons in 2004. Steve Suo, *The Mexican Connection*, THE SUNDAY OREGONIAN, June 5, 2005, at A1; Steve Suo, *Mexico’s Math Problem Adds Up to a U.S. Meth Problem*, THE SUNDAY OREGONIAN, June 5, 2005, at A1. In 2005, Mexico cut its importation of pseudoephedrine to 134 metric tons, and for 2006 was aiming for 76 metric tons. Steve Suo, *Mexico Cuts Imports of Meth Ingredients*, THE SUNDAY OREGONIAN, Nov. 20, 2005, at A1. “The Mexican authorities have now taken specific steps to prohibit brokers from importing pseudoephedrine and have reduced imports of the substance by one half on the basis of an estimate of actual licit requirements.” INT’L NARCOTICS CONTROL BD., PRECURSORS AND CHEMICALS, *supra* note 11, at 2.

the ability of the drug cartels to acquire adequate pseudoephedrine to feed the “super labs,” as evidenced by extreme measures and extreme violence among and between drug cartels.<sup>112</sup>

In India, one of the two primary source nations for diverted ephedrine and pseudoephedrine, the government has been taking strong action to prevent unlawful diversions.<sup>113</sup> However, it appears that China, the other primary source nation, has not yet taken strong action to prevent unlawful diversions.<sup>114</sup> In any event, these recent efforts to both domestically and internationally control pseudoephedrine have cut the average purity of meth from seventy-seven percent in the spring of 2005 to fifty-one percent in the spring of 2006.<sup>115</sup>

Much progress has been made, but without a doubt, there is more work to be done.<sup>116</sup> That work includes, but is not limited to:

- (1) Encouraging more states to make pseudoephedrine a prescription drug, or at a minimum adopt the full Oklahoma rule. If the purity of drug cartel meth continues to decline, there will be even more incentive for group smurfing and small toxic meth labs.

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112. See, e.g., *Gunmen Kill Four in Mexican Pseudoephedrine Heist*, REUTERS, July 25, 2006; see also Lourdes Garcia-Navarro, *Morning Edition: Mexican Border Town Caught in Drug War* (NPR radio broadcast Sept. 21, 2005); *All Things Considered: Violence Surges Along U.S.-Mexico Border* (NPR radio broadcast Feb. 12, 2006); *Day to Day: Drug Violence Rocks Acapulco* (NPR radio broadcast Feb. 22, 2006); Lourdes Garcia-Navarro, *Morning Edition: Mexico's Drug Wars Leave Rising Death Toll* (NPR radio broadcast Sept. 21, 2006); Lourdes Garcia-Navarro, *All Things Considered: Tijuana's Drug Boom Reflects Mexico's New Problem* (NPR radio broadcast Oct. 16, 2006). In the face of escalating violence, Mexico has responded, at least initially, not by abandoning its commitment to control pseudoephedrine, but by clamping down on the drug cartels. See *Mexico Launches War on Drug Lords, Calderon Vows War Against Notorious Drug Gangs*, ASSOC. PRESS, Dec. 12, 2006; *Police Find \$206 Million in Drug Cash in Mexican House*, REUTERS, Mar. 16, 2007, available at <http://uk.reuters.com/article/wtMostRead/idUKN1643855620070317>.

113. See Pradeep Thakur, *Firms Making Prohibited “Stimulants” Under Lens*, TIMES OF INDIA, Aug. 22, 2006, available at <http://timesofindia.indications.com/articleshow/1914073.cms> (explaining that the Narcotics Control Bureau is monitoring the investigation of six companies that produce ephedrine); *Narcotic Drug's Easy Availability Worries Police, Medicos*, HEALTH NEWS ONLYPUNJAB.COM, Aug. 21, 2006, <http://onlypunjab.com/fullstory2k5-insight-police+medicos-status-22-newsID-111115.html>. Earlier efforts also successfully plugged some of the pseudoephedrine control gaps in Canada. See 2005 INT'L NARCOTICS REP., *supra* note 1, at 28. However, it appears that more work is needed to close the Canadian gap. See Steve Suo, *B.C. Drug Traffickers Expanding Into Meth*, THE OREGONIAN, Dec. 4, 2006, at A1.

114. Steve Suo, *Mexico Halts Meth Chemical at Pacific Port*, THE OREGONIAN, Dec. 14, 2006, at A1 (detailing a situation in which 19.5 tons of pseudoephedrine was seized by Mexican authorities in Michoacan).

115. Suo, *Crackdown Puts Meth Trade in a Bind*, *supra* note 61, at A1; see *Meth Use Receding in Some Regions*, ASSOC. PRESS, Apr. 1, 2007, available at <http://washingtonpost.com/wp-dyn/content/article/2007/04/01/AR2007040100415.html>.

116. See generally INT'L NARCOTICS CONTROL BD., PRECURSORS AND CHEMICALS, *supra* note 11.

States that are relying upon Subtitle A of the CMEA, with its gaping hole, have a huge potential risk.<sup>117</sup>

(2) Encouraging Congress to amend Subtitle A of the CMEA to fix the gaping hole.<sup>118</sup>

(3) Providing the international community with the tools and support necessary to quickly and efficiently shut down all gaps that develop in the international flow of ephedrine and pseudoephedrine, to ensure that those two key precursors do not feed the “super labs” of drug cartels.<sup>119</sup>

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117. See *supra* notes 86 and 94 and accompanying text; see also Rob Bovett & Craig Durbin, Presentation at the Annual Conference of the Nat’l Methamphetamine & Chemicals Initiative: A Case for Quickly Moving Pseudoephedrine to Schedule III (May 17-18, 2006), available at <http://www.oregondec.org/NMCIBrochure.pdf>.

118. *Id.*

119. INT’L NARCOTICS CONTROL BD., PRECURSORS AND CHEMICALS, *supra* note 11, at 4. The key is to maintain flexibility and speed. *Id.*

As has been seen in the past, when adequate controls are introduced in one country, traffickers will immediately target other countries in the region where controls may not be as strong. Following the introduction of stricter controls in Mexico, attempts to divert 3,000 kg of ephedrine and 3,000 kg of pseudoephedrine through Belize and 350,000 pseudoephedrine tablets through Nicaragua were uncovered.

*Id.* There may be a need to amend Subtitle B of the CMEA, but most importantly the need to amend will simply require being out there, with staff, “visiting all these countries, making friends, establishing connections, because people trust when they meet eye to eye, face to face, not once, but frequently. Then people trust. Then information flows. Then cases are made. Then things happen.” Interview by PBS Frontline with Gene Haislip, *supra* note 24. After speaking for years with supply-side policy makers, Steve Suo of *The Oregonian* recently reported the following short list of ideas gleaned from those policy makers:

**[1] Shortening the distribution chain.** Mexico has banned middlemen from handling ephedrine and pseudoephedrine. Only pharmaceutical companies may import the chemicals. India and China could do the same, prohibiting sales from ephedrine factories to chemical brokers within the country or overseas.

**[2] Boosting technical training for Indian regulators.** The DEA’s chemicals office recently announced it will exchange personnel with Mexico’s health agency, COFEPRIS. Congress could expand such efforts. The Methamphetamine Trafficking Prevention Act of 2006, a bill co-sponsored by Sen. Gordon Smith, R-Ore., would authorize \$2 million for training countries that traffic in meth and its ingredients.

**[3] Helping the U.N. audit Chinese manufacturers.** Wong Hoy Yuen, the U.N. project coordinator for precursor control in East Asia, has proposed a pilot program that would audit sales records of Chinese ephedrine manufacturers for suspicious patterns. Wong estimates it would cost \$100,000, but the program is on hold for lack of funding. Congress could finance it through the State Department.

**[4] Encouraging participation in the U.N.’s ephedrine “signature” program.** Investigators someday could identify sources of diversion by testing ephedrine seized at meth labs against chemical profiles of ephedrine provided by manufacturers. The project has been in the works for two years, but not all Indian and Chinese manufacturers have volunteered their assistance.

**[5] Providing forensic laboratory equipment to India.** A. Shankar Rao, director of India’s Narcotics Control Bureau for New Delhi, is a fan of the U.N.’s ephedrine

- (4) Developing and implementing comprehensive science-based prevention, enforcement, and treatment programs.<sup>120</sup>

#### IV. CONCLUSION

After a long and frustrating struggle, strategies to curb the manufacturing of methamphetamine are working. Small toxic meth labs have all but disappeared in states that have effectively controlled pseudoephedrine. Meth purity is plummeting and meth price is increasing due to stronger international controls on ephedrine and pseudoephedrine. There is now a window of opportunity—a golden opportunity—to take the next step and deal with the underlying issue of addiction, through science-based prevention, enforcement, and treatment. We must begin the process of healing lives and families and ending the vicious cycle of addiction.

*One-hundred years from now,  
it will not matter what your bank account was,  
the sort of house you lived in, or the kind of car you drove.  
But the world may be different because you were  
important in the life of child.*

—Anonymous

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signature program. But even if the signatures were available, his agency lacks the facilities to exploit the data in investigations.

**[6] Paying ephedrine factories not to produce.** The U.S. Agency for International Development spent \$216 million in 2006 to help Latin American farmers grow crops other than cocoa, the ingredient in cocaine. USAID could use some of the money to help ephedrine makers retool at a time when sales to North America have dropped 75 percent since 2004. That year, countries worldwide valued their imports of ephedrine and pseudoephedrine from Germany, India, China and Czech Republic at \$84 million, U.N. data show.

Steve Suo, *Cutting Off the Pipeline*, THE SUNDAY OREGONIAN, Dec. 3, 2006, at A18.

120. G.A. Res. 60/178, ¶ 13, U.N. GAOR, 60th Sess., U.N. Doc. A/RES/60/178 (Mar. 22, 2006). For 150 years, we have based drug control policy, at least in part, on fear. We need to ensure that, henceforth, we base domestic and international drug control policy on science and facts. All nations “must renew their efforts, at the national, regional and international levels, to implement” comprehensive measures to “counter the abuse and recreational use of amphetamine-type stimulants, especially by young people, and to disseminate information on the adverse health, social and economic consequences of such abuse.” *Id.*



**Lincoln County District Attorney**  
 225 West Olive Street, Room 100, Newport, Oregon 97365  
 541-265-4145, FAX 541-265-3461, www.co.lincoln.or.us/da/

**Rob Bovett**  
 District Attorney

**Marcia Buckley**  
 Chief Deputy

**Rob Bovett**

**Drug Policy Bio**

- Rob serves as the elected District Attorney for Lincoln County, Oregon. Rob also serves as legal advisor for the Oregon Narcotics Enforcement Association. Rob is the primary author of Oregon’s meth lab control laws, and helped author federal laws to control international diversion of meth lab chemicals.



- Rob served as Chair of Oregon’s Meth Task Force, and currently serves on the Advisory Board of the National Methamphetamine & Pharmaceuticals Initiative (NMPI).
- Rob is co-founder and President of the Oregon Alliance for Drug Endangered Children.



- Rob created the Lincoln County Meth Initiative, focusing on science-based prevention, enforcement, and treatment.
- Rob recently authored a law review article entitled *Meth Epidemic Solutions*, 82 North Dakota Law Review 1195.



- Rob has provided over 400 presentations regarding drug policy, and has appeared on numerous programs, including ABC World News, Good Morning America, National Public Radio, and PBS NewsHour and FRONTLINE.
- Rob is the recipient of the 2006 Oregon Governor’s Gold Award for outstanding public service, and the 2008 NMPI national “Impact” award.



- Rob is married and has four children – two in college, one in high school, and one in the National Guard – so Rob is aging a bit faster than normal.



The “No Meth Not Here” campaign banner image above was created in the Spring of 2007 by students at the Siletz Valley School as part of the Methamphetamine Awareness Project (MAP), a part of the Lincoln County Meth Initiative (LCMI).

