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Samantha S. McKinley

Joseph L. Fink III

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“SPEED LIMITS:” STATES’
APPROACHES TO REGULATING ACCESS
TO METHAMPHETAMINE CHEMICAL PRECURSORS
WITH STATUTES AND REGULATIONS LIMITING
PSEUDOEPHEDRINE AVAILABILITY

SAMANTHA S. MCKINLEY[†] AND JOSEPH L. FINK III^{††}

I. INTRODUCTION

Methamphetamine is a stimulant medication lawfully distributed under the brand name Desoxyn®.¹ According to the federal Controlled Substances Act,² the United States Drug Enforcement Administration (DEA) classifies methamphetamine as a classified Schedule II substance.³ Illicit methamphetamine comes in a variety of forms and is known by many names. Some of the most common street names include “meth,” “crank,” “crystal,” and “speed.” Typically, methamphetamine is obtained as a white, odorless, bitter tasting powder or crystal substance. However, methamphetamine can be made in other forms. The most common route of administration is oral, although methamphetamine can be smoked, injected, or snorted.⁴ Each particular method of administration will affect the onset of the drug’s effect differently, making direct injection and snorting the favorites for illicit use because these routes allow for fast onset of effects. It is a powerfully addictive drug, which is easy to make and relatively inexpensive to purchase.

In the early 1980s, methamphetamine abuse was a small problem limited to the West Coast. However, over the last two decades the problem has exploded with an eastward drift, and now touches virtually the entire United States. It has devastated many small rural communities and is

[†]Third-year professional student, University of Kentucky College of Pharmacy. B.S. 1987, University of Florida; J.D. 1991, Whittier Law School; D.C. 1999, Northwestern Health Sciences University. Member of the Florida Bar.

^{††}Professor of Pharmacy, Professor of Public Health, and Professor of Health Administration, University of Kentucky. B.S. Pharm., 1973, Philadelphia College of Pharmacy and Science; J.D. 1973, Georgetown University Law Center. Member of the Kentucky and Pennsylvania Bars.

1. Merck Manuals Online Med. Library, Drug Names: Generic and Trade, <http://www.merck.com/mmhe/drugnames-index/trade/d.html> (last visited June 20, 2007).

2. Controlled Substances Act, 21 U.S.C. §§ 801-971 (2000).

3. 21 U.S.C. § 812(c) (2000).

4. U.S. Drug Enforcement Admin., DEA Briefs and Background, Drug & Drug Abuse, Drug Description, http://www.dea.gov/concern/methamphetamine_factsheet.html#3 (last visited June 13, 2006).

quickly moving into urban areas. The National Institute on Drug Abuse estimates that more than 1.2 million Americans have tried methamphetamine.⁵ The drug is seductive and the initial payoffs are big.

Methamphetamine gives the buyer more bang for the buck than any other drug on the street. A user can feel the affects of taking methamphetamine for eight to twenty-four hours depending upon individual tolerance.⁶ This energy boost is so alluring that it has even captured the interest of new young mothers.⁷ It helps new moms with weight loss, boosts energy levels to create Superwoman status and lifts inhibitions to raise self-esteem.⁸ The use of methamphetamine transcends all boundaries of social or economic classes and can be found in the hands of teenagers, factory and construction workers, corporate risers, and stay-at-home mothers. For these reasons, it should be no surprise that methamphetamine has captured the focus of law enforcement agencies and lawmakers across this country.

II. DIFFERENTIATING BETWEEN METHAMPHETAMINE, EPHEDRINE, AND PSEUDOEPHEDRINE

The active ingredient for synthesizing methamphetamine can be either ephedrine or pseudoephedrine.⁹ When snorted, swallowed, injected, or smoked, the cooked cold products produce a long lasting high and euphoric feeling. Although the exact mechanism of action is unknown, it is generally believed that methamphetamine causes the monoamine transporter to reverse its direction of flow within the brain.¹⁰ This results in further

5. NAT'L INST. ON DRUG ABUSE, NIDA ADDICTION TREATMENT DISCOVERY PROGRAM 4, available at http://www.drugabuse.gov/about/organization/DPMCDATDP/ATDP_2006_Guide.pdf.

6. NAT'L INST. ON DRUG ABUSE, METHAMPHETAMINE ABUSE AND ADDICTION, available at <http://www.nida.nih.gov/PDF/RRMethamphetamineam.pdf>.

7. Elizabeth Fish, *Mother's (Dangerous) Little Helper*, BABYTALK, Apr. 2006 at 62, available at <http://www.parenting.com/mom/article10,19840,1175602,00.html>.

8. *Id.*

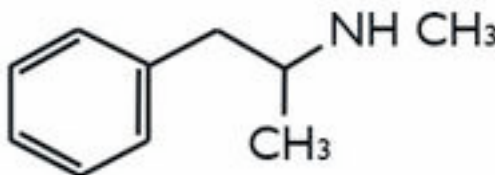
9. U.S. Food and Drug Admin., *Legal Requirements for the Sale and Purchase of Drug Products Containing Pseudoephedrine, Ephedrine, and Phenylpropanolamine*, <http://www.fda.gov/cder/news/methamphetamine.htm> (last visited Jan. 11, 2007).

10. See Annette E. Fleckenstein et al., *New Insights into the Mechanisms of Action of Amphetamines*, 47 ANNUAL REV. PHARMACOLOGY TOXICOLOGY 681, 683 (2001) (explaining the reverse transport of monoamines as a result of methamphetamine). Mechanism of action is the action or process by which a pharmacologically active substance produces an effect on a living organism or in a biochemical system. The Freedictionary.com, <http://www.thefreedictionary.com/p/mechanism-of-action> (last visited Jan. 11, 2007). Monoamine transporter is a protein structure involved in the movement of monoamines (substances with only one nitrogen group such as norepinephrine, dopamine, and serotonin) in biological systems. STUART IRA FOX, HUMAN PHYSIOLOGY 168-70 (8th ed. 2004). The synaptic cleft is the area of microscopic space between the pre-synaptic axon terminal and the post-synaptic cell. *Id.* At 168. A neurotransmitter is a chemical substance "that is released from the axon terminal of a presynaptic neuron on excitation, and that travels across the synaptic cleft to either excite or inhibit a target cell" to cause effect.

release of monoamines to the synapse and blocks the re-uptake of these neurotransmitters causing them to remain longer within the synaptic cleft.¹¹

However, the desirable upfront benefits are only a part of a stimulant use story that often carries an unhappy ending. One neuropsychiatrist explained this well when he said, “[m]eth first stimulates and then blows out the brain’s pleasure centers until, finally . . . ‘nothing feels good.’”¹² Methamphetamine is an extremely difficult addiction to overcome and chronic use causes a dramatic shift in a person’s physical appearance. Methamphetamine use will in short order rot teeth, wrinkle skin, and create an intense itching, which will lead to scratching and scarring. It can convert a young, full-faced person to a desiccated, aged, toothless person with a face covered with bloody, open sores in little time.

Methamphetamine is fairly easy to manufacture in rudimentary laboratories from commonly available chemicals including non-prescription decongestants, such as ephedrine and pseudoephedrine. Methamphetamine is a synthetic stimulant drug used for both medicinal and illegal recreational purposes. Like most stimulants, methamphetamine can produce a very strong euphoria and thus carries a great potential for addiction.



Methamphetamine

Source: structures taken from www.chemicalforums.com.¹³

BENJAMINE FRANK MILLER & CLAIRE BRACKMAN KEANE, *ENCYCLOPEDIA & DICTIONARY OF MEDICINE, NURSING AND ALLIED HEALTH* 1025 (5th ed. 1992).

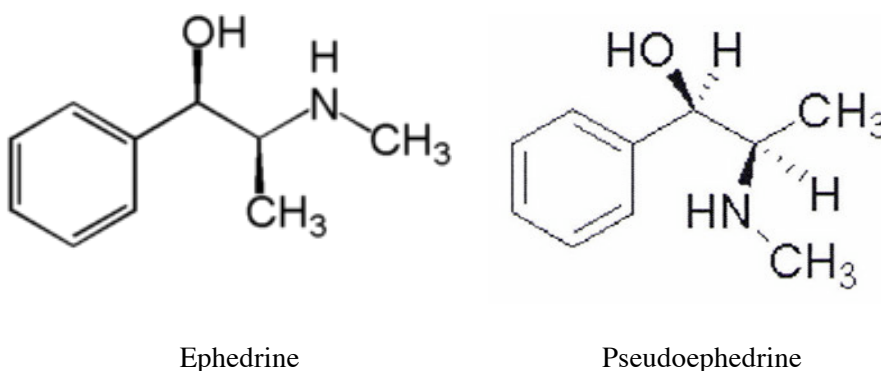
11. See Evan L. Riddle et al., *Mechanisms of Methamphetamine-Induced Dopaminergic Neurotoxicity*, 8 AM. ASS’N PHARMACEUTICAL SCIENTISTS E413, E413-14 (2006) (indicating that methamphetamine prevents re-uptake and causes an increased concentration of neurotransmitter).

12. Virginia Heffernan, *An Illegal Drug From Labs That Can’t Be Shut Down*, N.Y. TIMES, Feb. 14, 2006, at B8.

13. ChemicalForums.com, *The Chemical Structure of Methamphetamine*, <http://www.chemicalforums.com/index.php?page=molecules#methamphetamine> (last visited Jan. 11, 2007).

Both ephedrine and pseudoephedrine are sympathomimetic amines commonly used as decongestants.¹⁴ Each is marketed in many over-the-counter products in a hydrochloride or sulfate salt form. Ephedrine is a chemical alkaloid derivative of Ephedra plants. Ephedrine exhibits a phenomenon known as “optical isomerism,” and has two chiral centers.¹⁵

On the other hand, pseudoephedrine is an isomer of ephedrine. In this way, ephedrine and pseudoephedrine are very similar and differ regarding chiral positioning. However, this slight structural difference appears to make pseudoephedrine the preferred decongestant because it has far lower central nervous system activity when compared to other Ephedra alkaloids including ephedrine.¹⁶



Source: structures taken from Remington.¹⁷

The chemical structures of ephedrine and pseudoephedrine are very similar to that of methamphetamine. In fact, the primary difference is the presence of the oxygen on the alcohol group of the benzylic position in the compound. The similarity in chemical structure to amphetamines along with availability and ease of obtaining them has made ephedrine and/or

14. Brian B. Hoffman, *Catecholamines, Sympathomimetic Drugs, and Adrenergic Receptor Antagonists*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 237-38 (Joel G. Hardman & Lee E. Limbird eds., 10th ed. 2001). Sympathomimetic amines refer to chemical substances that contain a nitrogen group and whose effects mimic the effects seen with activation of the sympathetic (fight or flight) nervous system liberating adrenaline like substances. *Id.* at 216; REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 1379 (21st ed. 2005).

15. REMINGTON, *supra* note 14, at 171, 187.

16. Tga.gov.au, Core Pseudoephedrine Product Information, <http://www.tga.gov.au/npmads/pi-pseudoephedrine.rtf> (last visited Jan. 11, 2007).

17. REMINGTON, *supra* note 14, at 1385, 1387.

pseudoephedrine a perfect and highly sought after chemical precursor for the illegal manufacturing of methamphetamine.

III. THE MAKING OF METHAMPHETAMINE

The processing required to make methamphetamine from precursor substances is easier and more accessible than ever. The chemical reactions created in the cooking process serve the purpose to remove the oxygen group from the hydroxyl group on the pseudoephedrine, which is the only structural difference between pseudoephedrine and methamphetamine (see illustrations above). However, the effects of methamphetamine are much more potent and long lasting. Many different recipes for conversion to methamphetamine can be found on the Internet. Although most sites are not trustworthy, almost every method involves highly dangerous chemicals and processes.

A. THE ESSENTIALS

The beginning ingredient is usually an over-the-counter tablet product containing pseudoephedrine because it produces the highest quantity and purity of methamphetamine.¹⁸ Single ingredient products are preferred, again because of quantity and purity, but are not absolutely necessary. The tablets are then dissolved in a nonaqueous solvent like alcohol to remove the active ingredient from the excipients.

The recovered product is then processed by one of two usual methods. Most production methods involve the hydrogenation of the hydroxyl group on the ephedrine or pseudoephedrine compound, a form of oxidation chemical reduction. One of the most popular methods for converting pseudoephedrine or ephedrine to methamphetamine in the United States uses red phosphorus and iodine in the reaction to extract the methamphetamine base. This forms hydroiodic acid and is a fairly dangerous process from which many methamphetamine cooks have sustained deadly burns.

Another popular method is similar to a Birch reduction reaction, in which sodium or anhydrous ammonia (often available as farm fertilizer) and lithium metal (from lithium batteries) are mixed with the pseudoephedrine to create the methamphetamine base directly. This has also been called the “Nazi Method” because it supposedly mirrors a methamphetamine-making procedure followed by the Germans during World War II.¹⁹

18. Food Mktg. Inst., *Facts About Methamphetamine Precursors* 1, www.fmi.org/gr/Methamphetamine.pdf.

19. J. Steven Cline, *Illegal Methamphetamine Laboratories as a Public Health Hazard*, 71 POPULAR GOV'T (Special Issue) 24, 24 (2005).

This reduction process is extremely dangerous since the alkali metal and liquid anhydrous ammonia are both extremely reactive and the ammonia is very susceptible to explosion when the reactants are added.

B. OTHER CHEMICALS AND SUPPLIES USED IN MANUFACTURING METHAMPHETAMINE

There are, however, many other products used in the making of methamphetamine. The exact mix affects the purity of the product. Some of these products are precursor ingredients; others are supplies commonly used in methamphetamine production and are by no means comprehensive.²⁰

Precursors include products containing pseudoephedrine, acetone, ether (e.g., engine starter fluid), rubbing or isopropyl alcohol, methanol (e.g., gasoline), toluene (e.g., brake cleaner), red phosphorous (e.g., road flares and matchbook covers), iodine, sodium hydroxide or lye, white vinegar, lithium (e.g., batteries), anhydrous ammonia (e.g., fertilizer), sulfuric acid (e.g., drain cleaner), rock salt, and paint thinner.²¹ Some of the supplies used include aluminum foil, coffee filters, propane tanks, pyrex or corning dishes, jugs, bottles, funnels, cheesecloth, a blender, rubber tubing, paper towels, rubber gloves, gas can, tape or clamps, hotplate, strainer, and books (e.g., “How to Make Methamphetamine”).²²

C. THE ENTICEMENTS

To this day super laboratories operated by drug traffickers in Mexico or California remain the largest sources and producers of methamphetamine for the United States and rely more on diverted shipments of laboratory grade precursors rather than over-the-counter products.²³ Small, make-shift clandestine laboratories have flourished, in part because the cooking process for methamphetamine is quick, simple, and inexpensive. Clandestine laboratory operations can produce \$1,000 of methamphetamine from

20. Precursor ingredients refer to substances from which more biologically active substances are formed. MILLER & KEANE, *supra* note 10, at 1202. See Methamphetamine Watch Program, Background on Methamphetamine, http://www.methwatch.com/background/what_is_methamphetamine_index.aspx#3 (last visited Jan. 25, 2006) (explaining that methamphetamine can be made from commonly available, legitimate household products).

21. Methamphetamine Watch Program, Background on Methamphetamine, *supra* note 20; StreetDrugs.org, Methamphetamine Labs, <http://www.streetdrugs.org/methamphetaminelabs.htm> (last visited Jan. 25, 2006).

22. *Id.*

23. MICHELLE R. CHESLEY, METHAMPHETAMINES: AN EPIDEMIC OF CLANDESTINE LABS AND HEALTH RISK 4 (1999), <http://www.health.state.mn.us/divs/eh/methamphetamine/lab/mchesley.pdf>.

approximately \$100 of materials.²⁴ With this kind of lucrative profit margin, many people are lured into manufacturing methamphetamine. The average methamphetamine “cook” annually teaches ten other people how to make the drug.²⁵

D. THE DANGERS

The portion of methamphetamine that is made domestically in well-hidden mobile laboratories has cost taxpayers millions of dollars in clean-up, law enforcement, rehabilitation efforts, foster care, and medical aid.²⁶ Regardless of which production method is used, each method has inherent dangers. Many of the chemicals used are caustic or corrosive, and some of the processes create noxious and harmful fumes. The cooking process produces waste in liquid and solid form and carries the risk of producing a dangerous explosion. This waste is most often discarded in a way that contaminates the soil and groundwater. Thus, the production process is a danger to the environment, not just to those involved in the cooking process.

Because of the dangers, specially trained professionals, wearing full hazardous materials protection suits, must be used to dismantle a methamphetamine laboratory. It is estimated that for every pound of methamphetamine produced, five pounds of hazardous waste are also produced in the cooking process.²⁷ This type of clean up and hazard imposes a great financial burden on society.

Domestic laboratories also pose a huge danger to communities, law enforcement and children. Thousands of young and innocent children are suffering the consequences of the methamphetamine epidemic. In the worst cases, these children endure horrible abuse and even die at the hands of their own addicted parents. Many others are neglected while their parents are too high to notice. In the best cases, the children are discovered and then shuttled between relatives and foster homes, competing in a life filled

24. Joseph T. Rannazzisi, Deputy Chief, Office of Enforcement Operations, Drug Enforcement Admin., *Comprehensively Combating Methamphetamine: Impact on Health and the Environment* (Oct. 20, 2005), <http://www.usdoj.gov/dea/speeches/s102005.html>.

25. DrugFree.org, *Methamphetamine Frequently Asked Questions*, http://www.drugfree.org/Portal/DrugIssue/MethamphetamineResources/methamphetamine_faq.html (last visited May 30, 2007).

26. See WhiteHouseDrugPolicy.gov, *FactSheet: Impact of Methamphetamine on the Environment*, http://www.whitehousedrugpolicy.gov/news/press05/methamphetamine_environment_factsheet.html (last visited May 30, 2007) (discussing the costs of methamphetamine).

27. Armand McClintock, Assistant Special Agent, Indianapolis District Office Drug Enforcement Admin., *Fighting Methamphetamine in the Heartland: How Can the Federal Government Assist State and Local Efforts?* (Feb. 6, 2004), <http://www.usdoj.gov/dea/pubs/cngrtest/ct0220604.htm>.

with broken promises, violence, grief, and distrust. Many of these children are easily lost back into a life of crime or become reliant on society to support their livelihood. Many local and state police forces have responded by creating specialized task forces educated in responding to methamphetamine-involved cases. Also, many local communities have initiated task forces to assist local authorities, citizens, and child victims.

IV. CHANGE IN LEGISLATION

There are more than 700 over-the-counter products that contain ephedrine and/or pseudoephedrine, which could potentially be moved behind counters.²⁸ However, the majority of enacted legislation focuses only on the solid dosage forms of these products, and may even explicitly exempt any liquid formulations.²⁹ Liquid formulations may be exempt from tight regulation because, although chemists have made batches of methamphetamine from conversion of the liquid pseudoephedrine products, the process is more complex and less well known.³⁰ One can speculate that current illicit drug manufacturers are reluctant to spend the energy and resources for liquid formulation conversion when there has been such easy and convenient access to solid forms and a history of cooking guidelines. However, as regulations and restrictions curtail methamphetamine production, liquid formulations may become a greater concern.

A. SHARED JURISDICTION

Partially as a result of the rapid eastward spread of methamphetamine, the Comprehensive Methamphetamine Control Act of 1996³¹ (CMA) was signed into law on October 3, 1996.³² The CMA's primary purpose was to control the distribution of certain chemical precursors that could be used to

28. See In.gov, List Containing Over-the-Counter Products that Contain Pseudoephedrine and Ephedrine, http://www.in.gov/cji/methfreeindiana/Product_List.pdf (listing 777 products and disclaiming that this list is exhaustive).

29. Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, 120 Stat. 256 (codified as amended in scattered sections of 21, 22, and 42 U.S.C.); Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104-237, 110 Stat. 3099 (codified as amended in scattered sections of 21 and 28 U.S.C.); NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS, RESTRICTIONS ON OVER-THE-COUNTER SALES/PURCHASES OF PRODUCTS CONTAINING PSEUDOEPHEDRINE, available at <http://www.natlalliance.org/pdfs/Pseudoephedrine%20Products%20Overview%20November%202006%20Revised%20Version.pdf> [hereinafter STATE RESTRICTIONS].

30. Lee Rood, *Current Controls Have Had Little Effect*, DESMOINESREGISTER.COM, Jan. 9, 2005, <http://Desmoinesregister.com/apps/pbcs.dll/article?AID=/20050109//NEWS01/501090350>.

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

32. *Id.*

manufacture methamphetamine.³³ These precursors include ephedrine, pseudoephedrine and phenylpropanolamine which could be found in many over-the-counter products.³⁴ To avoid interfering with access to many common over-the-counter products, CMA specifically exempted “ordinary” over-the-counter sales of such products from its scope.³⁵ However, the methamphetamine problem continued to grow despite this legislative boundary.³⁶

In the wake of spreading illegal and dangerous methamphetamine laboratories and no federal law guidance, one by one the states began to enact restrictions on the sale of ordinary over-the-counter cold products containing ephedrine and pseudoephedrine.³⁷ In addition, many pharmacies and other retailers elected to limit consumer access to pseudoephedrine products irrespective of discrepancies in individual state laws and the lack of federal law.³⁸ Many companies like Target and Wal-Mart voluntarily placed the products behind the counter early on in the history of methamphetamine restrictions.³⁹

In spite of such voluntary restrictions and added responsibility for pharmacies and retailers, methamphetamine crimes continue to rise.⁴⁰ Due to the lack of federal law, methamphetamine producers could stockpile precursor supplies in states that did not have restrictions.⁴¹ In addition, even states that require sales logs do not have any cross reference structure in place, leaving an opportunity for methamphetamine makers to shop at many local outlets for their source of precursors.⁴²

33. § 401(d), 110 Stat at 3108.

34. *Id.*

35. *Id.*

36. Derick Quenzer & Steve Suo, *How Legislation Changed Meth Purity*, available at http://www.house.gov/larsen/methamphetamine/pdf/1004methamphetamine_purity.pdf.

37. See generally STATE RESTRICTIONS, *supra* note 29 (reviewing state bills and/or regulations establishing or enhancing restrictions on over-the-counter sales/purchases of pseudoephedrine).

38. Steve Ivey, *Anti-Methamphetamine Bill Would Place Restrictions on Pseudoephedrine*, CHI. TRIB., Nov. 26, 2005, at 1, available at http://www.redorbit.com/news/health/314171/antimethamphetamine_bill_would_place_restrictions_on_pseudoephedrine/index.html.

39. *Id.*

40. Quenzer & Suo, *supra* note 36.

41. Am. Pharm. Ass’n, *Pseudoephedrine Diversion: Regulatory and Scientific Resources*, 13 PARTNERS IN SELF-CARE 8-9 (Apr. 2005) [hereinafter *Pseudoephedrine Diversion*].

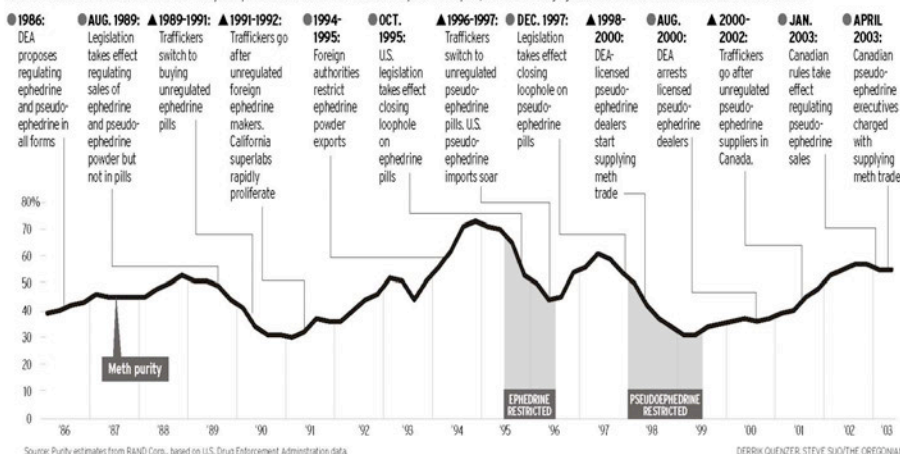
42. *Id.*

The following chart demonstrates how the methamphetamine supply has historically responded to legislative initiatives.⁴³ As a result, at least in part of this trend, the media and governmental officials have taken notice and the federal government has been called to act.

HOW LEGISLATION CHANGED METH PURITY

● Legislation/law enforcement ▲ Traffickers

The methamphetamine supply is uniquely susceptible to disruption by government, as revealed by changes in the drug's purity over the past two decades. Whenever new legislation limited access to the essential chemicals, production slowed, and traffickers watered down their product. The declines in purity began between the time Congress voted to impose tighter scrutiny over legitimate chemical sales and when the rules took effect. Traffickers always adapted because lawmakers left them loopholes to exploit, and federal drug agents were slow to enforce the laws that were enacted.



43. Quenzer & Suo, *supra* note 36.

B. NATIONAL RECOGNITION AND THE 2006 ENACTMENT OF THE
COMBAT METHAMPHETAMINE EPIDEMIC ACT OF 2005

The Combat Methamphetamine Epidemic Act of 2005⁴⁴ (CMEA) was, in essence, Congress’s response to the cry for additional control in relation to the methamphetamine epidemic.⁴⁵ The purpose was to close the gaps of the earlier CMA and provide centralized control to fight methamphetamine abuse.⁴⁶ However, loopholes still remained.⁴⁷ To close some of the outstanding loopholes, Congress passed new federal requirements to control the sales of pseudoephedrine as part of the USA PATRIOT Improvement and Reauthorization Act⁴⁸ (PATRIOT Act) in March 2006.⁴⁹

The CMEA was reauthorized and extended by Congress in the PATRIOT Act.⁵⁰ CMEA places ephedrine, pseudoephedrine and phenylpropanolamine in a new CSA category of “scheduled listed chemical products.”⁵¹ Products falling into this new class are subject to sales restrictions, storage requirements, and record keeping rules.⁵² Some of the requirements went into effect on April 8, 2006,⁵³ while others require compliance by September 30, 2006.⁵⁴ In a clarification to the American Pharmacists Association (APA), the DEA stated that the new law is applicable to over-the-counter “sales” but does not apply to valid prescriptions

44. Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, 120 Stat. 256 (2006).

45. *Pseudoephedrine Diversion*, *supra* note 41, at 11.

46. Ryan Lenz, Anti-Methamphetamine Laws Pose Dilemma for States (Oct. 9, 2005), <http://officer.com/article/article.jsp?siteSection=6&id=26363>.

47. *Id.*

48. USA PATRIOT Improvement and Reauthorization Act of 2005, Pub. L. No. 109-177, 120 Stat. 192 (2006) (codified in scattered sections of 18, and other titles of U.S.C.).

49. §§ 701-756, 120 Stat. at 256-77.

50. *Id.*

51. 21 U.S.C. § 802 (45)(A) (2006).

52. 21 U.S.C. § 830(d) (2006).

53. *Id.* Those changes effective April 8, 2006 impose a 3.6 grams daily sales limit, a 9.0 grams thirty day purchase limit, and require all non-liquid forms to be sold in blister packs or unit dose packets or pouches. *Id.* In addition, mail-service pharmacies must verify patient’s identification before shipping the product, and are subject to a 7.5 gram thirty-day purchase limit. 21 U.S.C. § 830(e)(1)(A) (2006).

54. 21 U.S.C. § 830 (2006). The changes, which became effective September 30, 2006, mandate that products must be placed behind a counter or in a locked cabinet, the seller must maintain a written or electronic logbook, purchasers must present a photo identification and sign the logbook, and sellers must self-certify to the U.S. Attorney General that their sales personnel have been trained as required by regulations. 21 U.S.C. § 830(b) & (e) (2006). Of particular note, sales of sixty milligram or less of pseudoephedrine are exempt from the logbook and identification requirements. 21 U.S.C. § 830(e) (2006).

for such products.⁵⁵ Since September 30, 2006 the law also requires the maintenance of a transaction logbook.⁵⁶ Because CMEA is a federal statute, states may, of course, impose more stringent requirements.

C. EMPLOYEE TRAINING UNDER THE CMEA

According to CMEA, all retailers of methamphetamine precursors must have trained their employees on the new requirements by September 30, 2006, and have self-certified to the DEA that the training occurred.⁵⁷ The DEA developed the training program which consists of nineteen slides.⁵⁸ Retailers must use the content supplied by the DEA in the training of their employees, but may supplement with additional material as they see fit or which their particular state requires.⁵⁹ These requirements are a part of the “interim final regulation.”⁶⁰ It has been speculated that consumers should expect more changes regarding the logbook, training, and ways to address privacy issues arising from the logbook utilization.⁶¹

D. SYNTHETIC DRUG CONTROL STRATEGY

On June 1, 2006, the Bush Administration went a step further in the fight against methamphetamine and released the Synthetic Drug Control Strategy (SDCS).⁶² The primary goal of SDCS is the reduction of methamphetamine.⁶³ The strategy is to focus on the use and production of methamphetamine and on the non-medical use of controlled substance prescriptions.⁶⁴ One of the keys to decreasing the methamphetamine epidemic is cooperating with Mexico in reduction efforts and to prevent the import of methamphetamine and its precursors across the border.⁶⁵

55. Pharmacist.com, PSE Restrictions Working, but Methamphetamine Problems Continue, http://www.pharmacist.com/articles/h_ts_1206.cfm (last visited July 22, 2006).

56. 21 U.S.C. § 830(e)(1)(A)(iii) (2006).

57. AM. PHAR. ASS’N, DEA INTERIM FINAL REGULATION: EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE REQUIREMENTS 1 (2006), available at <http://www.pswi.org/Pseudoephedrine093006.pdf>.

58. *Id.* at 6.

59. *Id.*

60. *Id.*

61. Ed Lamb, *Methamphetamine Control Laws Open Door for Patient Counseling*, 12 Pharmacy Today 18 (May 2006).

62. OFFICE OF NAT’L DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT, SYNTHETIC DRUG CONTROL STRATEGY, A FOCUS ON METHAMPHETAMINE AND PRESCRIPTION DRUG ABUSE (2006), available at http://www.whitehousedrugpolicy.gov/publications/synthetic_drg_control_strat/synth_strat.pdf [hereinafter SYNTHETIC DRUG CONTROL STRATEGY].

63. *Id.* at 5.

64. *Id.* at 5-6.

65. *Id.* at 16-17.

The SDCS is a companion document to the President’s National Drug Control Strategy and the CMEA. In addition, it includes detailed plans for unprecedented cooperation with Mexico and other international governments to drastically reduce the flow of methamphetamine and precursors into the United States.⁶⁶ Besides a call for a fifteen percent reduction in methamphetamine abuse in three years, the SDCS expects a twenty-five percent reduction in domestic methamphetamine laboratories.⁶⁷ Furthermore, the SDCS contains a three-prong approach to United States’ international efforts, including improving global intelligence regarding precursors, effective implantation of the CMEA, and strengthening law enforcement and border control.⁶⁸

Over the last several years, there have been numerous stories in the media highlighting how methamphetamine production can harm children.⁶⁹ Children are often used as cheap/free labor in the cooking process.⁷⁰ Young children are very vulnerable to the toxicity and poisoning and are often victims rather than active participants in their parents’ or other adults’ illegal production of methamphetamine. A core element of the Bush Administration response was supporting Drug Endangered Children (DEC) alliances.⁷¹ DEC programs train first responders on the best way to help protect children who are found in the vicinity of methamphetamine laboratories.⁷² Many states have enacted DEC programs.⁷³

V. THE NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS

Much of the information presented within the State Specific Provisions, which will be discussed in Section VI, was compiled utilizing and relying heavily upon the data and resources provided by the National Alliance for Model State Drug Laws (Alliance) via its official website.⁷⁴ The Alliance

66. *Id.* at 9.

67. *Id.* at 7.

68. SYNTHETIC DRUG CONTROL STRATEGY, *supra* note 62, at 11.

69. Laura Elmore, *Protection of Children Exposed to Methamphetamine Production*, 71 POPULAR GOV’T 28 (2005); *see also* Nat’l Alliance for Drug Endangered Children, Evidence-Based Practices and Research, <http://www.nationaldec.org/EvidenceBasedPrac&Rsrch/evidencebasedprac.htm> (last visited Jan. 23, 2007) [hereinafter Evidence-Based Practices and Research] (containing links to illustrative stories).

70. Evidence-Based Practices and Research, *supra* note 69.

71. SYNTHETIC DRUG CONTROL STRATEGY, *supra* note 62, at 41.

72. *Id.*

73. *See* Nat’l Alliance for Drug Endangered Children, <http://www.nationaldec.org/states/states.htm> (last visited Jan. 23, 2007) (providing information about all states that have DEC programs in place).

74. Nat’l Alliance for Model State Drug Laws, Home Page, <http://www.natlalliance.org> (last visited Feb. 22, 2007).

provides a valuable service in pulling such data into a collection of works for the purpose of tracking and facilitating the understanding of regulations regarding methamphetamine use. The Alliance is committed to the updating and maintaining of the information provided over their website for content accuracy. The information presented herein, regarding state regulations of pseudoephedrine and ephedrine products, draws heavily on the work of the Alliance. The authors here recognize that no amount of thanks is sufficient to express our gratitude for the work produced and available from the Alliance in collecting, organizing, and disseminating information of this type.

A. MISSION OF THE ALLIANCE

The National Alliance for Model State Drug Laws is an information portal for “governors, state legislators, attorneys general, drug and alcohol professionals, community leaders, the recovering community, and others who strive for comprehensive, effective state drug and alcohol laws and policies.”⁷⁵ The Alliance provides several services such as drafting, researching, and analyzing model drug and alcohol laws and related state statutes; provides access to a national network of drug and alcohol experts; and facilitates working relationships among state and community leaders and drug and alcohol professionals.⁷⁶

B. FORMING THE ALLIANCE

The Alliance is a nonprofit organization that serves as an ongoing resource on the model laws and related state legislation.⁷⁷ It is funded by Congressional appropriations, and, in coordination with the Office of National Drug Control Policy, it holds state model drug law Summits across the country.⁷⁸ These events are designed to educate state officials about the model laws and policies.⁷⁹

VI. STATE SPECIFIC PROVISIONS

As previously noted, while federal legislation such as the CMEA, the Patriot Act and the SDCS were being considered and created, the majority of states enacted laws that placed restrictions on the sale of

75. Nat'l Alliance for Model State Drug Laws, About the Alliance, <http://www.natlalliance.org> (last visited Feb. 22, 2007).

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

methamphetamine precursors, especially pseudoephedrine. To support comparisons made throughout this section, a review of the 2005 state statutes and/or regulations establishing or enhancing restrictions on the over-the-counter sales of ephedrine and/or pseudoephedrine products was conducted utilizing information available from the Alliance website.⁸⁰

A. FEDERAL DRUG SCHEDULE UTILIZED

In order to appropriately discuss state approaches to drug schedules, it is useful to briefly survey the federal drug schedule, because doing so will provide a common starting ground for a discussion of state methods. The Comprehensive Drug Abuse Prevention and Control Act⁸¹ was enacted in 1970.⁸² Title II of this Act is the Controlled Substances Act (CSA), which is the legal foundation of narcotics enforcement in the United States.⁸³ The CSA places all drugs into one of five classifications or schedules.⁸⁴

Schedule I drugs carry a high tendency for abuse and have no accepted medical use. Pharmacies do not sell Schedule I drugs and they are not available even with a prescription.⁸⁵ Examples include Lysergic acid diethylamide (LSD), methylenedioxymethamphetamine (MDMA or Ecstasy) and gamma hydroxybutyrate (GHB).

Schedule II drugs also have a high tendency for abuse but do have an accepted medical use.⁸⁶ These drugs can produce a dependency or addiction with chronic use.⁸⁷ This schedule includes examples such as cocaine,

80. Nat'l Alliance for Model State Drug Laws, Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *available at* <http://www.natlalliance.org/publications.asp> (last visited Feb. 22, 2007) [hereinafter Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation]; OVERVIEW OF STATE LEGISLATIVE/REGULATORY RESTRICTIONS ON OVER-THE-COUNTER SALES/PURCHASES OF PRODUCTS CONTAINING PSEUDOEPHEDRINE, *available at* <http://www.natlalliance.org/publications.asp> (last visited June 6, 2007) [hereinafter OVERVIEW OF STATE LEGISLATIVE/REGULATORY RESTRICTIONS]. One may well expect that the state-by-state information provided herein will be altered for many states during the next applicable legislative session to comply with the recently enacted federal law or to increase restrictions. Thus, the data provided here is for a comparison basis only and is not to be relied on as absolute; this is an area of rapid legislative and regulatory change. Additionally, the state specific information that follows is date sensitive material and current only through June 6, 2007.

81. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, 84 Stat. 1242, 1236.

82. *Id.*

83. U.S. DRUG ENFORCEMENT ADMIN., THE CONTROLLED SUBSTANCES ACT, *available at* <http://www.usdoj.gov/dea/pubs/abuse/1-csa.htm> (last visited June 12, 2007).

84. 21 U.S.C. § 812 (2006).

85. 21 U.S.C. § 812(b)(1) (2006).

86. 21 U.S.C. § 812(b)(2) (2006).

87. *Id.*

amphetamines, and morphine.⁸⁸ These drugs are available by prescription and require stringent record keeping and storage.⁸⁹ There are no refills permitted on drugs prescribed in this class; instead, the patient must get a new prescription each time.⁹⁰

Schedule III drugs have less potential for abuse or addiction and have an accepted medical use.⁹¹ This category includes anabolic steroids, hydrocodone (in combination with aspirin or acetaminophen), and codeine.⁹² Schedule III drugs are available with a valid prescription, which may be refilled up to five times in six months, and may be stored among lesser controlled products on open shelves within the prescription department.⁹³

Schedule IV drugs have a low potential for abuse or addiction and have an accepted medical use.⁹⁴ Schedule IV examples include Valium, Xanax, and phenobarbital, and are available by prescription.⁹⁵

Schedule V drugs have an even lower potential for abuse or dependence.⁹⁶ There is less chance of addictive side effects and they have a current medical use.⁹⁷ This schedule includes such drugs as cough suppressants with codeine.⁹⁸ Schedule V drugs are regulated and not typically found in over-the-counter areas, but do not require a prescription in most states.⁹⁹

B. STATE SCHEMES

The federal government's five schedule scheme for classifying substances subject to potential abuse has been adopted by the states in their statutes and regulations. Until recently, ephedrine and pseudoephedrine were not included in any state listing of scheduled drugs subject to restricted distribution. These methamphetamine precursors were unregulated and readily available at any time of the day, and every day of the week at locations ranging from pharmacies to roadside mom-and-pop gas stations and convenient stores.

88. 21 U.S.C. § 812(c) (2006).

89. 21 U.S.C. § 829(a) (2006).

90. *Id.*

91. 21 U.S.C. § 812(b)(3)(2006).

92. 21 U.S.C. § 812(c) (2006).

93. 21 U.S.C. § 829(b) (2006).

94. 21 U.S.C. § 812(b)(4) (2006).

95. 21 U.S.C. § 829(b) (2006).

96. 21 U.S.C. § 812(b)(5) (2006).

97. *Id.*

98. 21 U.S.C. § 812(c) (2006).

99. 21 U.S.C. § 829(c)-(d) (2006).

The DEA has the federal statutory authority to place abusable medications in one of the appropriate schedules, but in doing so must consult with the Secretary of Health and Human Services.¹⁰⁰ The latter official, typically with input from both the United States Food and Drug Administration and the National Institute on Drug Abuse, a division of the National Institutes of Health, will make a recommendation based on the potential for abuse associated with the substance.

Many states have included the targeted methamphetamine precursors, ephedrine and pseudoephedrine, into the Schedule V classification, in an effort to regulate acquisition and possession. There are a few states that have taken an even stronger regulatory stance by placing methamphetamine precursors into the more stringent classifications like Schedule IV, Schedule III and even Schedule II.

1. *Precursors*

As a major part of this law review project, the authors, utilizing information provided by the Alliance, reviewed the regulating schemes in all fifty states, plus the District of Columbia.¹⁰¹ The following list identifies the states that have regulated the acquisition of ephedrine and pseudoephedrine (“precursors”). The actual schedule that these precursors were assigned by each state is indicated. If the precursors are treated differently, this has been indicated following the states identification (“*” signifies that only ephedrine is regulated, and “**” signifies only pseudoephedrine is regulated).

Schedule II: Colorado*, Idaho, Louisiana, Washington

Schedule III: Nevada, South Dakota*

Schedule IV: Missouri, Nebraska*, Oklahoma*, Oregon, Wisconsin*

Schedule V: Arkansas, Illinois, Iowa, Kansas, Minnesota, Missouri, New Mexico, Oklahoma, West Virginia, Wisconsin

A majority of states do have written exemptions from the Schedule V provisions. These include solid oral dosage forms and soft gelatin caplets formulated pursuant to FDA regulations and packaged in two dose blister packs. However, most manufacturers have ceased production of such blister packs rendering the exemptions mute.

100. 21 USC § 811(a)-(b) (2006).

101. Legislative Chart (Jan. 2007), available at www.natlalliance.org/pdfs/Legislative%20Chart%20January%202007.pdf; Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80.

Although states not included above continue to allow precursors to remain as unscheduled substances, the overwhelming majority have recently enacted point of sale restrictions on ephedrine and/or pseudoephedrine. Many, if not all, of the states referenced above have enacted both schedule provisions and point of sale restrictions.

2. *Point of Sale Restrictions*

“Point of Sale Restrictions” (POS restrictions) is a term which describes those particular state laws or regulations that place restrictions on ephedrine, pseudoephedrine and products containing such active ingredients at the point at which they are sold.¹⁰² POS Restrictions can include quantity restrictions, packaging restrictions, placement within a store, record keeping, etc. State lawmakers have selected from the non-inclusive list of POS restrictions as they have deemed appropriate for their constituents.

A higher level of restriction would, of course, be to make chemical precursors available only by prescription. The Durham-Humphrey Amendment to the Federal Food, Drug and Cosmetic Act¹⁰³ was enacted in the early 1950s to clarify the distinction between those medications available without a prescription and those requiring professional supervision of their use and, hence are only available by prescription.¹⁰⁴ It has also been suggested that intermediate levels of control should be established involving either an authorized prescriber’s request for initial dispensing with refills available at the discretion of the pharmacist, or an approach under which both initial authorization for dispensing and that for refills would be controlled by the pharmacist.¹⁰⁵

The aim of most POS restrictions is to reduce the availability of ephedrine and pseudoephedrine as methamphetamine precursors. A reduction in precursor availability would be the catalyst to reduce the number of methamphetamine laboratories, reduce the amount of methamphetamine available for street purchase, and reduce the number of methamphetamine associated fatalities and child endangerment cases. In addition, creating a tracking system that would provide a reach back assessment including, how baseline methamphetamine use is established, where the majority of

102. Legislative Chart 1, *supra* note 101.

103. Pub. L. No. 82-215, 65 Stat. 648 (1951) (codified as amended at 21 U.S.C. § 353 (2000)).

104. 21 U.S.C. § 353(b) (2000).

105. Maven J. Myers & Joseph L. Fink III, *Legal Considerations in Establishing Third and Fourth Classes of Drug Products*, 31 F.D.C.L.J. 4, 4-10 (1976).

methamphetamine is being produced, and the methamphetamine laboratory entrepreneur profile, seems a worthy task.

As mentioned previously, most states have enacted POS restrictions even if they have not added methamphetamine precursors specifically to a schedule. The statutes and regulations of all fifty states, plus the District of Columbia, were reviewed to tabulate the following list of states that have enacted POS restrictions regarding the acquisition of ephedrine and pseudoephedrine containing products.¹⁰⁶ Any special provisions or current proposed legislation to amend restrictions, presumably to enhance restrictions, are indicted as “AP” following the state’s identification.

- a. *Jurisdictions that currently have no POS restrictions in place:* Connecticut, District of Columbia, Maryland, Massachusetts, New Hampshire, New York, Pennsylvania, and Rhode Island
- b. *States that restrict quantity:* California, Kansas, Kentucky, New Jersey, New Mexico, Utah, and Wisconsin
- c. *State that restricts packaging:* Nevada
- d. *State that restricts quantity and packaging:* Arkansas
- e. *States that restrict quantity and display/offer advertising:* Arizona (AP), Delaware, Florida, Hawaii (AP), Idaho, Louisiana, Michigan (also bans internet and mail order sales), Michigan, Missouri, Montana, Ohio, Oklahoma, Pennsylvania, South Dakota (AP), Tennessee, Texas, Vermont, Virginia, Washington, and West Virginia (AP)
- f. *States that restrict quantity, packaging, and display/offer advertising:* Alabama, Alaska, Colorado, Georgia, Illinois, Indiana, Iowa, Maine, Minnesota, Mississippi, Nebraska, North Carolina, North Dakota, South Carolina, and Wyoming

In addition, Connecticut has pending legislation that would place ephedrine and pseudoephedrine in the Schedule V classification. New Hampshire has pending legislation that would result in the requirement of a prescription for the purchase of these methamphetamine precursors.

3. *Purchaser Requirements*

Some state laws provide restrictions as to those able to purchase ephedrine and pseudoephedrine products, as well as how the products must

106. Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80; Legislative Chart, *supra* note 101.

be purchased. The following is a list of current purchaser requirements and the number of states that utilize that particular restriction/provision.¹⁰⁷

- a. *Purchaser must show proof of identity using a valid photo identification instrument (generally a driver's license or some other government or school issued identification):* Alabama, Arkansas, California, Delaware, Iowa, Kansas, Kentucky, Louisiana, Maine, Minnesota, Mississippi, Missouri, Montana, Nebraska, North Carolina, Oklahoma, Oregon, Tennessee, Texas, Virginia, Washington, West Virginia, and Wisconsin
 - b. *Minimum age to purchase is sixteen years old:* Texas
 - c. *Minimum age to purchase is eighteen years old:* Alabama, Arkansas, California, Delaware, Kentucky, Minnesota, Missouri, Nebraska, North Carolina, North Dakota, Washington, West Virginia, and Wisconsin
 - d. *Purchaser must sign a written/electronic log or record of receipt of the individual sales transaction which is maintained by the seller:* Alabama, Arkansas, Delaware, Iowa, Kansas, Kentucky, Louisiana, Minnesota, Montana, North Carolina, Oklahoma, Tennessee (only written), Texas, Virginia, West Virginia, and Wisconsin
 - e. *Log or record requirement exists but does not require the purchaser to sign:* Indiana (no logging of convenience packages and records must be in accordance with format approved by state police), Maine (log is voluntary), Michigan (log is required only if the products are not stored behind a counter or in a locked case), Oregon, South Dakota, and Tennessee
4. *People That May Sell or Transfer Ephedrine and Pseudoephedrine Products*

Although specific, the regulations governing those allowed to sale or transfer methamphetamine precursors vary from state to state.¹⁰⁸

- a. *A pharmacy, pharmacist, pharmacy technician, pharmacy intern or clerk in compliance with the law:* Arkansas, Iowa, Kansas, Kentucky, Maine, Minnesota, Missouri, Oklahoma (licensed pharmacist or registered pharmacy technician only), Tennessee, and Wisconsin

107. Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80.

108. *Id.*

- b. *A pharmacy OR any retail establishment:* Colorado, Delaware, Florida, Georgia, Hawaii, Indiana, Louisiana, Michigan, Mississippi, Nebraska (must also be eighteen years old to sell products), New Jersey, North Carolina, North Dakota, South Dakota, Virginia
- c. *A pharmacy OR a certified/authorized retail establishment in compliance with the law:* California, Montana, Texas, and Washington (sellers must be licensed by or registered with the Department of Health)

5. *Retailer/Wholesaler/Manufacturer Registration*

A few states have enacted regulations that require a retailer, wholesaler and/or manufacturer of products containing ephedrine or pseudoephedrine to register with the defined state authority regarding the handling of such products.¹⁰⁹

- a. *Wholesalers that are not already licensed:* Georgia and West Virginia
- b. *Those that are not licensed by the Board of Pharmacy:* Alabama
- c. *Retailer certification is required:* Missouri, Montana, Washington, and Wyoming
- d. *A permit is required:* California

6. *Placement of Ephedrine and Pseudoephedrine Products*

Most states that have enacted placement restrictions have required only one of the following methods be utilized.¹¹⁰ However, this does not rule out the contingency that in certain circumstances some combination could be required. Also, many retailers have taken it upon themselves to voluntarily apply these methods in specific combinations that work for their specific retail chain.

- a. *Behind the counter or in an area that is not accessible to the public:* Alabama, Arkansas (sole active product only), Delaware, Florida (sole active product), Georgia (sole active is pseudoephedrine), Hawaii, Indiana, Iowa, Maine, Michigan, Minnesota, Mississippi, Montana, Nebraska, North Dakota

109. *Id.*

110. *Id.*; OVERVIEW OF STATE LEGISLATIVE/REGULATORY RESTRICTIONS, *supra* note 80, at 2.

- (sole active products), South Dakota (sole active product), Texas, Virginia, Washington, and Wyoming
- b. *In a locked case:* Alabama, Arkansas (sole active products), Delaware, Hawaii, Indiana, Iowa, Maine, Michigan, Mississippi, Montana, Nebraska, Oregon (in full view of pharmacy), South Dakota (sole active product), Tennessee, Texas, Virginia, West Virginia, and Wyoming
 - c. *Within an area that is in the direct line of sight of employees:* Hawaii, Indiana, Virginia (multi-active product), and Wyoming
 - d. *Within a specific distance of a staffed counter:*
 - i. *Within ten feet:* Missouri
 - ii. *Within twenty feet:* Michigan and South Dakota
 - iii. *Within twenty-five feet:* Tennessee
 - iv. *Within thirty feet:* Indiana (for convenience packages), Louisiana, Maine (for 60 mg single dose packages only), Mississippi (for multi-active ingredient products), Texas, Virginia (for multi-active ingredient products), and Wyoming
 - e. *In an area under constant video surveillance with signage that warns of surveillance in use:* Hawaii, Indiana, Michigan, North Dakota, Virginia (multi-active product), and Wyoming
 - f. *Requires use of anti-theft mechanism and/or alarm:* Michigan, South Dakota (for sole and multi-active, liquid, and pediatric products), Virginia (multi-active products), and Wyoming
 - g. *Requires use of restrictive shelving which controls dispensing time frames (allows for product to be released only every specified amount of time):* Indiana and Virginia (multi-active products)
 - h. *Only a limited number of packages may be displayed in a public area:*
 - i. *No more than 1 package of any type/brand:* North Dakota
 - ii. *No more than 3 packages or 9 grams of each product can be placed upon shelving at any one time:* Louisiana
 - iii. *Behind the pharmacy/prescription counter:* Missouri, North Carolina, Oregon (must be only in view of pharmacy), Texas, and West Virginia

7. *Quantity Limitations*

In addition to purchaser restrictions, many states have addressed the issue of quantity of methamphetamine precursor product that is available to consumers.¹¹¹

a. States with thirty day quantity limitations:

- i. *Nine gram limitation:* Arkansas, Delaware, Kentucky, Louisiana, Mississippi, Missouri, Montana, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, South Dakota, Tennessee, and West Virginia
 - ii. *7.5 gram limitation:* Illinois, Iowa, and Wisconsin
 - iii. *Six gram limitation:* Alabama (if purchased with the “intent to manufacture methamphetamine”), and Minnesota
- b. States with seven day quantity limitation:* Indiana (no more than three grams, however, convenience packages are exempt), and Kansas (no more than three packages)
- c. Twenty-four hour quantity limitation:* Illinois, Iowa (no more than 360 mg of liquid pseudoephedrine product), Nebraska (no more than 1,440 mg of pseudoephedrine product), and Washington (no more than one transaction in a twenty-four hour period, and no more than two packages or one package which totals three grams in one sale)
- d. Single transaction quantity limitation:* Arkansas (no more than three packages, nine grams, or ninety-six units), Hawaii and Pennsylvania (no more than three packages or nine grams), Illinois (no more than two packages), Michigan (no more than two packages or forty-eight tablets), Missouri (no more than two packages or six grams of pseudoephedrine as the sole active ingredient, or no more than three packages or nine grams of pseudoephedrine when part of a multi-active ingredient product), and North Carolina (no more than two packages or six grams)

Interestingly, the single transaction limitation is often combined with a thirty day quantity limitation. Combining both limitations places a ceiling

111. Highlights—Illinois Methamphetamine Precursor Control Act 1, *available at* www.natlalliance.org/pdgs/Illinois%20Act.pdf; OVERVIEW OF STATE LEGISLATIVE/REGULATORY RESTRICTIONS, *supra* note 80, at 2, 5, 6; Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80.

on the amount that a person may sell in a single transaction, plus a cap on how much can be purchased within a monthly period.

8. *Required Log or Record of Receipt Information*

As a general rule, states that mandate that a record be kept of precursor purchases typically require the log to show the purchaser's name, date of the transaction, quantity of the item purchased, and name of product purchased.¹¹² However, some states require the purchaser's address, driver's license number or other proof of the photo identification provided, and/or the seller's initials or signature, as additional information.¹¹³

9. *Packing Restrictions*

- a. Most states require that ephedrine and pseudoephedrine products be dispensed only if packaged in accordance with the law.¹¹⁴
- b. The following states even require that products containing methamphetamine precursors be packaged in blister packs or unit dose packages (two units in each pack) if blister packs are not feasible: Alabama (30 mg or more), Arkansas, Colorado, Georgia (sole active product), Illinois, Maine, Minnesota, Nebraska, North Carolina (30 mg or more of sole active product), North Dakota, and Wyoming.
- c. Additionally, some states place further restrictions upon the dosage of packing by requiring that no more than two unit doses be in each pack, and if blister packaging is not feasible, then the product must be in unit dose pouches or packages. These states are: Arkansas, Colorado, Illinois, Maine, Minnesota, Nebraska, North Dakota, and Wyoming.
- d. The maximum amount of ephedrine and pseudoephedrine product allowed in one package is most commonly controlled by a three gram restriction. However, the following states imposed the other quantity restrictions: Illinois and Iowa (360 mg liquid products), Indiana (120 mg convenience packages),

112. Specific state references were purposely omitted because the authors chose to concentrate on more important areas. Please consult the Alliance website for up-to-date information.

113. Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80.

114. *Id.*; Highlights—Illinois, *supra* note 111, at 1.

Maine (60 mg single dose packages), Nebraska (1,44 g), and North Dakota (two grams.)

10. *Posting of State Law Required in Retail Locations*

Only a few states require retail locations selling ephedrine and pseudoephedrine products to post a copy of the governing state law in the premises. These states include: Iowa, Michigan, North Carolina (purchasers must sign an acknowledgement that references the state’s law regarding over-the-counter sales), and South Dakota.¹¹⁵

11. *Retailer/Employee and Owner/Operator Immunity*

Very little has been established in the way of prescribed immunity for those involved with the sale of ephedrine and pseudoephedrine products. However, the few states that have addressed this issue in limited regard include: Georgia, Massachusetts, and North Carolina.¹¹⁶

- a. *For injuries resulting from sales of regulated products:* South Dakota
- b. *For compliance with laws:* Alabama, Indiana, Maine, North Carolina, and Washington
- c. *For employee training:* Alabama, Georgia, Michigan (at the time of citation the defendant must have a written policy in place for employees to prevent illegal sales), Minnesota, Mississippi, North Dakota, and Wisconsin
- d. *If employee signs acknowledgement of restrictions:* Louisiana

As of the time of this writing, no circumstances were noted where the limits of these immunity grants had been challenged.

VII. PRE-EMPTIONS AND EXEMPTIONS

A. STATE LAW PREEMPTION

In many states, the legislation enacted pre-empted any municipalities that had imposed restrictions regarding the sale or purchase of over-the-counter products, which were more restrictive than those provisions imposed under the state law. This type of preemption affected the following states: Alabama, Arizona, California, Florida, Georgia, Indiana,

^{115.} *Id.*

^{116.} *Id.*

Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Missouri, North Carolina, North Dakota, South Dakota, Tennessee, and Texas.¹¹⁷

Localities and municipalities may still impose restrictions. However, ephedrine and pseudoephedrine products may not be regulated in any way that is more or less restrictive than the active state law.

B. EFFECTIVE DATES

In 2005, thirty-three states passed provisions establishing or amending restrictions on over-the-counter sales of products containing ephedrine and pseudoephedrine.¹¹⁸ In February 2005, Arkansas and South Dakota were the first to establish or amend restrictions. In March 2005, Iowa and Kentucky agreed that restrictions were needed. In April 2005, Tennessee and West Virginia joined in. In May 2005, Nebraska did likewise. In June 2005, Delaware, Missouri, New Jersey, and North Dakota enacted restrictions. In July 2005, Alabama, Colorado, Florida, Georgia, Hawaii, Indiana, Minnesota, Mississippi, Montana, and Wyoming followed suit. In August 2005, Louisiana, Oregon, and Texas saw the wisdom in passing similar restrictions. In October 2005, Arizona, Maine, Virginia, and Wisconsin agreed that restrictions were needed. Oklahoma did likewise in November 2005. Michigan accomplished the same in December, before 2005 ended. In January 2006, California, North Carolina, and Washington followed the previous states in enacting restrictions.

C. EXEMPTIONS AND/OR EXCEPTIONS TO RESTRICTIONS ON THE SALE/TRANSFER OR PURCHASE OF PRECURSORS

Even with all of the restrictions that have been established by legislation there are, as always, a myriad of exceptions. The following is a list of the current exemptions from governmental restrictions:

1. Purchaser presents a valid prescription;¹¹⁹
2. The product is sold/transferred, purchased, or possessed in that person's legitimate and authorized (lawful) course of business (i.e., pharmacies, physicians, common transit carriers, manufactures, and distributors);¹²⁰
3. Liquid products;¹²¹

117. *Id.*

118. *Id.*

119. Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80.

120. *Id.*

121. *Id.* This category includes liquid capsules and liquid gelcaps. *Id.* The majority of states have exempted ephedrine and pseudoephedrine products in the over-the-counter liquid

4. Pediatric products intended for administration to children under the age of twelve;¹²²
5. Products found not to be used in illegal manufacturing or present no significant risk of use in the manufacturing of methamphetamine;¹²³ and
6. Products formulated to prevent diversion.¹²⁴

Although, the states one by one, began to place restrictions on the sale of ephedrine and pseudoephedrine products, individual state regulation left many opportunities for methamphetamine producers to shop state lines as well as multiple locations for their ingredients. Handwritten logs are not sufficient for maintaining any cross reference database to check buyers within a region. The mass diversity in approaches among states provided a good environment for political and legal discussion, but the outcome was a failure due to the void in tracking ability across regions and the limited deterrence it provided.

VIII. ALTERNATIVES FOR PHARMACEUTICAL MANUFACTURERS AND RETAILERS

As a result of the increasing regulatory restrictions on the sale and distribution of products containing ephedrine and pseudoephedrine, many pharmaceutical manufacturing companies tried to address the public concerns and save their own marketing strategies.¹²⁵ The pharmaceutical manufacturing companies such as Pfizer and Leiner health products did this by pulling their products off the market, reducing their decongestant inventory available, and/or reformulating products to use alternative decongestants such as phenylephrine.¹²⁶

formulation from POS restrictions, but have authorized a state agency to enact regulation of liquid product forms if diversion and conversion for use in manufacturing of methamphetamine becomes evident. *Id.* Some states have utilized the authority to impose tighter regulation on liquid formulations. *Id.* In these more restrictive states, some of the restrictions that apply to liquid product forms include: products where ephedrine or pseudoephedrine is not the sole active ingredient, allowable but only in small or low dosage, and/or have placed a limit on the amount that can be sold in a single transaction. *Id.*

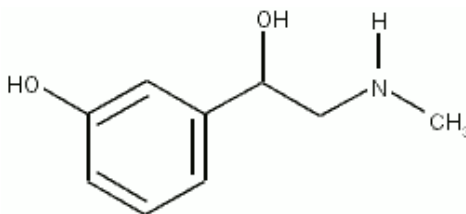
122. Regional Comparative Charts—2005 Enacted Ephedrine and Pseudoephedrine Legislation, *supra* note 80. At times there may be single dose limit restriction placed upon these pediatric products for the exemption to be applicable (e.g., no more than ten mg for a solid or liquid product). *Id.*

123. *Id.*

124. *Id.* This exemption is most commonly granted to a manufacturer only. *Id.*

125. See Donna Leinwand, *Drugmakers Take Action to Foil Methamphetamine Cooks*, USA TODAY, June 28, 2005, available at http://www.usatoday.com/news/health/2005_06_28_methamphetamine_x.htm.

126. *Id.*



Phenylephrine

*Source: structure taken from Remington.*¹²⁷

Both pseudoephedrine and phenylephrine work to reduce congestion, but pseudoephedrine is considered to be more effective.¹²⁸ However, many consumers remain upset and confused over the variability in product, procedure and regulation from retailer to retailer and across state lines. Are manufactures assuming consumer ignorance? Just switch ingredients, put it in a very similar box, in a very similar spot and no one will notice or question. There is a lack of advertisements that exclaim that phenylephrine is just as good as pseudoephedrine or that offer any explanation for the switch. Admittedly, these are not required, especially for over-the-counter products. However, pseudoephedrine is no average over-the-counter product anymore. Additionally, with such national recognition and consumer confusion would it not be progressive for a manufacturer who benefited in the millions of dollars from consumer loyalty to inform and educate their customers? Maybe the manufacturers are leaving education of consumers to the retailers and pharmacists.

In response to a national outcry for control, the Bush Administration stepped forward with its enactment of federal legislation and policy through CMEA and SDCS to address the methamphetamine epidemic.¹²⁹ One may speculate that current drug policy restrictions are more politically motivated than socially motivated. If so, then current policy in fact might cause a shift of supply that is actually more in favor of large scale criminal organizations to meet demand. However, with the enactment of a federal law there exists a possibility to develop a national database for monitoring pseudoephedrine

127. REMINGTON, *supra* note 14, at 1381.

128. Bruce Buckley, *Where's My Cold Medicine? PSE: Impact of Behind-the-Counter Placement*, PHARMACY TODAY OTC SUPPLEMENT 4 (Feb. 2006).

129. Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, 120 Stat. 256 (2006); SYNTHETIC DRUG CONTROL STRATEGY, *supra* note 62, at 1.

purchases by individuals across state lines. Currently, several states are addressing the development of computerized tracking systems to monitor pseudoephedrine containing products.

Walgreen's, a pharmacy chain, has recently designed an electronic database to track sales of medications that can be used to make methamphetamine.¹³⁰ This database goes beyond the one first introduced by Wal-Mart which only accounted for individual store sales.¹³¹ Walgreen's computerized tracking system has replaced the old paper records that were considered by most to be ineffective in tracking individual sales and profiling methamphetamine makers.¹³² Walgreens customers who buy the targeted products must provide photo identification and sign a log.¹³³ Employees trained on the system then enter the customer and sales information into the tracking system which is tied into the cash registers and pharmacy database.¹³⁴ Because Walgreens pharmacy database is nationwide, this improved record keeping allows the first nationwide methamphetamine precursor tracking.¹³⁵ Such a nationwide database is an important tool to prevent methamphetamine makers from circumventing pseudoephedrine restrictions by traveling among stores within a region. Applause goes out to Walgreens for absorbing the cost of innovation to further the cause and improve community ties.

IX. THE UNKNOWN

Monitoring pharmaceutical manufacturers raises some patient privacy issues which are left for additional research and discussion. For example, in late 2005, Tennessee law enforcement officials began posting the names of convicted methamphetamine manufacturers on a website, called the Methamphetamine Offender Registry.¹³⁶ This database is modeled after the sex offender registry and allows users to enter a name or county to receive a display of those convictions in the region.¹³⁷ Other issues include

130. Valerie Dowdle, *AG Touts Tracking of Meth Ingredient*, MEDILL NEWS SERVICE, July 3, 2006, available at <http://www.thetimesonline.com/articles/2006/07/03/news/illiana/541537b1ac72df558625719f00818eef.txt>.

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. Ellen Barry, *Tennessee Posts Convicted Methamphetamine Makers on Web*, <http://www.latimes.com/news/nationworld/nation/la-na-registry30dec30,1,1393837.story> (last visited Jan. 4, 2006).

137. *Id.*

controlling the accuracy of information collected, response time, and retail price increases.

Of course, the CMEA is a federal law and thus provides only a floor of restriction. Individual states remain capable of imposing stricter guidelines and addressing areas untouched by the federal law. In light of such governmental structure and power, certain issues like precursor classification, scripting, samples, and posting are important. If precursors are classified as Schedule II through V, they will require a valid written prescription. This places the burden of a medically necessary evaluation and determination upon the physician and/or pharmacists as is required by the DEA for drugs in these classes.

Depending upon the specific classification, the provision may require that the patient physically meet with the physician for each new prescription rather than merely having the doctor call the prescription into the pharmacy without a face-to-face meeting. In addition, how the law will affect free drug samples permitted by a physician is yet to be seen. It is also unknown whether the physician will have to log such samples for tracking regulations.

Because the states will remain free to adjust the restrictions, and considering the outrage that has been expressed by numerous consumers regarding the time and hassle created by the restrictions and logging requirements, perhaps mandatory posting of state and federal law would be appropriate. These posting rules would be comparable to the employment or surveillance notices that are already in place for retailers. However, it seems most consumer frustration has been directed toward the retail establishments and not at the legislature. Therefore, there may be a political motive for not mandating the requirements be posted.

And while it is yet to be seen just how much CMEA will impede the spread of the methamphetamine epidemic, the impact on consumer access to cold products has been substantial. This is especially true in remote areas, which are serviced by a limited number of pharmacies with limited hours of operation. Consumers could be further inconvenienced by having a mandatory pharmacist consult imposed. Restrictions on pseudoephedrine could also increase the dangers of polypharmacy and/or self-medication as consumers explore replacements and alternatives.¹³⁸ The outcomes are to be revealed, but the American Pharmacists Association and many pharmacists think that the restrictions open a wonderful opportunity for

138. Polypharmacy is "either the concomitant use of multiple drugs or the administration of more medications than are indicated clinically." JOSEPH T. DIPIRO ET AL., *PHARMACOTHERAPY: A PATHOPHYSIOLOGIC APPROACH* 108 (6th ed. 2005).

both consumers and pharmacists to interact more regarding use of cough/cold and allergy medications which are among the most widely used non-prescription products sold in pharmacies.¹³⁹ Pharmacists can help consumers understand why the ephedrine and pseudoephedrine products were moved, how to use the medications safely, and to properly store an on hand supply for times when the pharmacy may be closed.

X. CONCLUSION

Regardless of the pros and cons of legal restrictions on methamphetamine, a person is hard pressed to not recognize that methamphetamine abuse is a great problem in the United States. State and local authorities are kept so busy responding to domestic laboratories which have the potential to cause explosions, fires, and death, that they are unable to maintain monitoring over larger drug traffickers bringing methamphetamine and precursors across state lines. Time had long past for recognition of this epidemic in federal legislation and policy like that found in the CMEA and SDSC. It is yet to be seen what loopholes, if any, remain in the CMEA. Although a deep financial burden is placed upon the government and its taxpayers, some national control measures, including tight regulation of pseudoephedrine products nationwide, are a reasonable way to curtail the methamphetamine problem and place a damper upon the activities of domestic laboratories that have proven to be so toxic and dangerous to the communities in which they operate.

The authors' concern is that even if the restrictions eliminate the estimated small percent of the methamphetamine supplied by domestic laboratories using pseudoephedrine products obtained from retailers, what effect will there be on the remaining large percent produced by super laboratories in Mexico and brought into the United States by criminal organizations in truckloads. The Bush Administration believes that it has addressed this concern with the enactment of the SDSCS and its three tiered approach to reduce the amount of methamphetamine and precursors that are brought across United States borders. There will probably be many people watching and monitoring the effect of the SDSCS. The area of methamphetamine legislation has no doubt embarked upon its historic journey, but remains in its infancy. For those intrigued by law making and the political process the methamphetamine journey will prove to be an interesting one.

139. Bruce Buckley, *supra* note 128, at 14.