

# Partners

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## Pseudoephedrine Diversion: Regulatory and Scientific Responses

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## Program Preview

**M**ethamphetamine is the fastest growing illicit drug in the United States. By stimulating the release of excessive amounts of monoamine neurotransmitters (dopamine, serotonin, norepinephrine), methamphetamine causes intense central nervous system stimulation, including feelings of pleasure and euphoria that are similar to, but much longer lasting than, those of cocaine. Methamphetamine abuse is associated with a number of serious short- and long-term health problems, not least of which is the possibility of persistent, perhaps permanent, brain damage.

The diversion of pseudoephedrine-containing products for conversion to methamphetamine by "small toxic labs" is a dangerous and rapidly expanding problem for pharmacists, retailers, and law enforcement officials across the country. Although federal legislation has been enacted since 1988 to curtail the production of methamphetamine, small toxic labs continue to flourish. In response, a number of states have imposed or are considering imposing strict limits on the sale of products containing pseudoephedrine. Federal legislation also is pending. The measures mandated by these various state and national efforts have important implications for both pharmacists and patients.

Pharmacists in all practice settings, but especially those practicing in community pharmacies, need to be aware of the quickly evolving developments surrounding methamphetamine abuse and pseudoephedrine diversion. This monograph provides a brief introduction to the realities of methamphetamine abuse and the process by which the drug can be produced from readily available ingredients. It also explains steps that have been taken or are being proposed to help curb this problem and discusses the possible effects of these measures.

## Learning Objectives

At the conclusion of this program, the pharmacist should be able to:

1. Discuss the characteristics and consequences of methamphetamine abuse.
2. Identify the main sources of methamphetamine in the United States and explain how pseudoephedrine-containing products are diverted to make methamphetamine.
3. Describe the hazards posed to both people and the environment by small toxic labs.
4. Outline existing and proposed federal and state legislation intended to decrease methamphetamine production by large and small illicit laboratories.
5. Discuss the implications for pharmacists of various methamphetamine-control strategies, as well as opportunities presented for expanded self-care services.

## Introduction

**M**ethamphetamine is a central nervous system (CNS) stimulant that is structurally and pharmacologically similar to amphetamine and ephedrine.<sup>1,3</sup> It was synthesized during the early 1900s from amphetamine and was used initially as a nasal decongestant and bronchial inhalant.<sup>4</sup> Methamphetamine hydrochloride currently is available by prescription as Desoxyn, with approved indications for the treatment of attention-deficit/hyperactivity disorder and the short-term treatment of obesity.<sup>2</sup> It is subject to control under Drug Enforcement Administration (DEA) Schedule II.

But increasingly, methamphetamine is best known as a powerfully addictive drug of abuse that can be synthesized clandestinely and fairly easily from inexpensive and commonly available chemicals, including the nonprescription decongestant pseudoephedrine.<sup>1,5</sup> Data from the 2003 National Survey on Drug Use and Health indicate that approximately 12.3 million Americans ages 12 years and older have tried methamphetamine at least once during their lifetimes.<sup>6,7</sup> Of those, 1.3 million people reported using methamphetamine during the past year, and 607,000 reported using it during the past month.<sup>6</sup>

Methamphetamine generally is considered to be the fastest growing illicit drug in the United States.<sup>8</sup> Although methamphetamine abuse initially was concentrated in the Western states—particularly the area around San Diego, California—the drug has made its way eastward across the country, as well as westward to Hawaii.<sup>9</sup> Methamphetamine abuse is a substantial problem in many areas of the West and Southwest and an increasing problem in both rural and urban sections of the South and Midwest. It is an emerging problem in major urban areas in the East. In a recent survey conducted by the National Association of Counties, nearly 60% of county officials cited methamphetamine as their largest drug problem—ahead of cocaine, marijuana, and heroin.<sup>10</sup>

As methamphetamine spreads to new areas, its use also is spreading from the traditional base of white, male, blue-collar workers to more diverse population groups.<sup>9</sup> For example, young adults who attend “raves” or frequent private night clubs increas-

ingly are using methamphetamine. Use of the drug is increasing among homeless and runaway youth. Methamphetamine use also appears to be growing among workers who must stay alert during long hours of repetitive work (e.g., long-haul truck drivers, construction workers, workers in manufacturing plants), as well as among people employed in the entertainment, sales, retail, and legal fields.<sup>11,12</sup> Urban women reportedly are turning to methamphetamine as the “superwoman drug,” using it to “be super-wife, super-employee, and super thin.”<sup>13</sup>

What has been referred to as “America’s first major home-grown drug epidemic”<sup>14</sup> has important implications for pharmacists, particularly those practicing in community settings. To help stem the tide of methamphetamine abuse, a growing number of states have enacted or are considering enacting multiple measures to limit access to nonprescription products containing pseudoephedrine. Federal legislation also is pending. Pharmacists have been compelled to make (or may soon need to make) drastic changes in the way they display and sell products containing pseudoephedrine. Consumers who suddenly are faced with new procedures and restrictions when they attempt to purchase pseudoephedrine products may not understand the reasons for the changes.

This monograph describes the characteristics and consequences of methamphetamine abuse and outlines the process by which pseudoephedrine is converted to methamphetamine by so-called “small toxic labs.” It also explains steps that have been taken or are being proposed to help curb this problem and discusses implications and opportunities for pharmacists.

## Characteristics and Consequences of Methamphetamine Abuse

Methamphetamine hydrochloride is a white, odorless, bitter-tasting crystalline powder that dissolves easily in water or alcohol.<sup>11</sup> Most users self-administer the drug orally, but it also may be smoked, snorted, or injected.<sup>9,15</sup> The many names by which methamphetamine is known on the street include “meth,” “speed,” “crank,” and “chalk.” In its smoked

form—a large, usually clear crystal of high purity—methamphetamine may be referred to as “ice,” “crystal,” or “glass,” among others.<sup>5,9,11,16</sup>

Methamphetamine is an adrenergic agonist that stimulates the release of massive amounts of monoamine neurotransmitters (dopamine, serotonin, norepinephrine) from presynaptic neurons.<sup>15,17</sup> The excessive concentrations of dopamine in particular cause feelings of pleasure and euphoria that are similar to, but much longer lasting than, those of cocaine—as long as 12 hours.<sup>3,11,17</sup> When methamphetamine is injected or smoked, users report experiencing an immediate (within 5 to 10 seconds) and intense but short-lived “rush” or “flash.”<sup>16</sup> Euphoria develops more slowly when the drug is snorted or ingested orally: snorting produces effects within about 3 to 5 minutes, and oral ingestion produces effects within about 15 to 20 minutes.<sup>11</sup> Addiction and tolerance to the pleasurable feelings may develop quickly, prompting more frequent use at higher and higher doses, or a switch to a different route of administration.<sup>16,18</sup>

## Short-Term Effects

Some of the more common short- and long-term effects of methamphetamine abuse are listed in Table 1. As a powerful CNS stimulant, methamphetamine causes increased wakefulness, increased physical activity, and decreased appetite, even in small doses.<sup>11</sup> Users may go on drug binges, called “runs.”<sup>11,18</sup> During these binges, it is not unusual for users to inject as much as 1 g of methamphetamine every 2 to 3 hours over several days (or even up to a week) while refraining from eating and sleeping. The binge ends only when the user runs out of methamphetamine or is too dazed to continue. When the binge finally does end, the exhausted user “crashes” and may sleep continuously for hours or even days.

The CNS stimulation produced by methamphetamine also can lead to irritability, tremors, and aggressiveness.<sup>11,16,17</sup> Other physiologic effects of methamphetamine use include increased respiration, increased blood pressure, tachycardia, vasodilation, and possibly nausea, vomiting, and diarrhea. Hyperthermia can occur with large doses and may be fatal.<sup>11,17</sup> Symptoms associated with severe, life-

Table 1.

## Selected Effects of Methamphetamine Abuse

### Short-Term Effects

- Aggressiveness
- Decreased appetite
- Decreased fatigue/increased wakefulness
- Euphoria and rush
- Hyperthermia
- Increased activity
- Increased attention
- Increased respiration
- Irritability
- Tremors

### Long-Term Effects

- Anxiety
- Confusion
- Dependence
- Insomnia
- Stimulant psychosis
  - Auditory and visual hallucinations
  - Delusions (e.g., a sensation that bugs are crawling on or under the skin)
  - Mood disturbances
  - Paranoia
  - Repetitive motor activity (e.g., picking at skin)
- Stroke
- Violent behavior
- Weight loss

Source: References 4, 11, 16, and 17.

threatening toxicity include cardiac arrhythmia or failure, subarachnoid hemorrhage, ischemic stroke, intracerebral hemorrhage, convulsions, or coma.<sup>15</sup>

## Long-Term Effects

Chronic methamphetamine abuse is associated with a number of deleterious effects, including anxiety, confusion, insomnia, and weight loss. Heavy users of methamphetamine tend to withdraw from

social contacts and may exhibit progressive occupational deterioration.<sup>1,11</sup>

Perhaps of greatest concern, the long-term use of methamphetamine induces a psychotic state (known as “stimulant psychosis” or “methamphetamine psychosis”) with symptoms that are virtually indistinguishable from schizophrenia.<sup>4,18,19</sup> These symptoms include:<sup>11</sup>

- Intense paranoia, which can result in both homicidal and suicidal thoughts.
- Visual and auditory hallucinations.
- Mood disturbances.
- Delusions (e.g., the sensation of insects crawling on the skin).
- Out-of-control rages that can be accompanied by extremely violent behavior.

There is growing evidence that chronic methamphetamine use causes persistent, perhaps permanent, damage to dopaminergic and serotonergic neurons.<sup>17,20-22</sup> The neurons are not thought to be destroyed outright; instead, the nerve endings (terminals) are cut back, and regrowth appears to be limited.<sup>16</sup> Up to 50% of the dopamine-producing neurons in certain parts of the brain can be damaged after either single, large doses of methamphetamine or prolonged use of small doses.<sup>11,17</sup> The damage to serotonin-producing neurons may be even more extensive.<sup>11</sup> Consequences of neuronal damage include slowed motor function and impaired memory.<sup>20,21,23</sup> Long-term users may develop Parkinsonian symptoms, because the patterns of damage are similar to those seen in patients with Parkinson’s disease.<sup>16,17</sup>

Discontinuing methamphetamine use is not associated with any physical manifestations of withdrawal.<sup>11</sup> But symptoms do occur, including:<sup>9,11</sup>

- Intense craving for the drug.
- Depression, anxiety, or both.
- Disturbed sleep patterns.
- Increased appetite.

Former users also are prone to recurrences of methamphetamine psychosis for months or even years after drug use ceases.<sup>11</sup>

There currently are no effective pharmacologic treatments for addiction to methamphetamine (or any amphetamine).<sup>9,18</sup> Antidepressant medications may be prescribed to counteract the depressive symptoms that frequently accompany methamphetamine withdrawal.<sup>9</sup>

## Other Consequences of Methamphetamine Abuse

In addition to the many adverse effects that are attributable directly to methamphetamine, abuse of this drug also is associated with indirect health risks.<sup>1</sup> Notable among these is the increased risk of human immunodeficiency virus (HIV) infection and hepatitis B and C.<sup>11</sup> Users who inject methamphetamine may reuse or share contaminated syringes, needles, or other paraphernalia. Also, the use of methamphetamine is growing among (1) sexually active bisexual and homosexual men and (2) both male and female commercial sex workers.<sup>1,9</sup> These populations are particularly vulnerable to contracting and spreading sexually transmitted diseases, especially HIV.<sup>9</sup>

As the use of methamphetamine becomes more widespread, fetal exposure to the drug is becoming an increasing problem.<sup>11</sup> Methamphetamine abuse during pregnancy may result in prenatal complications, increased rates of premature delivery, and abnormal reflexes and extreme irritability in newborns.<sup>11,18</sup> It also is suspected to cause congenital deformities.

The children of methamphetamine users often suffer from severe neglect and abuse. Children may go unwashed and unfed for days when parents crash after a run.<sup>24</sup> As one pediatrician in Oklahoma described it, “The parents are basically worthless.... When they’re not stoned, they’re sleeping if off; when they’re not sleeping, they don’t eat; and it’s not in their regimen to feed the kids.”<sup>24</sup> During an unfortunately typical raid on a meth lab in a Missouri house, three children younger than 5 years of age were found living without electricity or running water.<sup>13</sup> The house was infested with roaches and rodents, and the rugs and counters were soaked with toxic chemicals associated with methamphetamine production.

The need to remove children from dangerous and dysfunctional home environments is taxing the child welfare system, particularly in rural areas that don’t have strong social service networks. In the National Association of Counties survey mentioned earlier, 40% of child welfare officials reported that methamphetamine abuse was responsible for an increase in the number of children removed from homes.<sup>24</sup> For example, Tennessee officials reported a near dou-

## A Skeleton Waiting for the Bus

*U.S. Attorney General Alberto R. Gonzales recounted the following story in remarks made in July 2005 to the National District Attorneys Association meeting.*

I begin with a story about a 4-year-old Colorado boy named Romeo. Romeo's parents were running a methamphetamine lab in their home.

One day, at 5:00 AM, a SWAT team was making the final preparations to execute a search warrant on the lab. As the final checks were made, one of the detectives on surveillance reported that he saw a "skeleton" coming out the front door.

His fellow officers thought he must have been hallucinating. But then his colleagues got a better look and saw the same thing: it was Romeo dressed in a skeleton costume and looking up and down his street. The officers at first thought that he was acting as a lookout for his parents.

An officer later approached Romeo. He asked Romeo why he was dressed in a skeleton outfit and standing on his front porch, and why he was looking up and down the street at such an early hour in the morning.

Romeo's eyes lit up as he explained that later that day his nursery school was holding a Halloween party. As he told the story, his shoulders slumped. He told the officer that he really wanted to go to the party, but he hadn't been able to wake up his mom for the last few days and didn't know where the bus stop was. Romeo said he thought that if he got up early enough and put his costume on, he might be able to see the bus and catch it as it drove by.

*Source: Reference 13.*

bling in the number of children placed in foster care because of methamphetamine, from 400 children in 2003 to 700 children in 2004.<sup>24</sup>

## Sources of Methamphetamine

The methamphetamine available in the United States comes from both foreign and domestic sources. Mexico is the primary foreign source, although Canada, China, and Southeast Asia are recent additional sources.<sup>5,6</sup> Mexican labs may produce as much as half of the methamphetamine sold in the United States.<sup>25</sup>

Domestic methamphetamine production is divided between "super labs" and small toxic labs. Super labs—labs that are capable of producing more than 10 pounds of methamphetamine in 24 hours—are believed to account for most (>65%) domestic production. These large-capacity facilities are operated primarily by ethnic Mexican drug trafficking organizations (and to a lesser extent by outlaw motorcycle gangs).<sup>5,26</sup> Most are located in California. They manufacture methamphetamine from large quantities of precursor chemicals (e.g., bulk powder or tablet forms of pseudoephedrine or ephedrine) that are smuggled illegally into the United States or obtained through illicit distribution channels.

During the past 10 years, there has been an alarming increase in the number of makeshift small toxic labs that "cook" methamphetamine from a variety of legitimate household products and other ingredients available readily in stores.<sup>5,6</sup> These smaller labs may be set up virtually anywhere, including apartments, hotel rooms, rented storage spaces, barns, tool sheds, and even trucks or cars.<sup>4,8,18,27</sup> Because little equipment is needed, small toxic labs usually are portable and can be dismantled and moved quickly and stored easily.<sup>18</sup>

The small toxic labs have proliferated in part because the process of cooking methamphetamine is relatively simple, quick, and inexpensive. Small toxic labs can produce \$1,000 worth of methamphetamine from approximately \$100 in materials.<sup>28</sup> The usual starting ingredient is a nonprescription product containing pseudoephedrine, preferably a single-ingredient tablet. The product is dissolved in a non-aqueous solvent (e.g., alcohol) to remove the active ingredient. Then, depending on the technique used, the recovered pseudoephedrine is converted to

methamphetamine by one of two methods:

- The pseudoephedrine is heated with red phosphorus and hydroiodic acid (created from iodine and hypophosphorous acid), after which the methamphetamine base is extracted.
- The pseudoephedrine is mixed with lithium and sodium or anhydrous ammonia to create methamphetamine base directly (known as the Birch reduction or “Nazi” method, purportedly because the German government used it during World War II).

The chemical reactions created by these methods are geared toward removing the oxygen from the hydroxyl group on pseudoephedrine (which, as illustrated in Figure 1, is the only structural difference between pseudoephedrine and methamphetamine). “Recipes” with specific instructions for each process are readily available on the Internet and even in some commercially available books, and they are passed around frequently among users. (According to one methamphetamine control organization, the average user who knows how to make the drug teaches the procedure to 10 other people each year.<sup>4</sup>)

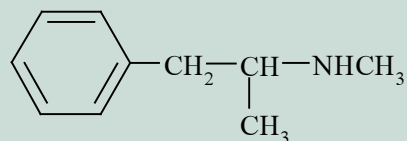
The small toxic labs usually are run by addicts or small groups of addicts (“cells”) who limit their production of methamphetamine to quantities sufficient for their immediate personal use.<sup>27</sup> (They don’t need to make much: a single ounce of methamphetamine is estimated to supply slightly more than 100 “hits.”<sup>4</sup>) Although they may sell small quantities of methamphetamine—usually to friends or acquaintances—they do so mostly to obtain the cash needed to purchase supplies for future batches, not to make a large profit.<sup>27</sup>

According to information provided by the Illinois Attorney General’s office, the typical meth cell is headed by a “meth cook”—a person who has learned the technique of making methamphetamine.<sup>27</sup> The remaining members of the cell (usually 7 to 10 people at various stages of addiction) perform various specific roles that support the methamphetamine production process. For example, they may:<sup>27,29</sup>

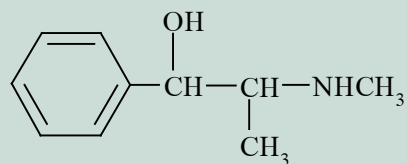
- Go from store to store (“smurf”) to purchase or steal products containing pseudoephedrine. Some may engage in “shelf sweeping,” remov-

Figure 1.

### Structural Formulas of Methamphetamine and Pseudoephedrine



Methamphetamine



Pseudoephedrine

ing all of the available stock from the shelf quickly and exiting the store hurriedly.

- Drive around the countryside to steal anhydrous ammonia from farmers’ storage tanks, especially at night.
- Visit local stores to purchase or steal the other needed equipment and chemicals.

## Dangers Associated With Methamphetamine Production by Small Toxic Labs

Although small toxic labs may account for less than 20% of all of the methamphetamine used in the United States, their rapid proliferation has created a disproportionate danger in many communities.<sup>17</sup> The danger stems from the hazardous substances involved in the production of methamphetamine and the violent behavior of methamphetamine users.

## Dangers From Hazardous Substances

Many of the ingredients used to make methamphetamine, as well as some of the by-products of the cooking process, are reactive, corrosive, flammable, explosive, or toxic.<sup>8,17,30</sup> (Some examples of ingredients used to produce methamphetamine are provided in Table 2.) These substances can and do cause fires, explosions, and other uncontrolled reactions.<sup>8</sup> According to some experts, meth cooks often seal windows to keep the strong odors associated with methamphetamine production from escaping and revealing the location of the lab; this practice prevents flammable gasses from escaping and increases the likelihood of fires and explosions.<sup>27</sup> As many as one third of known small toxic labs are discovered because they catch fire or blow up.<sup>8</sup>

These fires and explosions often injure or kill the people involved in making methamphetamine.<sup>5,27</sup> Examples of two cases reported to the Agency for Toxic Substances and Disease Registry Hazardous Substances Emergency Events Surveillance system between January 1, 2000, and June 30, 2004, are provided in Table 3. Sadly, the fires and explosions also may injure or kill other people in the vicinity, including children who may be present. For example, at any given time, between 30% and 90% of burn patients at Arkansas Children's Hospital are being treated for injuries caused by meth lab explosions.<sup>13</sup>

But the dangers are not limited to fires and explosions. Small toxic labs produce volatile air emissions and spills that can be hazardous to people and the environment.<sup>8,27</sup> The production of 1 pound of methamphetamine also creates 5 to 7 pounds of toxic waste.<sup>18</sup> Meth lab operators often pour these toxic substances down household drains or storm drains, bury them, or dump them directly onto the ground in yards, fields, or rural roads.<sup>4,18,30</sup> Injury occurs when people inhale the toxic or corrosive vapors, or come into contact with toxic or corrosive substances that are absorbed into the skin.<sup>32</sup>

Acute exposure to toxic or corrosive substances is a particular problem among law enforcement officials and first responder personnel who discover small toxic labs or are called to small toxic lab incidents.<sup>18,32</sup> Low-level exposure to these substances

Table 2.

### Examples of Precursor Ingredients and Supplies Used Commonly in Methamphetamine Production

- Nonprescription medications containing pseudoephedrine
- Acetone
- Ether (from engine starter fluid)
- Rubbing or isopropyl alcohol
- Methanol (from gasoline additives)
- Toluene (from brake cleaner)
- Red phosphorus (obtained from road flares or matchbook covers)
- Iodine
- Sodium hydroxide (lye)
- White vinegar
- Lithium (obtained from lithium batteries)
- Anhydrous ammonia (from fertilizer)
- Sulfuric acid (from drain cleaner)
- Rock salt
- Paint thinner
- Aluminum foil
- Coffee filters
- Propane tanks

Source: References 5 and 31.

may cause headache, dizziness, nausea, and fatigue.<sup>27,32</sup> Exposure to higher levels is associated with more serious injuries, including:<sup>27,32</sup>

- Respiratory irritation (e.g., coughing, difficulty breathing, throat irritation).
- Eye irritation.
- Chemical burns to the skin, eyes, mouth, and nose.
- Shortness of breath.
- Chest pain.
- Pulmonary edema.

In some instances, respiratory failure, coma, and even death can ensue.

The process of cleaning up a former small toxic lab site is a complex, dangerous, expensive, and time-consuming one.<sup>30</sup> The toxic waste created by methamphetamine production can persist in the soil and groundwater for years. Because the contaminated soil usually must be incinerated, the costs associ-

ated with cleaning the site can range anywhere from \$5,000 to more than \$150,000.<sup>4</sup>

## Dangers From Violent Behavior

The people who make, sell, and use methamphetamine often are well-armed and dangerous. As described earlier, methamphetamine addiction may lead to paranoid psychosis accompanied by unpredictable and extremely violent behavior. It is not unusual for users to kill each other in drug-related disputes.<sup>27</sup> In one recent case in Indiana, a 10-year-old girl reportedly was abducted and murdered because she stumbled on someone making or using methamphetamine.<sup>33</sup>

Once again, law enforcement officials and first responder personnel appear to be at particular risk. They may be fired on by the people they surprise during raids on small toxic labs. Small toxic labs also have been known to be booby-trapped, injuring or killing the people who discover them.<sup>6,18</sup>

## Existing Federal Methamphetamine Legislation

Until recently, efforts at the federal level to stem the growing tide of methamphetamine production and use have focused largely on controlling the diversion of large amounts of precursor chemicals to super labs. Notable pieces of federal legislation with which pharmacists should be familiar are:

- The Chemical Diversion and Trafficking Act of 1988.
- The Comprehensive Methamphetamine Control Act of 1996.
- The Methamphetamine Anti-Proliferation Act of 2000.

### Chemical Diversion and Trafficking Act of 1988

The Chemical Diversion and Trafficking Act of 1988 (CDTA) was an amendment to the Controlled Substances Act of 1970.<sup>30</sup> It imposed mandatory controls over certain listed chemicals used in the illic-

Table 3.

### Sample Case Reports of Small Toxic Lab Incidents

**Iowa.** In November 2002, three occupants (aged 18, 19, and 20 years) of an apartment were making methamphetamine in a bathroom using ether, muriatic acid, and other unspecified chemicals. A flash fire occurred; two men received thermal burns, and a woman received non-chemical-related trauma injuries when she jumped through a window. Both men were admitted to a hospital; the woman was treated at a hospital but not admitted. Twenty-four apartment building residents were evacuated for 3 hours while police, firefighters, and emergency medical technicians responded and initiated cleanup.

**Minnesota.** In June 2004, two men (aged 31 and 41 years) were manufacturing methamphetamine in a camper when a flash fire and explosion occurred. Chemicals being used included acetone, propane, and other unspecified solvents and chemicals. Both men received thermal burns and transported themselves to the hospital without assistance from emergency medical services. The older man was treated at the hospital and admitted with burns on his hands, arms, and knees. The younger man received burns on 80% of his body and died at the hospital. The fire had burned out by the time authorities responded.

Source: Reference 8.

it production of controlled substances, including reporting, record keeping, identification, and import/export requirements for transactions that reach or exceed certain threshold amounts. The CDTA makes the unauthorized trade in the listed chemicals equivalent to trafficking in illegal drugs. Under the CDTA, the DEA has the authority to stop shipments of controlled chemicals from U.S. suppliers to companies outside the United States suspected of reselling or diverting them to drug traffickers.

Methamphetamine is one of the controlled substances targeted by the CDTA. To help stem the illicit production of methamphetamine by super labs within and outside the United States, the CDTA imposes mandatory controls over transactions involving ephedrine or pseudoephedrine in bulk powder form. Nonprescription products containing ephedrine,

pseudoephedrine, or phenylpropanolamine were exempted from these controls. (Products containing phenylpropanolamine were removed from the market in 2000 for safety reasons unrelated to methamphetamine production.)

## Comprehensive Methamphetamine Control Act of 1996

The Comprehensive Methamphetamine Control Act of 1996 (MCA) broadened the controls on listed chemicals used in the production of methamphetamine.<sup>34</sup> It increased the penalties for the trafficking and manufacturing of methamphetamine. Most relevant to pharmacists, it expanded the controls over products containing ephedrine, pseudoephedrine, and phenylpropanolamine.<sup>6</sup>

Notably, the MCA removed the blanket exemption that previously had applied to nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine. Under the MCA requirements, purchases of nonprescription products were limited to 24 g of pseudoephedrine, phenylpropanolamine, or ephedrine (as the base) in a single transaction. However, “ordinary over-the-counter” products continued to be exempt from these transaction thresholds. These products were defined as containing:

- Solid dosage forms packaged with not more than 3 g pseudoephedrine or phenylpropanolamine base per package, contained in blister packs, with not more than two dosage units per blister.
- Solid dosage forms packaged with not more than 3 g pseudoephedrine or phenylpropanolamine base per package, contained in unit dose packets or pouches if the use of blister packs was not technically feasible.
- Liquid dosage forms containing not more than 3 g pseudoephedrine or phenylpropanolamine base per package.

These packages sometimes are referred to as “safe harbor” packaging.

## Methamphetamine Anti-Proliferation Act of 2000

The Methamphetamine Anti-Proliferation Act of 2000 (MAPA), which superceded the previous acts, was passed specifically to address the diversion of

drug products containing pseudoephedrine and phenylpropanolamine from retail and mail order sources.<sup>35</sup> The MAPA further reduced the threshold for single transactions involving products containing pseudoephedrine or phenylpropanolamine to 9 g (as the base). It also added a requirement that packages contain not more than 3 g of pseudoephedrine or phenylpropanolamine (as the base) for single transactions. The maximum number of tablets that fall within these requirements for products containing pseudoephedrine are shown in Table 4.

Both threshold requirements must be met in a given transaction. For example, a 100-count bottle of pseudoephedrine hydrochloride 60 mg exceeds the package size requirement of not more than 3 g of pseudoephedrine base (which is 61 tablets). The sale of this bottle would be regulated under the MAPA, even though it is below the 9-g transaction threshold of 184 tablets. The transaction would be allowed, but it would be subject to the record keeping, reporting, and identification requirements of a regulated transaction, and the retail distributor would be subject to the DEA chemical registration requirement.

Note, however, that the MAPA continues to exempt “ordinary over-the-counter” products from these transaction thresholds in retail settings. Mail-order transactions involving pseudoephedrine or phenylpropanolamine are subject to a 9-g transaction threshold regardless of packaging.

The MAPA contains many other provisions besides the threshold purchase and packaging requirements. Among them are strengthened sentencing guidelines for Act violators, training of federal and state law enforcement officers on methamphetamine investigations and the handling of the chemicals used in meth labs, and expanded substance abuse prevention efforts.<sup>6</sup>

## State Efforts to Combat the Methamphetamine Epidemic

Despite the current retail thresholds and other federal initiatives, operators of small toxic labs still are able to obtain sufficient amounts of pseudoephedrine to make their product. This has led many states, par-

Table 4.

### Number of Pseudoephedrine Tablets That Equal a Threshold Transaction

Product	No. Tablets	
	Per Package	Per Transaction
Pseudoephedrine hydrochloride		
120 mg	31	92
60 mg	62	184
30 mg	123	367
Pseudoephedrine sulfate		
120 mg	33	98
60 mg	65	195
30 mg	130	390

Source: Reference 35.

ticularly those hit hardest by the methamphetamine epidemic, to adopt more stringent local requirements.

In April 2004, Oklahoma became the first state to enact strict, comprehensive methamphetamine-control legislation. Solid dosage forms of pseudoephedrine have been classified as a Schedule V drug. Products containing pseudoephedrine may be sold only by licensed pharmacies. They must be stored behind the pharmacy counter and may be dispensed, sold, or distributed only by a pharmacist or licensed pharmacy technician. Purchasers must produce photo identification and sign a written log or receipt. Purchases are limited to 9 g per 30-day period (although combination products formulated as liquids, liquid capsules, or gel capsules currently are exempt from these restrictions). A recently enacted amendment to this legislation established a statewide online database that will link pharmacies, enabling them to check whether a customer already has purchased the maximum allowable amount of pseudoephedrine.

The Oklahoma law does appear to be reducing the number of small toxic labs in that state. From January 2004 to May 2005, the number of meth lab seizures reportedly decreased by 95%.<sup>13</sup> This success has led a number of other states to adopt or consider adopting methamphetamine control legislation, incor-

porating various combinations of restrictions such as:

- Limiting the sales of products containing pseudoephedrine or ephedrine.
- Classifying pseudoephedrine and ephedrine as Schedule V substances.
- Requiring that products containing pseudoephedrine or ephedrine be sold by pharmacists only.
- Regulating the placement of products containing pseudoephedrine or ephedrine.
- Requiring people purchasing products containing pseudoephedrine or ephedrine to show photo identification.
- Requiring people purchasing products containing pseudoephedrine or ephedrine to sign a logbook.

Oregon recently enacted even stricter methamphetamine controls. As of July 1, 2006, pseudoephedrine, ephedrine, and phenylpropanolamine will be reclassified as Schedule III controlled substances. Products containing any of these substances will be available by prescription only.

Summary information about the provisions of existing state methamphetamine laws is provided in Table 5. The landscape of methamphetamine control legislation is a rapidly changing one; although the information in Table 5 was current at the time this monograph was published, pharmacists should contact their state pharmacy associations or boards of pharmacy to learn the specifics of methamphetamine control measures in the states in which they practice.

## New Federal Efforts to Combat the Methamphetamine Epidemic

A quick glance at Table 5 reveals that existing regulations vary from state to state. But what the table does not reveal is that these variations can be dramatic, particularly with regard to sales limits and product placement. These interstate variations cause problems and confusion for pharmacies that do business in more than one state, as well as for pharmacists who work in more than one state (e.g., pharmacists who float among pharmacies located near state borders).

Table 5.

Current State Laws Governing the Sale of Pseudoephedrine<sup>a</sup>

State	Type of Restriction				
	Sales Limit	Age Restriction	Show ID or Sign Logbook	Placement Restrictions	Schedule V
Alabama	Yes	Yes	Yes	Yes	...
Arizona	Yes	...	...	Yes	...
Arkansas	Yes	Yes	Yes	...	Yes
California	Yes	...	...	...	...
Colorado	Yes	...	...	...	...
Delaware	Yes	Yes	Yes	Yes	...
Florida	Yes	...	...	Yes	...
Georgia	Yes	...	...	Yes	...
Hawaii	Yes	...	...	Yes	...
Illinois	Yes	...	Yes	Yes	...
Indiana	Yes	Yes	Yes	Yes	...
Iowa	Yes	Yes	Yes	Yes	Yes
Kansas	Yes	Yes	Yes	Yes	Yes
Kentucky	Yes	Yes	Yes	Yes	...
Louisiana	Yes	...	Yes	Yes	...
Maine	Yes	...	Optional	Yes	...
Michigan	Yes	Yes	Yes	Yes	...
Minnesota	Yes	Yes	Yes	Yes	Yes
Mississippi	Yes	...	Yes	Yes	...
Missouri	Yes	Yes	Yes	Yes	Yes
Montana	Yes	...	Yes	Yes	...
Nebraska	Yes	Yes	Yes	Yes	...
New Jersey	Yes	...	...	...	...
New Mexico	Yes	...	...	Yes	...
North Dakota	Yes	Yes	Yes	...	...
Oklahoma	Yes	Yes	Yes	Yes	Yes
Oregon	Yes	...	Yes	Yes	C-III <sup>b</sup>
South Dakota	Yes	...	...	Yes	...
Tennessee	Yes	...	Yes	Yes	...
Texas	Yes	Yes	Yes	Yes	...
Washington	Yes	Yes	Yes	Yes	...
West Virginia	Yes <sup>c</sup>	Yes	Yes	Yes	Yes
Wisconsin	Yes	Yes	Yes	...	Yes
Wyoming	Yes	...	...	Yes	...

<sup>a</sup>Information current as of August 2005.

<sup>b</sup>Pseudoephedrine has been reclassified as a Schedule III controlled substance in Oregon.

<sup>c</sup>Possession limit, not sales limit.

Source: Reference 35.

In some cases, the discrepancies among the regulations have merely shifted the methamphetamine burden from one state to another. According to a recent *Time* magazine article, Kansas “saw a rash of meth cooks cross the state line” after the Oklahoma law was passed.<sup>36</sup>

This amalgam of state laws has led to calls for new, stricter federal methamphetamine legislation. The leading current proposal—the Combat Meth Act of 2005, cosponsored by Senators Jim Talent (R-Mo.) and Dianne Feinstein (D-Calif.)—is similar in many ways to the Oklahoma law. In the version approved by the Senate Judiciary Committee in July 2005, the Combat Meth Act would<sup>37</sup>:

- Classify pseudoephedrine as a Schedule V controlled substance.
- Require that nonprescription medications containing pseudoephedrine be sold only from behind a pharmacy counter, by a pharmacist or pharmacy technician.
- Require purchasers to show photo identification and sign a register.
- Limit an individual’s purchase of products containing pseudoephedrine to 7.5 g (about 250 30-mg tablets) per 30-day period.

The bill also provides funds for enforcing and prosecuting methamphetamine offenses, cleaning up toxic areas, treating methamphetamine abusers, and assisting children affected by methamphetamine abuse. A national methamphetamine research, training, and technical assistance center would be created to assist in these endeavors.

However, new federal methamphetamine legislation solves the problem of conflicting state regulations only if it supercedes those regulations. That may not be the case with the Combat Meth Act. Before the bill was approved by the Senate Judiciary Committee, an amendment was added that would allow states to adopt and enforce their own regulations, as long as they are at least as strict as those in the federal law.<sup>37</sup> (At the time this monograph was finalized, the Combat Meth Act still needed to be voted on by the full Senate. A similar measure had been introduced in the House of Representatives by Roy Blunt, R-Mo.)

In October 2004, the federal government released the *National Synthetic Drugs Action Plan*, a comprehensive strategy for reducing the production, traffick-

ing, and use of synthetic drugs (particularly methamphetamine) and the diversion of pharmaceuticals. The Action Plan provides key recommendations in four core areas: prevention, treatment, regulation of chemicals and drugs, and law enforcement. The complete report, as well as a 6-month interim progress report, are available on the Office of National Drug Control Web site at [www.whitehousedrugpolicy.gov/publications/national\\_synth\\_drugs/](http://www.whitehousedrugpolicy.gov/publications/national_synth_drugs/).

## Implications for Pharmacists

Pharmacists clearly are the health care professionals affected most directly by the rapid changes surrounding the nonprescription availability of pseudoephedrine. Pseudoephedrine is the most effective oral decongestant currently available, and one of only two still available without a prescription (phenylephrine is the other). As the many state and federal methamphetamine control proposals are debated and adopted, it is important for pharmacists to understand the implications of various restrictions for both themselves and the patients they serve. Some of these implications are explored below.

### Targeting Single-Ingredient Pseudoephedrine Products

In many states that have restricted sales of pseudoephedrine (including Oklahoma), the restrictions are limited to solid dosage forms or single-ingredient products. The thinking has been that meth cooks are unable to extract usable pseudoephedrine from gel caps, syrups, or combination products and therefore target primarily single-ingredient tablets.

Unfortunately, this thinking may not be accurate. The June issue of the DEA *Microgram Bulletin* reports the results of two studies: one conducted by forensic chemists at the Washington State Patrol Crime Laboratory in Marysville, and one conducted by an independent forensic laboratory on behalf of McNeil Consumer and Specialty Pharmaceuticals.<sup>38</sup> Using approaches similar to those employed by small toxic lab operators, investigators were able to produce methamphetamine using pseudoephedrine extracted

from the following types of single-ingredient and multi-ingredient products:

- Caplets (e.g., “severe cold formulas”).
- Powders (e.g., those that are dissolved in hot liquids).
- Water-based liquids (e.g., cough syrups).
- Alcohol-based liquids (e.g., nighttime multi-ingredient products).
- Softgels.

The steps needed to extract pseudoephedrine from multi-ingredient products were described as more difficult than those used with single-ingredient tablets, but not excessively complicated. Therefore, truly effective legislation may need to target *all* pseudoephedrine-containing products, not just single-ingredient tablets or products.

## Reclassifying Pseudoephedrine as a Schedule V Controlled Substance

Reclassifying pseudoephedrine as a Schedule V controlled substance could have some unanticipated ramifications. For example, in 15 states, the definition of Schedule V requires patients to have a written prescription from a physician. Also, only about 15,000 of the more than 200,000 retail food stores in the United States have pharmacies.<sup>39</sup> Restricting the sale of pseudoephedrine-containing products to pharmacy outlets has the potential to severely limit access to the medication, especially for patients in rural areas. (The Combat Meth Act would allow special exceptions to some of its provisions if the absence of a pharmacy would create a hardship for a community.)

Other Schedule V restrictions, such as requiring products to be stored in the pharmacy area, could limit patients’ choice of product as well. The Consumer Healthcare Products Association estimates that there are more than 4,200 brand-name and store-brand products containing pseudoephedrine currently on the market.<sup>40</sup> Clearly, no pharmacy would have room for even a fraction of those products behind the counter. A study by the market information firm Information Resources, Inc., found that the number of pseudoephedrine products available to consumers in Oklahoma was reduced by more than one third after the comprehensive methamphetamine-control legislation was enacted.<sup>41</sup>

## Regulating the Placement of Pseudoephedrine-Containing Products

The space issue is not necessarily a deterrent, though. Even without stricter federal methamphetamine legislation, a number of pharmacies—notably, some of the largest national and regional pharmacy chains—already have elected to restrict consumer access to pseudoephedrine-containing products. In April 2005, Wal-Mart, Target, CVS, Walgreen’s, Kmart, and Albertson’s (which operates more than 2,000 pharmacies nationwide under names including Savon and Osco Drug) announced that they would move many single-ingredient and combination products behind the pharmacy counter. Other chains have followed suit since then. Target announced that products containing pseudoephedrine would not be sold in stores that do not have a pharmacy; in stores that do have a pharmacy, customers are limited to two packages of pseudoephedrine-containing products per transaction.

These moves certainly make it more difficult for methamphetamine users to obtain large supplies of pseudoephedrine (e.g., they all but eliminate the possibility of shelf sweeping). However, they also make it more difficult for patients to obtain oral decongestants for legitimate medical use. In busy stores, patients may not be willing to wait in the pharmacy line to get their cold medication. Conversely, patients who need to have prescriptions filled could be inconvenienced and angered by having to wait for pharmacy personnel to assist people with purchases of products containing pseudoephedrine. Moving pseudoephedrine-containing products behind the pharmacy counter also may increase the potential for robberies, similar to those committed by addicts seeking OxyContin (oxycodone HCl controlled-release tablets).

## Retail Sales Limits on Pseudoephedrine-Containing Products

In a policy statement adopted at the APhA2005 Annual Meeting and Exposition in Orlando, Florida, the APhA House of Delegates voiced support for retail sales limits on nonprescription products that contain

methamphetamine precursors (Figure 2). (The policy did not include support for the type of restricted access described above.) The Consumer Healthcare Products Association also has come out in favor of sales limits; that trade group advocates limiting the sale of nonprescription drug products containing pseudoephedrine to two packages, or 6 g, per transaction.<sup>42</sup>

Sales limits probably would curtail, but certainly would not eliminate, the diversion of pseudoephedrine. Without a national online database similar to the one that will link pharmacies in Oklahoma, retail sales limits might simply lead to more smurfing. In March 2005, Minnesota police arrested four people and seized more than 6,700 pseudoephedrine tablets from their vehicle.<sup>38</sup> The two men and two women had been following a circuitous route through Iowa, South Dakota, North Dakota, and Minnesota, stopping in stores and each purchasing the maximum allowable amount of pseudoephedrine.

Figure 2.

### 2005 APhA House of Delegates Adopted Policy Statement on Efforts to Limit Methamphetamine Access

APhA supports legislation that balances the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.

APhA supports stringent enforcement of criminal laws against individuals who engage in the illegal trafficking of methamphetamine and methamphetamine precursors.

APhA supports retail sales limits of nonprescription products that contain methamphetamine precursors to prevent diversion.

APhA supports education of employees involved in the distribution chain of methamphetamine precursors about diversion, methamphetamine abuse, and prevention of abuse. APhA supports patient/consumer education of consequences of methamphetamine abuse.

APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.

## Increased Vigilance by Store Personnel

Along with retail sales limits on nonprescription products that contain methamphetamine precursors, both APhA and the Consumer Healthcare Products Association support efforts to increase the awareness and vigilance of store personnel. Stores that participate in the Consumer Healthcare Products Association's Meth Watch program place methamphetamine precursor products where they can be monitored easily (but remain accessible to customers) and post Meth Watch signs and tags strategically on their doors and windows, around their cash registers, and on the shelves where precursor products are located. Employees are trained to recognize, but not to confront, suspicious customers, and to contact law enforcement with as much identifying information as possible. More information about the program is available at [www.methwatch.com](http://www.methwatch.com).

In addition to those efforts, the DEA advises employees to be alert for people who purchase any of the following items (all potential methamphetamine precursors) in unusual quantities or under unusual circumstances:

- Camping fuel.
- Lithium batteries.
- Large quantities of matches.
- Iodine.
- Coffee filters.
- Rock salt.
- Battery acid.
- Swimming pool acid.

As with retail sales limits, increased vigilance by store personnel probably would curtail, but certainly would not eliminate, the diversion of pseudoephedrine and other methamphetamine precursors. And it could place store personnel in potentially dangerous situations, given the tendency for methamphetamine users to display erratic and possibly violent behavior.

## Marketing or Reformulating Products With Alternative Ingredients

Partly in response to the increasing relocation of pseudoephedrine-containing products behind pharmacy counters, manufacturers have begun to consider alternatives. Pfizer Consumer Healthcare, which markets the single-ingredient product Sudafed (as well as a number of combination products), introduced Sudafed PE in February 2005. Sudafed PE contains phenylephrine 10 mg; phenylephrine had not previously been available as a single-ingredient product.

Additional new products or reformulations of existing products are likely to follow. As part of the announcement that Wal-Mart would move all pseudoephedrine-containing products behind pharmacy counters, company officials said that they had been in discussions with suppliers "regarding the reformulating of these products with alternative ingredients."<sup>43</sup> Pfizer reportedly is reformulating its entire Sudafed line, with most products expected to be changed by late 2005.<sup>43</sup>

In Oklahoma, many consumers appear to be choosing to switch to phenylephrine-containing products, rather than spend the extra time to request pseudoephedrine products at the pharmacy counter. During the initial 12-month period following enactment of the comprehensive methamphetamine control legislation, volume sales of pseudoephedrine products decreased by 16% compared with the previous year, while sales of phenylephrine products increased by 24%.<sup>41</sup>

The unfortunate aspect of this trend is that phenylephrine is far from an ideal oral decongestant. It has both a low bioavailability (approximately 38%) and a short half-life (2.5 hours).<sup>44</sup> A more desirable alternative would be to reformulate pseudoephedrine-containing products in ways that would prevent their conversion to methamphetamine, or render the final product unusable.

## Opportunities for Pharmacists

Given the rapid changes surrounding this difficult issue, it is impossible to predict the eventual outcome of methamphetamine legislation or the ultimate fate of pseudoephedrine. In the meantime, though, pharmacists can take advantage of the uncertain situation to create stronger relationships with patients.

The relocation of pseudoephedrine-containing products behind the pharmacy counter presents a tailor-made opportunity for self-care counseling. Pharmacists can use these interactions to acquaint patients with the value that pharmacists can bring to patient's self-treatment decisions. Because patients don't always know which particular pseudoephedrine-containing product they want, the pharmacist can ask a few targeted questions to elicit a patient's chief complaints, determine the most appropriate product, and possibly improve treatment outcomes. For example, patients might have been in the habit of using a combination product with excessive or even inappropriate active ingredients.

Pharmacists also might recommend the use of topical decongestants for patients who are bothered primarily by nasal congestion. Topical products generally are accepted to be more potent than systemic decongestants.<sup>45</sup> Because systemic absorption of topical decongestants is minimal, they can be used safely by patients with hypertension, as well as women who are or might become pregnant and women who are breast-feeding. Patients should be cautioned not to use topical products for more than 3 to 5 days, to prevent rhinitis medicamentosa (the apparent rebound congestion seen when the drug is discontinued).<sup>44,45</sup>

Enterprising pharmacists might take advantage of the pseudoephedrine situation to develop and offer comprehensive self-care management services. One approach might be to create a "Self-Care Club" with an annual or seasonal membership fee that entitles patients to a set number of short (e.g., 15-minute) self-treatment consultations and medication reviews.

# Conclusion

The problems associated with the methamphetamine epidemic have no simple answers. Clearly, methamphetamine abuse exacts a devastating toll on the people who use the drug, as well as the communities in which it is manufactured. Effective measures to curb methamphetamine abuse are sorely needed; unfortunately, none of the measures currently under consideration appears to be sufficient to end the epidemic, and all have important implications for pharmacists and patients alike. As this difficult situation continues to unfold, pharmacists should keep abreast of developments and seize all opportunities to help patients achieve their self-care goals.

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# CE ASSESSMENT QUESTIONS

INSTRUCTIONS: For each question, circle the letter corresponding to the correct answer on the C.E. Examination Form. **Please review all of your answers to be sure you have marked the proper letter.** There is only one correct answer to each question.

- The number of Americans ages 12 years and older who have tried methamphetamine at least once during their lifetimes has been reported to exceed:**
  - 1 million.
  - 7 million.
  - 12 million.
  - 20 million.
- Methamphetamine abuse initially was concentrated among:**
  - White, male, blue-collar workers.
  - Young adults who attend "raves."
  - Homeless and runaway youth.
  - People employed in the entertainment industry.
- Compared with cocaine, the feelings of pleasure and euphoria produced by methamphetamine are:**
  - Slightly longer lasting.
  - Much longer lasting.
  - Slightly shorter lasting.
  - Much shorter lasting.
- The term "flash" refers to:**
  - A method of "cooking" methamphetamine.
  - The intense but short-lived euphoria that occurs immediately after injecting or smoking methamphetamine.
  - A street name for methamphetamine.
  - None of the above.
- The short-term effects of methamphetamine use include all of the following except:**
  - Decreased appetite.
  - Hypothermia.
  - Increased respiration.
  - Tremors.
- Which of the following is a symptom of methamphetamine psychosis?**
  - Intense paranoia.
  - Visual and auditory hallucinations.
  - Delusions (such as the sensation of insects crawling on the skin).
  - All of the above.
- Methamphetamine users often face an increased risk of:**
  - Human immunodeficiency virus infection.
  - Hepatitis B.
  - Hepatitis C.
  - All of the above.
- What percentage of the methamphetamine consumed in the United States is believed to come from Mexico?**
  - 10%.
  - 30%.
  - 50%.
  - 70%.
- "Small toxic labs" are thought to account for about \_\_\_\_\_ of the methamphetamine used in the United States.**
  - 20%.
  - 40%.
  - 60%.
  - 80%.
- When methamphetamine producers engage in "smurfing," they are:**
  - Attempting to convert pseudoephedrine to methamphetamine.
  - Attempting to sell small quantities of manufactured methamphetamine to friends.
  - Going from store to store to purchase or steal products containing pseudoephedrine.
  - Driving around the countryside to steal anhydrous ammonia from farmers' storage tanks.
- Which of the following items is known to be used in the production of methamphetamine by small toxic labs?**
  - Brake cleaner.
  - Coffee filters.
  - Road flares.
  - All of the above.
- How much toxic waste is created for each 1 lb of methamphetamine produced?**
  - 1 to 2 lb.
  - 2 to 4 lb.
  - 5 to 7 lb.
  - 8 to 10 lb.
- The mandatory controls imposed by the Chemical Diversion and Trafficking Act of 1988 over transactions involving bulk powder forms of ephedrine or pseudoephedrine were aimed largely at stemming methamphetamine production by:**
  - Foreign producers.
  - Super labs.
  - Small toxic labs.
  - All of the above.

- 14. To be considered as an exempt “ordinary over-the-counter” product under the Comprehensive Methamphetamine Control Act of 1996, packages containing solid dosage forms of pseudoephedrine must:**
- Not contain more than 3 g pseudoephedrine base per package.
  - Contain the dosage units in blister packs, with not more than two dosage units per blister.
  - Contain the dosage in unit dose packets or pouches if the use of blister packs is not technically feasible.
  - All of the above.
- 15. Why would a 100-count bottle of pseudoephedrine hydrochloride 60 mg be subject to the provisions of the Methamphetamine Anti-Proliferation Act of 2000?**
- It exceeds the package size requirement of not more than 3 g of pseudoephedrine base.
  - It exceeds the 9-g transaction threshold.
  - Both a and b are correct.
  - None of the above.
- 16. Provisions of the comprehensive methamphetamine-control legislation enacted in Oklahoma include all of the following except:**
- Reclassifying all dosage forms of pseudoephedrine as Schedule V drugs.
  - Requiring regulated dosage forms of pseudoephedrine to be stored behind the pharmacy counter.
  - Limiting purchases of regulated dosage forms of pseudoephedrine to 9 g per 30-day period.
  - All of the above.
- 17. As approved by the Senate Judiciary Committee, the Combat Meth Act of 2005 contains which of the following provisions?**
- Reclassifies pseudoephedrine as a Schedule V controlled substance.
  - Limits purchases of products containing pseudoephedrine to 7.5 g per 30-day period.
  - Requires purchasers to show photo identification and sign a register.
  - All of the above.
- 18. Investigators have found that “meth cooks” most likely are able to extract pseudoephedrine from:**
- Single-ingredient products only.
  - Solid dosage forms only.
  - Any product that contains pseudoephedrine, including multi-ingredient products.
  - None of the above.
- 19. Since comprehensive methamphetamine-control legislation was enacted in Oklahoma, the number of pseudoephedrine products available to consumers appears to have decreased by more than:**
- 10%.
  - 25%.
  - 33%.
  - 50%.
- 20. As measures to restrict access to products containing pseudoephedrine increase, pharmacists can expect to see an increase in the number of nonprescription products containing:**
- Ephedrine.
  - Phenylephrine.
  - Phenylpropanolamine.
  - All of the above.

## C.E. Credit:

To obtain 2.0 contact hours of continuing education credit (0.2 CEUs) for “Pseudoephedrine Diversion: Regulatory and Scientific Responses” complete the assessment exercise, fill out the “C.E. Examination Form” page at the end of this publication, and return that page to APhA. You also can go to [www.pharmacist.com](http://www.pharmacist.com) and take your test online for instant credit. C.E. processing is free to APhA members, \$10 for nonmembers. A Statement of Credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before September 1, 2008, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is 202-000-05-191-H03.



“Pseudoephedrine Diversion: Regulatory and Scientific Responses” is a home-study continuing education program for pharmacists developed by the American Pharmacists Association and supported by a grant from McNeil Consumer & Specialty Pharmaceuticals.

# C.E. EXAMINATION FORM

## Pseudoephedrine Diversion: Regulatory and Scientific Responses

To receive **2.0** contact hours of continuing education credit (**0.2 CEU**), please provide the following information:

1. Type or print your name and address in the spaces provided.

2. Mail this completed form for scoring to:  
American Pharmacists Association—CE Exam  
P.O. Box 791082  
Baltimore, MD 21279-1082

3. CE processing is free for APhA members. If you are not an APhA member, enclose a \$10.00 handling fee for grading the assessment instrument and issuing the Statement of Credit.

A Statement of Credit will be awarded for a passing grade of 70% or better. If you fail the exam, you may retake the exam once. If you do not pass the second time, you may no longer participate in this continuing pharmacy education program. Please allow 6 weeks for processing. Pharmacists who complete this exercise successfully before **September 1, 2008**, can receive credit.



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### PARTICIPANT INFORMATION

NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_

STATE \_\_\_\_\_

ZIP \_\_\_\_\_

E-MAIL \_\_\_\_\_

WORK PHONE \_\_\_\_\_

HOME PHONE \_\_\_\_\_

How long did it take you to read the continuing education program and complete this test?

\_\_\_\_\_ Hours \_\_\_\_\_ Minutes

My signature certifies that I have independently taken this C.E. Examination:

\_\_\_\_\_

### C.E. ASSESSMENT QUESTIONS—ANSWERS

Please circle your answers (one answer per question).

1. a b c d  
2. a b c d  
3. a b c d  
4. a b c d  
5. a b c d

6. a b c d  
7. a b c d  
8. a b c d  
9. a b c d  
10. a b c d

11. a b c d  
12. a b c d  
13. a b c d  
14. a b c d  
15. a b c d

16. a b c d  
17. a b c d  
18. a b c d  
19. a b c d  
20. a b c d

### PROGRAM EVALUATION

#### PLEASE ANSWER EACH QUESTION.

	EXCELLENT				POOR
1. Overall quality of the program	5	4	3	2	1
2. The program was relevant to pharmacy practice	5	4	3	2	1
3. Value of the content	5	4	3	2	1

#### PLEASE ANSWER EACH QUESTION MARKING WHETHER YOU AGREE OR DISAGREE.

	Agree	Disagree
4. The program met the stated learning objectives:		
• Discuss the characteristics and consequences of methamphetamine abuse.	<input type="checkbox"/>	<input type="checkbox"/>
• Identify the main sources of methamphetamine in the United States and explain how pseudoephedrine-containing products are diverted to make methamphetamine.	<input type="checkbox"/>	<input type="checkbox"/>
• Describe the hazards posed to both people and the environment by small toxic labs.	<input type="checkbox"/>	<input type="checkbox"/>
• Outline existing and proposed federal and state legislation intended to decrease methamphetamine production by large and small illicit laboratories.	<input type="checkbox"/>	<input type="checkbox"/>
• Discuss the implications for pharmacists of various methamphetamine-control strategies, as well as opportunities presented for expanded self-care services.	<input type="checkbox"/>	<input type="checkbox"/>
5. The program increased my knowledge in the subject area.	<input type="checkbox"/>	<input type="checkbox"/>
6. The program did not promote a particular product or company.	<input type="checkbox"/>	<input type="checkbox"/>

#### Impact of the Activity

The information presented (check all that apply):

7. <input type="checkbox"/> Reinforced my current practice/treatment habits	<input type="checkbox"/> Will improve my practice/patient outcomes	<input type="checkbox"/> Provided new ideas or information I expect to use	<input type="checkbox"/> Enhances my current knowledge base
8. Will the information presented cause you to make any changes in your practice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
9. How committed are you to making these changes?	(Very committed) 5 4 3 2 1 (Not at all committed)		
10. Do you feel future activities on this subject matter are necessary and/or important to your practice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

### Follow Up

As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

- Yes, I am interested in participating in a follow-up survey.  No, I am not interested in participating in a follow-up survey.

You also can go to <http://www.pharmacist.com> and take your test online for instant credit.



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