Order Code RL33385

CRS Report for Congress
Received through the CRS Web

The Legal Regulation of Sales of Over-the-Counter Cold and Allergy Medication

April 21, 2006

Jody Feder
Legislative Attorney
American Law Division

The Legal Regulation of Sales of Over-the-Counter Cold and Allergy Medication

Summary

In response to a growing problem with illegal methamphetamine production and abuse, both the federal and state governments have recently taken steps to strengthen their regulation of the sale of over-the-counter cold medications that contain methamphetamine precursor chemicals such as ephedrine, pseudoephedrine, and phenylpropanolamine. At the federal level, the Drug Enforcement Agency (DEA) is the primary agency that regulates the restrictions that are imposed on the sale of such drug products under the Controlled Substances Act (CSA). Until recently, states had taken the lead with respect to strengthening such sales restrictions, but the 109th Congress recently enacted more stringent requirements with respect to methamphetamine — or "meth" — precursor chemicals as part of the reauthorization of the USA PATRIOT Improvement and Reauthorization Act (P.L. 109-177).

Contents

The Legal Regulation of Sales of Over-the-Counter Cold and Allergy Medication

Introduction

In response to rising rates of methamphetamine production and abuse across the country, many elected officials and law enforcement officers have been exploring new methods of curtailing such activities. One regulatory option gaining in popularity is to target the precursor chemicals that are key ingredients in methamphetamine production by placing restrictions on over-the-counter (OTC) sales of certain drug products — most notably, cold and allergy medicines — that contain ephedrine, pseudoephedrine, and phenylpropanolamine.[1] Because drug products that contain these three precursor chemicals can easily be converted into methamphetamine and because such medications are readily available at many retail outlets, limiting retail sales and reducing the opportunity for theft of these medications is expected to reduce methamphetamine production and abuse.

In general, federal and state legislative efforts to limit sales of OTC cold and allergy remedies that contain methamphetamine precursor chemicals include proposals to: require such products to be placed behind the counter; restrict sales to licensed pharmacies only via a prohibition on sales in other retail stores; limit the number of packages that can be purchased in a single transaction; and require customers to provide identification and a signature upon purchase. Proponents of such restrictions argue that such limits are the best way to prevent methamphetamine-related crime, but opponents contend that these restrictions limit access for law-abiding citizens who simply wish to buy medicine at the local convenience store when they catch a cold.[2]

Current regulation of OTC medications that contain methamphetamine precursor chemicals consists of a patchwork of federal and state laws in an array of areas. At the federal level, the Drug Enforcement Agency (DEA) enforces the Controlled Substances Act (CSA), which is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or

---

[1] In 2000, the FDA initiated action to remove phenylpropanolamine from the market due to safety concerns. Although many drug manufacturers voluntarily discontinued products containing phenylpropanolamine, some products continue to remain on the market. Therefore, the DEA continues to regulate the chemical. Clarification of the Exemption of Sales by Retail Distributors of Pseudoephedrine and Phenylpropanolamine Products, 69 FR 2062, 2062 (Jan. 14, 2004). *See also*, Food and Drug Administration, Phenylpropanolamine (PPA) Information Page, [http://tv.zap2it.com/tveditorial/tve_main /1,1002,271%7C95861%7C1%7C,00.html].

[2] Margot Roosevelt, *The Cold-Pill Crackdown*, TIME, Feb. 7, 2005, at 56.

importation of controlled substances.[3] The Food and Drug Administration (FDA) regulates OTC drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA), which governs, among other things, the safety and efficacy of OTC medications, including the approval, manufacturing, and distribution of such drugs.[4]

At the state level, state law enforcement agencies oversee the enforcement of state controlled substances laws, and state boards of pharmacy regulate pharmacy practice. Thus, some of the laws that govern OTC medications that contain methamphetamine precursor chemicals vary from state to state. Until recently, states had been taking a more active role with respect to strengthening the sales restrictions on such drug products, but the 109th Congress recently enacted more stringent requirements with respect to methamphetamine — or "meth" — precursor chemicals as part of the reauthorization of the USA PATRIOT Improvement and Reauthorization Act (P.L. 109-177). Both federal and state laws are detailed below.

Federal Law

As noted above, the CSA is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances. The primary purpose of the CSA is to facilitate the legal distribution of controlled substances for legitimate medical purposes while preventing their diversion for illegal manufacture, distribution, and use. Over the years, however, the scope of the CSA has expanded from controlling illegal drugs to regulating the chemicals that are used in the illicit production of those drugs. Since many of these precursor chemicals have legitimate uses, their regulation is generally less stringent, and some, like ephedrine, pseudoephedrine, and phenylpropanolamine, are legally marketed as non-controlled ingredients in certain OTC drug products, even though they are otherwise listed chemicals that are regulated under the CSA.[5]

Currently, federal law places some restrictions on retail sales of products containing methamphetamine precursor chemicals. In general, under the CSA, sales of listed chemicals that are contained in drug products that are lawfully marketed or distributed under the FFDCA are, with some exceptions, not regulated transactions,[6] which means that retailers are not subject to the statute's detailed registration, record-

---

[3] 21 U.S.C. § 801 et seq. For more information on the Controlled Substances Act, see CRS Report 97-141, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*.

[4] 21 U.S.C. §§ 301 et seq.

[5] Drug Enforcement Administration, U.S. Chemical Control, [http://www.usdoj.gov/dea/concern/chemical_control.html].

[6] 21 U.S.C. § 802(39)(A)(iv). Other activities are also excluded from the definition of regulated transactions, such as any transaction in a chemical mixture that the Attorney General (AG) has by regulation exempted because the mixture is formulated to prevent the illicit production of a controlled substance. *Id.* at § 802(39)(A)(vi). However, sales of FDA-approved drug products are regulated transactions if the AG determines that the drug or group of drugs is being diverted to obtain the listed chemical for purposes of producing a controlled substance or if the quantity of the listed chemical contained in the drug equals or exceeds the sales threshold established by the AG. *Id.* at § 802(39)(A)(iv).

keeping, and reporting requirements,[7] nor are they required to comply with the customer identification or drug security requirements.[8] This provision reflects the notion that the effort to regulate controlled substances should not unduly interfere with public access to OTC drug products that have legitimate medical uses.

More specifically, under the CSA, any transaction by a regulated seller or distributor in a "scheduled listed chemical product" — defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and that may be lawfully marketed or distributed under the FFDCA — is not a regulated transaction when such products are sold or purchased at retail, meaning they are sold or purchased for personal use.[9] The term regulated seller is defined to include grocery stores, general merchandise stores, drug stores, mobile retail vendors, or other entities whose sale of OTC products that contain methamphetamine precursor chemicals are limited almost exclusively to sales for personal use.[10]

Due to concerns about the illicit production and distribution of controlled substances such as methamphetamine, however, retail sales of such scheduled listed chemical products are subject to a number of restrictions, despite the fact that they are not deemed to be regulated transactions under the CSA. For example, retail sales of drug products that contain methamphetamine precursor chemicals are limited to no more that 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per person per day. Likewise, regulated sellers are prohibited from selling such products in non-liquid form (including gel caps) "unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches."[11] Individuals are also prohibited from knowingly purchasing more than 9 grams of ephedrine, pseudoephedrine, or phenylpropanolamine at retail or more than 7.5 grams of such substances by mail order during a 30-day period.[12]

In addition, the CSA makes it unlawful for an individual to possess a listed chemical such as ephedrine, pseudoephedrine, or phenylpropanolamine with intent to engage in the unauthorized manufacture of a controlled substance or to possess or distribute a listed chemical while knowing or having reasonable cause to believe that the chemical will be used in the unauthorized manufacture of a controlled substance.[13] Under the recent amendments, the statute also authorizes the Attorney General (AG) to establish annual production quotas for manufacturers of

---

[7] *Id*. at §§ 823(h), 830.

[8] 21 C.F.R. §§ 1310.07, 1309.71.

[9] 21 U.S.C. §§ 802(39)(A)(v) and (48).

[10] *Id*. at §§ 802(46) and (49).

[11] *Id*. at § 830(d).

[12] *Id*. at 844(a).

[13] *Id*. at § 841(c).

methamphetamine precursor chemicals,[14] makes it unlawful for individuals to manufacture such chemicals in excess of the established quota,[15] and establishes new requirements regarding the importation of such chemicals.[16]

As noted above, the FDA also has regulatory authority over OTC drugs that contain methamphetamine precursor chemicals. It is the FFDCA that governs, among other things, the safety and efficacy of OTC medications, including the approval, manufacturing, and distribution of such drugs.[17] Under the statute, there are two regulatory classifications for drugs: either prescription or OTC. In general, OTC drugs, unlike prescription drugs, do not pose a risk of misuse or abuse and can be safely and effectively used without the supervision of a medical practitioner. Thus, OTC drugs are usually publicly available for consumers to purchase for treatment of self-diagnosed conditions.

Because the FFDCA's regulatory scheme appears to contain only two classifications for drugs — either prescription or OTC — it is unclear whether the FDA has the legal authority to establish a third classification for drugs that could be sold behind the counter (BTC) with the advice and assistance of a licensed pharmacist. A category for BTC drugs would make such medications more available than prescription drugs but would preserve some degree of professional oversight for drugs that pose more risks than the average OTC medication. Indeed, some states have begun requiring pharmacies to move cold medications behind the counter in an effort to prevent their diversion for methamphetamine production. Because it is uncertain whether the FDA has the legal authority to establish a BTC classification for drugs, however, it is unclear whether the FDA could, short of reclassifying OTC drug products that contain methamphetamine precursor chemicals as prescription drugs, impose restrictions similar to the BTC requirements established in some states.[18]

On the other hand, the DEA does have authority to impose sales restrictions on regulated chemicals, including the authority to require that drug products that contain listed chemicals be kept behind the counter where only retail employees have access, and the agency has long imposed this requirement with respect to single-entity ephedrine drug products, which are medications that contain ephedrine as the sole active medicinal ingredient.[19] This requirement applies to all retail outlets, not just pharmacies, and is designed to make it more difficult for the product to be stolen off store shelves. This type of BTC requirement allows retail establishments to continue to sell such medications and should be distinguished from proposals to establish a

---

[14] *Id*. at § 826.

[15] *Id*. at § 842(b).

[16] *Id*. at §§ 852, 971.

[17] *Id*. at §§ 301 et seq.

[18] Robert I. Field, *Support Grows for a Third Class of "Behind-the-Counter" Drugs*, P&T Journal (May 2005), [http://www.ptcommunity.com/ptJournal/fulltext/30/5/PTJ3005260.pdf]; Rita Rubin, *Rx Out of the Box*, USA Today, Feb. 8, 2005, at 1D.

[19] 21 C.F.R. § 1309.71.

separate class of BTC drugs that would be kept behind the *pharmacy* counter and that would involve the oversight of a pharmacist, thereby preventing retail establishments such as grocery stores and convenience stores from selling such drug products.

Recent amendments to the CSA have greatly expanded the number of OTC drug products subject to the DEA-type of BTC requirements. Under these amendments, which do not take effect until September 30, 2006, retail sellers of scheduled listed chemical products must place such products behind the counter, meaning that customers may not have direct access to the product before the sale is made. Sellers can comply with this BTC requirement by storing such products in a locked cabinet that is located in an area to which the customers do not have direct access, and they must deliver the product directly into the custody of the purchaser. Sellers who are mobile retail vendors must place such products in a locked cabinet and may not sell more than 7.5 grams of ephedrine, pseuoephedrine, or phenylpropanolamine per customer during a 30-day period.[20]

In addition, under the amendments, the seller must maintain a logbook of sales of scheduled listed chemical products that identifies the product, the quantity purchased, the names and addresses of purchasers, and the dates and times of the sales. In order to purchase OTC drug products containing methamphetamine precursor chemicals, customers must present photo identification, sign the logbook, and provide their names, addresses, and dates and times of sale, and the seller must verify that the information entered into the logbook corresponds to the information on the photo identification and is otherwise correct. Finally, the seller must maintain each entry in the logbook for at least two years. These logbook requirements, however, do not apply to purchases of drug products that contain no more than 60 milligrams of pseudoephedrine.[21]

Under the amendments, employees who are responsible for delivering drug products containing methamphetamine precursor chemicals into a customer's custody or for obtaining payment for such products must undergo training to ensure that they understand the new CSA requirements, and sellers are required to certify to the AG that the seller has agreed to comply with the new statutory requirements and that the employees have participated in such training.[22]

It is important to note that the BTC and logbook requirements do not apply to retail sales of OTC products containing methamphetamine precursor chemicals if the seller is subject to the CSA's mail order reporting requirements. Under these requirements, individuals who sell OTC products containing methamphetamine precursor chemicals via the Postal Service or any private or commercial carrier must, with limited exceptions, submit a monthly report to the AG. This report must include information regarding the name of the customer, the quantity of the precursor

---

[20] P.L. 109-177, § 711(b)(1) (to be codified at 21 U.S.C. § 830(e)(1)(A)).

[21] *Id*.

[22] P.L. 109-177, § 711(b)(1) (to be codified at 21 U.S.C. § 830(e)(1)(B)).

purchased, and the address to which the precursor was sent.[23] In addition, sellers who engage in mail-order transactions involving scheduled listed chemical products must confirm the identify of the purchaser, and they may not sell products containing more than 7.5 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per customer during a 30-day period.[24]

Furthermore, it is important to note that the AG may exempt certain scheduled listed chemical products from the requirements of the CSA amendments if the AG determines that the product cannot be used in the illicit manufacture of methamphetamine.[25] Finally, the amendments specify that the CSA's preemption provisions remain in effect.[26] Under the statute's existing preemption requirements,[27] federal controlled substances law preempts state law where state requirements are weaker but not where state requirements are stronger. Thus, despite the recent CSA amendments, states remain free to enact stronger laws with respect to methamphetamine precursor drugs.

State Laws

As noted above, state boards of pharmacy regulate the practice of pharmacy, and state law enforcement agencies oversee state controlled substances laws. While states are not permitted to enact laws in these areas that are less strict than federal law, states may pass laws that are stricter, and several states have done so with respect to cold medications that contain methamphetamine precursor chemicals. Most of these new laws have established additional sales restrictions on such medications, including requiring these drugs to be placed behind the counter, limiting the amount that can be purchased, requiring customers to provide identification and a signature upon purchase, and placing such drug products on the schedule of controlled substances, thus effectively eliminating sales by non-pharmacy retail stores.

The first state to establish such restrictions was Oklahoma, which, in 2004, enacted a new law designed to crack down on the illegal production and abuse of methamphetamine in the state. Under the new law, Oklahoma added drug products containing pseudoephedrine — except for combination products in liquid or gel form

---

[23] 21 U.S.C. § 830(b)(3).

[24] *Id*. at § 830(e)(2).

[25] *Id.* at § 830(e)(3).

[26] The preemption doctrine derives from the Supremacy Clause of the Constitution, which establishes that the laws of the United States "shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding." U.S. CONST. art. VI, cl. 2. In applying this constitutional mandate, courts have recognized both express and implied forms of preemption.

[27] 21 U.S.C. § 903. ("No provision of [the CSA] shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision ... and that State law so that the two cannot consistently stand together.")

— to its list of Schedule V controlled substances and imposed an array of new sales restrictions, including the following: (1) such drug products may only be sold behind the pharmacy counter by, or under the supervision of, a licensed pharmacist or registered pharmacy technician; (2) individuals who purchase such drug products must provide photo identification and must sign a written log of the transaction; and (3) in the absence of a prescription, individuals may not purchase more than 9 grams of such products within any thirty-day period.[28]

More recently, Oregon further strengthened its laws with regard to cold medications that contain methamphetamine precursor chemicals. Enacted in 2005, the new legislation adds ephedrine, pseudoephedrine, and phenylpropanolamine to Schedule III of its controlled substances schedule,[29] making Oregon the first state in the nation to require prescriptions for medications that contain these chemicals. Over the past two years, at least thirty-nine states have followed the lead of Oklahoma and Oregon by enacting laws that place additional sales restrictions on cold medications and other products that contain methamphetamine precursor chemicals.[30]

In addition, out of concern about theft of cold remedies and in search of a uniform sales policy in the face of differing state requirements, several national chain stores that sell drugs containing methamphetamine precursor chemicals have voluntarily adopted new practices with respect to these products by requiring identification, moving such products behind the counter, and limiting the number of packages that can be purchased in a singe transaction.[31] The recent amendments to the CSA are likely to result in further changes to pharmacy practices with respect to OTC products containing methamphetamine precursor chemicals. Meanwhile, drug manufacturers, who are fearful of reduced profits in the wake of new sales restrictions, are reportedly investigating how to develop alternative drug products that cannot be as readily converted into methamphetamine.[32]

---

[28] 63 Okl. St. § 2-212.

[29] 2005 Ore. ALS 706.

[30] National Conference of State Legislatures, *State Crime Legislation in 2005*, March 3, 2006, [http://www.ncsl.org/programs/cj/05crime.htm].

[31] Margaret Webb Pressler, *Retailers Restrict Some Cold Medicines; Ingredient Can be Used to Make Meth*, Wash. Post., May 14, 2005, at A01. Copeland, *supra* note 19.

[32] Roosevelt, *supra* note 2 at 57.