Legal Backgrounder

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
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Vol. 20 No. 25 June 3, 2005

MEASURED, UNIFORM APPROACH NEEDED TO BATTLE "METH" MAKERS' ABUSE OF OTC MEDICINES

by

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Current legislative initiatives at the state and federal levels have focused on tighter control and regulation on the distribution of pseudoephedrine ("PSE") products because of the potential misuse of these products to make methamphetamine (or "meth"). Pseudoephedrine is found in many OTC medicines, including commonly used and medically necessary treatments for asthma, allergies, influenza, sinus conditions and the common cold. The proposed legislative and regulatory initiatives vary by jurisdiction and range from limiting the amount of retail sales to reclassifying PSE as a controlled substance. Unquestionably, methamphetamine abuse is a national health problem that must be addressed; however, a reasoned and uniform approach is needed to ensure that these useful products continue to be available to millions of patients.

PSE is available in a variety of preparations, frequently in combination with other active ingredients used to relieve multiple cough and cold symptoms. The medical usefulness of PSE products is beyond doubt: the Food and Drug Administration has specifically recognized them as safe and effective as nasal decongestants for treatment of sinus-related ailments and symptoms. By some estimates, colds annually account for over one million emergency department visits and tens of millions of ambulatory visits by children and adults. Self-care using PSE-containing OTC products provides effective treatment for symptoms of the cold and flu and reduces the need for unnecessary physician and emergency department visits and the costs associated with each.

Unfortunately, misuse of PSE and diversion of some PSE products have been identified by federal and state authorities as a source for illicit manufacturing of methamphetamine. In particular, "street cooks" are employing simple methods, including using household items, to manufacture meth. Although DEA estimates that only about twenty percent of all illicit meth production in the United States is the result of diversion of legitimate OTC products, meth is a serious health menace

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that requires appropriate legislative and regulatory attention. PSE products have been subject to federal and state regulation since the early 1990's. The federal Controlled Substances Act (CSA) regulates PSE as a List I chemical, meaning that manufacturers and distributors of products containing PSE are subject to certain registration, recordkeeping and reporting requirements.[1] Federal regulations also restrict retail sales of these products to reduce the potential for diversion.[2] For example, retail sales are limited to nine grams of PSE and package sizes of less than three grams in a single transaction.[3] Many states have adopted similar laws and regulations on PSE products to reduce the potential for diversion.

Given the continued problem with methamphetamine abuse, state legislators and regulators are understandably considering additional restrictions on the sale of PSE products. However, such actions should be appropriate to address the problem and must be balanced against the need to ensure that these safe and cost-effective products continue to be available to consumers. Most importantly, there is a critical need for uniformity in regulation among the states and between the states and the federal government. The lack of such uniformity will place a significant burden on manufacturers, distributors and retailers and reduce the availability of these medicines to consumers.

Many states have implemented or are considering some type of sales restriction either by limiting the amount of PSE that can be sold at retail, e.g. six grams, or by limiting the type and number of packages that can be sold to consumers, e.g., blister packs. Other states have implemented or are considering additional security measures requiring PSE products to be sold "behind-the-counter" or in a locked cabinet similar to tobacco products. Still other states have restricted retail sales of PSE to pharmacies where they may only be sold by a pharmacist or pharmacy staff. The most restrictive controls that have been placed on PSE products to date involve the reclassification of PSE as a Schedule V controlled substance. Oklahoma was the first state to take this step in 2004.[4] Other states are considering similar action. Reclassifying PSE as a controlled substance requires that the product may only be dispensed in a pharmacy and in most cases requires that consumers provide identification and sign a log book in order to purchase the products. There are also limits on how much PSE can be purchased in a thirty day period. These requirements are an added burden on pharmacies which must maintain these records and also because controlled substances are additionally subject to enhanced security, recordkeeping and reporting requirements.[5]

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[1] 21 U.S.C. §§ 802(34); 830.

[2] 21 C.F.R. § 1310.04(f).

[3] *Id.*

[4] 63 O.S. 2001, § 2-212.

[5] *See, e.g.*, 21 C.F.R. §§ 1301.72-76.

At the federal level, several bills have been introduced to further restrict the sale and distribution of PSE. For example, the Combat Meth Act of 2005 would place pseudoephedrine products in Schedule V under the federal CSA.[6] The Act would require that pseudoephedrine products be dispensed, sold or distributed only by a licensed pharmacist or licensed pharmacy technician. Purchasers of these products would have to produce a photo identification and sign a written log or receipt documenting transaction date, their name, and the name and quantity of the substance purchased. Also, customers would not be able to purchase more than nine grams within a thirty day period, unless they have a valid prescription. The bill gives some discretion to the Administrator of the Drug Enforcement Administration ("DEA") to exempt products from control if they are not used in the illegal manufacture of controlled substances. The DEA could also authorize the sale from non-pharmacy locations in areas where a pharmacy is not available.

The public interest demands that additional restrictions on OTC PSE products be balanced against ensuring that these products are still available to consumers. For example, under federal and most state laws, Schedule V controlled substances are defined as substances with a potential for abuse and a potential to cause psychological and physical dependence.[7] OTC PSE products do not readily meet this statutory definition despite the fact that the products can be a source of illicit manufacturing of a controlled substance. It should be noted that methamphetamine is strictly controlled in Schedule II of the federal CSA[8] and under state law. Thus, methamphetamine is already highly regulated and unlawful manufacturing and abuse are subject to significant civil and criminal penalties.

Although reclassifying PSE products in Schedule V would not necessarily require a prescription, they could only be purchased in pharmacies and only by providing identification and signing a log book to include the date and amount purchased. This will impact consumer access to these products and reasonably will be expected to impact the variety of products that are available to the consumer. Regulating pseudoephedrine as a Schedule V controlled substance also places additional registration, reporting and recordkeeping requirements on manufacturers, distributors and retailers. Retail restrictions, such as package limitations combined with stricter enforcement and higher penalties provide a more reasonable and measured response to the current problem. Also, designating these substances as controlled substances sends the wrong message to consumers about the safety of these OTC products when taken as directed.

These issues aside, the more troublesome problem is the lack of uniformity on regulation of PSE products. If current trends continue, manufacturers, distributors and retailers will have to comply with different requirements federally and in each state for distributing PSE products. This includes establishing separate policies and procedures by jurisdiction for how these products are

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[6] S. 103 and H.R. 314, 109th Cong., 1st Sess. (2005).

[7] 21 U.S.C. § 812(b)(5).

[8] 21 C.F.R. § 1308.12(d).

packaged, distributed and sold. The regulated industry will also have to establish procedures to comply with individual licensing, recordkeeping and reporting requirements. National manufacturers and distributors will be forced to implement different procedures in each state to comply with the different requirements or make a decision to significantly limit the availability of these products. Already, several national retail chains, including Target, WalMart and CVS, have implemented company-wide policies that restrict sales to pharmacies across the country.[9] This means that the products will be removed from stores without pharmacies even in states where such sales are legal.

In summary, federal and state legislation directed at further regulation of PSE should be balanced against the need to ensure that these medicines are available to consumers. This objective is better met by limiting retail sales and package sizes than requiring that such products only be available behind the pharmacy counter. More importantly, the current meth problem should be addressed by a national policy that includes a uniform standard for regulation of PSE. That can be accomplished through a federal law featuring a broad "field" preemption of state action on PSE. The current disparate approaches in the states are contrary to an effective national meth policy. A broad "field" preemption would ensure that industry and consumers alike are not subject to needless confusion about the availability and safety of these products.

[9] *See, e.g., Target Announces That All Products Containing Pseudoephedrine Will Be Placed Behind the Pharmacy Counter*, Apr. 18, 2004, http://www.target.com.