## Kentucky pharmacists' opinions of the potential reclassification of pseudoephedrine as a legend drug

Kathleen E. Monson, Patricia R. Freeman, Amie J. Goodin, Jeffery Talbert, and Karen Blumenschein

## Abstract

**Objectives**: To collect and analyze Kentucky pharmacists' opinions of the effectiveness of current methamphetamine precursor controls, to analyze proposed legislation to make pseudoephedrine (PSE) a legend drug, and to analyze the potential impact of such legislation on pharmacy practice and patients.

Design: Descriptive, nonexperimental survey study.

Setting: Kentucky; June through October 2012.

Participants: 431 Kentucky community pharmacists.

Intervention: Mailed survey.

**Main outcome measures**: Perceived efficacy of current methamphetamine precursor controls, anticipated impact on individual pharmacy practices and patients of proposed legislation to make PSE available by prescription only, and current opinions about the proposed legislation.

**Results**: Analysis of 431 community pharmacists showed that approximately 77% believed proposed legislation to make PSE available by prescription only would be effective in reducing methamphetamine abuse and methamphetamine-related laboratory incidents, with 56.2% indicating support for the proposed legislation. Pharmacists practicing in chain pharmacies were 2.9 times more likely to support the legislation than pharmacists practicing in independent pharmacies. Additional factors influencing pharmacist support included Kentucky region of practice, anticipated impact on time spent on PSE activities, pharmacy profit, methamphetamine abuse, and methamphetamine-related laboratory incidents. Pharmacists practicing in regions of Kentucky associated with higher methamphetamine abuse appear to more strongly support the proposed legislation.

**Conclusion**: Pharmacists are at the frontline of PSE distribution. Gaining a better understanding of issues surrounding the distribution of PSE will enhance the likelihood that future legislation may be crafted to reduce methamphetamine production, laboratory incidents, and abuse while minimizing inconvenience and cost.

**Keywords**: Community pharmacy, methamphetamine, pseudoephedrine, precursor regulation, over-the-counter, prescription.

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Kathleen E. Monson, PharmD, MPA, is Inpatient Pharmacist, St. Elizabeth Healthcare, Edgewood, KY; at the time of the research, she was a student pharmacist, College of Pharmacy, University of Kentucky, Lexington. Patricia R. Freeman, PhD, is Clinical Associate Professor. Amie J. Goodin, MPP, is Research Coordinator. Jeffery Talbert, PhD, is Director. Karen Blumenschein, PharmD, is Associate Professor, College of Pharmacy, Institute for Pharmaceutical Outcomes and Policy, University of Kentucky, Lexington.

**Correspondence:** Kathleen E. Monson, PharmD, MPA, 1 Medical Village Drive, Edgewood, KY 41017. Fax: 859-301-3958. E-mail: kathleen.monson@gmail.com

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**Previous presentation:** American Society of Health-System Pharmacists Midyear Clinical Meeting, Las Vegas, NV, December 2–6, 2012. Methamphetamine is a Schedule II controlled sub-Stance that is recognized as a major drug of abuse. It is often produced illicitly in small, clandestine laboratories through the use of precursor chemicals, including pseudoephedrine (PSE), an over-the-counter (OTC) decongestant.<sup>1</sup> Small quantities of methamphetamine are relatively easy and cheap to manufacture, requiring little knowledge, skill, or equipment. However, clandestine laboratories are extremely dangerous because of the nature of the volatile chemicals used in the manufacturing process, which can result in fires, explosions, and environmental contamination.<sup>1</sup>

Some efforts to curb methamphetamine abuse are aimed at controlling access to PSE used in illicit methamphetamine production. A series of federal methamphetamine precursor laws that impact PSE distribution at both the wholesale and retail level has been implemented during the past decade, including increased reporting and record-keeping requirements, mandatory registration with the U.S. Drug Enforcement Administration, packaging requirements, quantity limits, and placement of PSE-containing products behind the pharmacy counter.<sup>2</sup>

## At a Glance

Synopsis: This survey-based study of 431 community pharmacists in Kentucky found that fewer than 4% believe current controls against the use of precursor chemicals to produce methamphetamine are "very effective," while roughly one-half find electronic tracking and quantity limitations to be at least "somewhat effective." Comparatively, more than three-fourths of those surveyed anticipated that proposed legislation to make precursors such as pseudoephedrine (PSE) available on a prescription-only basis would be at least "somewhat effective" in reducing methamphetamine abuse and methamphetamine-related laboratory incidents. However, a majority of responding pharmacists also anticipated that such legislation would impact patients in a variety of ways, including limiting access to PSE for legitimate use.

**Analysis:** Methamphetamine abuse and production in clandestine laboratories appears to be increasing in Kentucky, but there is lack of consensus on how best to address this problem. The majority of pharmacists (56.2%) surveyed for this study support proposed legislation to reclassify PSE as a legend drug available by prescription only, with those working in chain pharmacies 2.9 times more likely than independent pharmacists to voice their support. This may be attributable to independent pharmacists' comparative flexibility in instituting individualized store policies regarding PSE purchases. It is hoped that future legislation will effectively reduce methamphetamine production, laboratory incidents, and abuse in Kentucky while minimizing inconvenience and cost to law-abiding citizens. In addition to federal legislation, Kentucky requires electronic tracking and the blocking of PSE sales that exceed the legal limit. In 2008, Kentucky became the first state to implement electronic tracking with Meth-Check, which is now known as National Precursor Log Exchange (NPLEx).<sup>2</sup> Kentucky also mandates a stricter PSE quantity limit than the federal limit of 9 grams per month. As of July 2012, Kentucky law limits PSE monthly sales to 7.2 grams per individual.<sup>3</sup> New legislation in the state includes the creation of a methamphetamine registry for those convicted of a methamphetaminerelated crime and blocks the sale of PSE to individuals listed in the registry.<sup>4</sup>

Despite both federal and state legislation aimed at controlling access to methamphetamine precursors, illicit manufacturers have found alternate methods to produce methamphetamine and obtain PSE, circumventing the laws and tracking systems. "Smurfing" is a popular practice for obtaining sufficient quantities of PSE for methamphetamine production<sup>5;</sup> it involves having several individuals purchase legal amounts of PSE.

Methamphetamine cases in Kentucky increased from 6% of total drug cases in 2007 and 2008 to 9% in 2009 and 11% in 2010.<sup>5</sup> Additionally, the number of laboratory seizures in Kentucky has risen from 428 in 2008 to 741 in 2009 and 1,078 in 2010, with production traditionally associated with western and south central Kentucky and indicators demonstrating production increasing in eastern Kentucky.<sup>5</sup> Recently proposed state legislation to change PSE from nonprescription to legend status was unsuccessful and highly controversial.

Proponents of requiring a prescription to purchase PSE argue that data from Oregon and Mississippi—the only states with such a requirement—indicate efficacy in reducing laboratory incidents and associated hazards.<sup>2</sup> Additional data show a decrease in methamphetaminerelated crimes, arrests, and admissions to substance abuse treatment facilities following implementation of prescription-only PSE legislation.<sup>2</sup> However, further data are needed to ensure the reduction in methamphetamine indicators is sustained. Proponents of prescription-only legislation also argue that a majority of the OTC PSE purchased is used for methamphetamine production.<sup>2</sup> Proponents believe OTC PSE represents a significant cost to society by creating hazards for the public and law enforcement.

Opponents of requiring a prescription to obtain PSE reason that the legislation would place additional burdens on physicians, pharmacists, insurance companies, and consumers.<sup>26,7</sup> Some opponents also believe consumers would face added costs and inconveniences for repeat doctor visits to obtain prescriptions for PSE. Additionally, some patients could opt for less effective treatment or no treatment at all, resulting in a lower quality of life.

Data are available regarding consumers' opinions

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