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PSEUDOEPHEDRINE: A **MORAL CRISIS** IN KENTUCKY

Introduction

Pseudoephedrine, once a relatively benign pharmaceutical used as a decongestant, has become a substance of misuse in the United States. When combined with readily available industrial products, it is synthesized inexpensively into methamphetamine intended for abuse. Within the Commonwealth of Kentucky, which carries the dubious distinction of the state with the highest drug diversion in Appalachia (1), its misuse has become an epidemic. Following a presentation by the Kentucky Narcotic Officers Association (KNOA) and the Kentucky State Police (KSP), the Kentucky Academy of Family Physicians (KAFP) Board of Directors deemed it necessary to support a mandate requiring prescription dispensing of pseudoephedrine. This article constructs the history and moral argument supporting this decision.

History of Pseudoephedrine Legislation

In 1976, the U.S. Food and Drug Administration allowed prescription pseudoephedrine to be sold for the first time over-the-counter. Transition from this native form to methamphetamine was relatively easy for chemists, and misuse within the drug population soon followed. Over three decades, it slowly became ingrained within the drug culture; with the advent of readily available industrial products, this rendered a low-technology synthesis within the capability of neophytes. As drug diversion continued to increase, the U.S. Congress in 2006 mandated that the product be returned behind the prescription counter with limits established for daily and monthly quantities given to an individual, and a register kept.

In recent years, annual sales of OTC pseudoephedrine have soared to over $600 million (2) - the logarithmic increase in relation to population and disease prevalence suggests that a majority is for misuse. In Kentucky, initially, misuse declined in 2006 after mandate of the federal registry. To combat this, drug diverters enlisted conspirators to purchase regular, multiple small quantities of the drug, a.k.a. "smurfing." As meth lab incidents began to increase, Kentucky, in 2008, instituted an electronic tracking of drug sales within pharmacies (METHCHECK); however, the incidence of illegal meth labs has continued to increase unabated. Meth lab incidents have steadily climbed in Kentucky: from 302 in 2007, to 743 by 2009; and, by year's end, is expected to pass 1,000 in 2010 - over a 25 percent increase from 2009.

In the fall of 2010, Sgt. Stan Salyards of the KNOA and Major Joe Williams of the KSP presented evidence before the KAFP Board regarding the current state of pseudoephedrine diversion in the Commonwealth. The KAFP Board, and subsequently the KAFP House of Delegates, passed a resolution of support for prescription pseudoephedrine. In September, a companion resolution to the Kentucky Medical Association (KMA) House of Delegates was forwarded by the Barren County chapter after a similar presentation by Tommy Lovings, head of the Warren County Drug Task Force. This resolution passed the KMA with the recommendation to support prescription pseudoephedrine.

Social Consequences

Pseudoephedrine's diversion into methamphetamine has profound social, economic and political consequences. It is beyond this article to present the case for each; however, an overview will be provided to allow the practitioner to appreciate the gravity of these issues to society, and the Commonwealth at large.

The "Meth Project," released in February

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2009 by the Rand Corporation, estimates that methamphetamine abuse costs the U.S. government (all of us) $23.4 billion annually. (3) In Kentucky, Major Joe Williams of KSP stated, "The total cost to KSP last year [2009] to remove 716 meth labs totaled $1,373,825." (4) Of particular note is that we do not have reliable information on the expense to the Commonwealth for burn unit care, emergency room care, child protective services, and other fiscal burdens which one can estimate to be at least as substantial.

The Oklahoma State Police give a fair estimate that the calculable expense of each meth lab is about $350,000. (5) This is inclusive of treatment programs, incarceration, mental health services, toxic waste disposal, child protective services, law enforcement, lost wages, and property damage. Likewise, they are unable to estimate the expense of secondary crime (crime used to procure resources for the drug addiction), health care needs (burn unit/emergency department/primary care), cost to families or the potential needs of unborn children.

The Case for Pseudoephedrine by Prescription

Amid the national despair of rising pseudoephedrine misuse, there have been islands of success. Empirical data from Oregon (6) and Mississippi (2) are available regarding the legislation of prescription pseudoephedrine. In 2006, Oregon enacted a law requiring prescription for all pseudoephedrine products. As a result, law enforcement's response to a meth lab scene for arrest and subsequent clean up has decreased 98 percent from 2004 (472) to 2009 (10). [See Figure 1.] Mississippi instituted a similar statute in July of this year, reporting a 65 percent decrease year-to-date: July-November 2009 (259); 2010 (94).

A compelling argument can be forwarded for returning pseudoephedrine to prescription drug status in Kentucky given our current understanding of the trends of misuse. As with any malignant process, the diversion and misuse of OTC pseudoephedrine evades any single plan of eradication. The National Methamphetamine and Pharmaceuticals Institute, composed of police and prosecutors, reports that smurfing is presently at epidemic proportions. (7) Analysis of the data, further supported by opinion from the KNOA and KSP, suggests that the present system is inadequate. What may have worked previously has now been rendered inadequate; in effect, the malignancy has mutated. An alternative approach has become necessary in the fight against misuse of pseudoephedrine in Kentucky.

By definition, pseudoephedrine now meets the criteria as a controlled substance, being a product that has potential for public misuse and abuse. One of many options the legislature might consider would be to define the product as a C-III, requiring KASPER reporting, and eliminate the requirement for METHCHECK. This would require physicians, pharmacists and other providers to stand between drug diverters and the legitimate need of the public.

In placing pseudoephedrine in a controlled status, thoughtful consideration must be given to public access to the drug. Primary care (and other) physicians perform this duty on a daily basis with other controlled substances. In point of fact, there are, of course, other alternatives available for symptomatic treatment of sinus disease. An important point not to be lost is that the drug is not generally used for disease treatment itself, rather, for symptomatic relief of discomfort. Further, physicians know and understand their patients and families; access to the product could be appropriately met by our traditional medical system. Substantial inconvenience has not been reported as problematic in the Oregon test case. In short, a critical point has been passed with regard to public safety taking precedent over convenience.

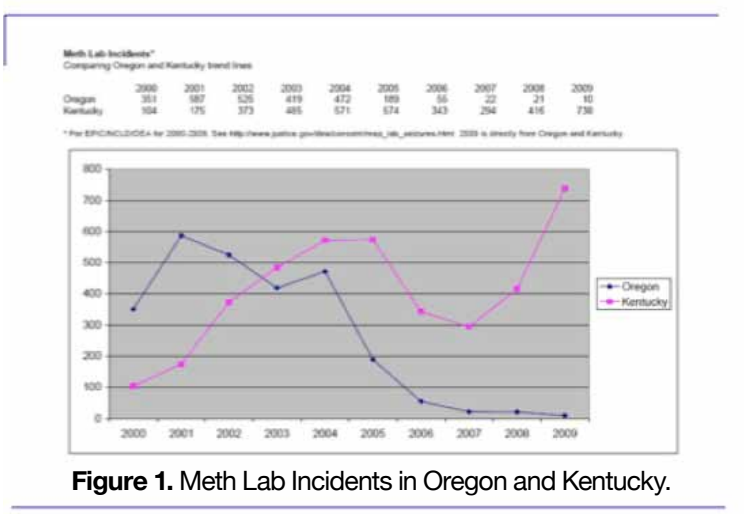

Figure 1. Meth Lab Incidents in Oregon and Kentucky.

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Conclusion

The diversion of OTC pseudoephedrine to methamphetamine has now become a matter of public health and safety. As stewards of the Commonwealth's health, Kentucky's physicians, in particular those serving in primary care, can no longer ignore the totality of health consequences that our current policies enable. While many arguments can be made for intervention, physicians need stand only behind one, and that is morality. In effect, open war is upon us, being prosecuted by a parasitic element of society that has ill-regard for injury to individuals, families or communities. To continue to stand idle in this circumstance places the future of the Commonwealth's health at risk, and this risk is both serious and substantial.

The considerable expense and progressive trend of misuse have begun to impact the Commonwealth's resources. Obligatory items such as incarceration, uncompensated health care and law enforcement allocated to the crisis can be expected to overshadow budgets. Ultimately, it can be expected that the fiscal matter will transition to a political matter when deficit resources lead to forced decision making.

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The war on drug misuse will require action on multiple fronts. In Kentucky, physicians of good conscience have recommended prescription status for pseudoephedrine. On a regional level, surrounding states should consider limiting access similarly in an effort to minimize cross-border access to the drug. On the federal level, government should discuss the elimination of imported pseudoephedrine. Ultimately, our partners in health, the pharmaceutical industry, will need to champion this effort and develop dosage forms, isomers or other novel agents that cannot be synthesized into substances of abuse.

In summary, the recommendations by the KAFP and KMA House of Delegates are not lightly made. The proposal to instill prescription drug status for pseudoephedrine will not be the only solution necessary to combat the assault against Kentucky's public health and safety by drug diversion into methamphetamine. It is, however, the one that is before us as physicians; indeed, we have irrevocably come to a time of action.

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