

Should Pseudoephedrine (PSE) be moved from Behind the Counter to Prescription-Only?

An analysis of PSE as an OTC medication and a precursor for methamphetamine production

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Executive Summary

Kentucky State Senator Tom Jensen recently sponsored Senate Bill 45, which would change pseudoephedrine (PSE) from an over-the-counter to a schedule V prescription-only drug.⁴⁸ The bill failed, but the debate continues as to whether Kentucky should make PSE, a precursor required to manufacture illicit methamphetamine, a controlled drug that is available by prescription only.

Methamphetamine abuse has been increasing in Kentucky as well as in the rest of the country, despite efforts to control the sale of PSE through federal and state legislation. The Combat Methamphetamine Epidemic Act (CMEA) of 2006 and Kentucky's initiative to electronically monitor the sales of PSE have both resulted in a decrease in the number of meth labs in Kentucky. However, those decreases were followed shortly by sharp rebounds, with the number of labs in 2010 surpassing 1,000.¹⁸

If previous measures have been unsuccessful, can we expect prescription-only legislation to have the desired effect of reducing methamphetamine abuse in Kentucky? This approach has seemed to have worked for Oregon, and has recently been adopted by Mississippi.²¹ The primary purpose of this paper is to analyze efforts made by Kentucky and other states to reduce methamphetamine abuse. In order to determine if those efforts were successful, research has been conducted concerning the number of methamphetamine labs and hospital admissions related to methamphetamine abuse in Kentucky as well as other states that have instituted laws more stringent than federal regulations. This analysis has been conducted over a range of years in order to compare the numbers of meth labs and hospital admissions both before and after

certain regulations were enacted in order to better determine the level of success of those measures.

In addition, this paper will address some other areas of concern related to the possibility of a prescription only PSE law in Kentucky such as; what are some of the methods methamphetamine abusers and ‘cookers’ have employed to bypass previous legislation, and how might they attempt to bypass future legislation? If it can be determined that new legislation would fail to lead to a decrease in methamphetamine abuse, then perhaps alternative means of controlled methamphetamine use should be considered. Finally, what is the practicality of making PSE prescription only? PSE is not the only over-the-counter (OTC) medication available to treat symptoms related to nasal congestion, but is it the best alternative? Are there other compelling reasons that might make a prescription-only law a benefit to the citizens of Kentucky? How might a prescription-only law be a hindrance to Kentucky citizens who use PSE for its intended purpose? These questions must be answered in addition to the primary research question in order to determine the advisability of a PSE prescription-only law in Kentucky.

Introduction

Kentuckians have a history of placing great emphasis on their strong moral beliefs as well as having a sense of entitlement for personal freedoms. Sometimes these characteristics seem to clash, as they did during the ratification and later repeal of the 18th Amendment: prohibition of alcohol.³² Kentucky was the third state to ratify the prohibition of alcohol on January 14, 1918, with the expectation that prohibiting alcohol would lead to improved health, lower crime rates, and a better environment for young people.³³ Fifteen years later, Kentucky voted to ratify the 21st Amendment, which repealed the 18th Amendment, effectively ending prohibition.³² Whether

Kentuckians voted to repeal prohibition on grounds of personal freedoms, the realization that prohibition simply did not work, or that prohibition created more problems than it solved is a matter of debate. The decision was likely fiscal as citizens became aware that the combination of loss of tax revenue from alcohol sales and the added expense of criminalizing the substance was bad for the economy.¹⁴

Kentucky citizens were prepared to stand behind a law that would interfere with their personal freedoms in exchange for reduced crime and pursuing their high moral values. In fact, many counties in Kentucky still prohibit the sale of alcohol to this day.¹⁵ Would Kentuckians stand behind a new law restricting access to a product in order to hopefully reduce crime? Or will Kentuckians be leery of such a law as they are reminded of the failures of prohibition?

Currently, Kentucky along with the rest of the nation faces a new drug problem: abuse of methamphetamine. Methamphetamine is a highly regulated drug which can be obtained by prescription in the form of the brand name Desoxyn which is used to treat symptoms of ADHD.⁹ An illegal form of methamphetamine can also be created using pseudoephedrine (PSE), a precursor that is available as an OTC nasal congestion remedy. Currently, Kentucky legislators are debating whether to limit the sale of PSE to prescription only. Few Kentuckians would advocate for the right to purchase OTC methamphetamine, but what about a precursor that is generally harmless if used appropriately and in the manner intended? Would Kentuckians sacrifice their ability to purchase OTC PSE in exchange for reducing the abuse of methamphetamine, particularly if there is a lack of OTC medications as effective as PSE at reducing nasal congestion symptoms? Would restricting PSE even lead to a reduction in abuse, or would abusers and producers figure out a way around the system? Answering these questions

would help determine whether the sale of PSE should be prescription-only in the state of Kentucky.

History

The stimulant methamphetamine was first synthesized in Japan in 1893.² Methamphetamine was subsequently used by American, German, English, and Japanese soldiers during World War II for its ability to enhance energy levels and alertness for prolonged periods of time.³ Methamphetamine production and abuse made its way from Japan to Hawaii and California following World War II, and has since become widely produced and abused throughout the United States.¹ Over the last 20 years, methamphetamine use has become epidemic throughout the country, particularly in rural areas.¹ The widespread abuse of methamphetamine, also known by its street names crystal meth, meth, speed, ice, crank, and poor man's cocaine, is due in part to its relative ease of production and highly addictive properties.¹⁶

Mechanism of Action

Methamphetamine is considered an anorexant, a stimulant, and a sympathomimetic.⁹ Abusers of methamphetamine can expect a reduced appetite along with stimulation of the “flight or fight” response. This includes increased heart rate due to direct actions on the heart muscle, increased blood pressure due to constriction of blood vessels, and the release of other stimulating hormones that can lead to aggression, anxiety, hostility, and paranoia.¹

The release of these hormones is part of why methamphetamine is such a highly addictive substance.¹ Methamphetamine ingestion, inhalation, or injection causes a release of excitatory neurotransmitters such as norepinephrine, serotonin, and dopamine.⁵ Norepinephrine is responsible for most of the stimulant effects of methamphetamine, while dopamine and serotonin

trigger reward pathways and enhance mood. Following methamphetamine use, whether the user is a chronic addict or a first time user, the person will typically experience withdrawal. The withdrawal can last for days for the occasional user, for chronic users it can last for weeks or even months.⁶ Withdrawal symptoms include fatigue, depression, anxiety, agitation, and suicidal ideation.⁶ For many users of methamphetamine, the only way to eliminate or prevent the symptoms of withdrawal is to continue using.

Costs of Abuse

Not only is methamphetamine highly addictive and easy to make, it is costing the United States approximately 20 billion dollars annually due to health care expenses, environmental damage, law enforcement costs, and lost production.⁷ This is a 2005 estimate; the current cost of fighting and treating methamphetamine abuse may be higher. Law enforcement costs include not only arresting meth producers, but also clean-up of homes that have meth labs. The total cost to law enforcement just to investigate and clean-up meth labs in Kentucky in 2009 was nearly 1.8 million dollars.¹⁹ Decontamination is essential before any person can re-enter the home in which a meth lab was in operation. Then there are numerous other costs that are more difficult to pin down such as the cost to a family with a methamphetamine addict: poor school performance of children of addicts, and lost wages for family members who have to miss work in order to support their addicted family members.

Specific Health Consequences

The combination of lack of sleep, lack of nutrient intake, and increased blood pressure can lead to heart disease, stroke, and myriad of other health complications. One common health issue is the development of “meth-mouth” which can occur after only a few months of chronic

use.³⁷ According to the American Dental Association, meth-mouth is likely induced by a number of factors directly resulting from methamphetamine use including dry mouth, and teeth grinding.³⁸ Indirect effects of methamphetamine abuse that contribute to meth mouth are poor dental hygiene that is common to drug addicts in general, and the consumption of sugared soft drinks common to those who abuse stimulants.³⁸

Another major health issue that has been shown in the media and used as a deterrent against methamphetamine abuse is the induction of the aging process, particularly concerning the face. Meth mouth is part of this; the aging process also includes facial sores resulting from picking and scratching when a user thinks they have bugs on their face.³⁹ The aging process is further enhanced because methamphetamine reduces blood flow to extremities, including the face, which, along with a poor diet, results in an inadequate nutrient supply; inevitably speeding up the aging process.³⁹

In addition to the adverse effects on the heart and the visual side effects of the enhanced aging process, methamphetamine addiction has deleterious effects on the brain. Methamphetamine abuse results in the release of oxidative enzymes which attack and destroy neurons in the brain.³⁶ Damage to neurons can be lifelong, persisting well after a person discontinues use of this drug.

Making Methamphetamine

The process of ‘cooking’ methamphetamine can be just as dangerous as injecting, smoking, or snorting. The danger imposed by making the drug is due to the fact that several highly toxic compounds are required to make methamphetamine. Methamphetamine production is relatively cheap and easy, requiring only the OTC product PSE or ephedrine to act as a

precursor, and some noxious chemicals such as red phosphorous and iodine to reduce ('reducing' is a chemical process whereby one chemical structure is changed into a similar but distinctly different structure) the precursor to methamphetamine. The chemicals needed to make methamphetamine, which may include lithium from batteries, are highly toxic and explosive. In fact, many meth labs are discovered following a fire or explosion resulting from the highly reactive process of "cooking" the drug.¹ In addition to the explosive nature of meth labs, it has been estimated that for every pound of methamphetamine produced, six pounds of toxic waste are also created.¹ That toxic waste is often dumped in rivers or drainage ditches.¹

Meth Lab Fires and Chemical Inhalation

Many methamphetamine "cookers" as well as innocent victims have been injured or lost their lives as a result of a methamphetamine explosion or fire. Recently, three children lost their lives in a meth lab fire in Georgia resulting in a large amount of national press.⁴⁰ Although this is just one example of the dangers of methamphetamine labs, there are numerous indications that treating meth burn victims is becoming an increasingly frequent event at burn units across the country.⁴¹ The implications of this finding are two-fold: first that innocent people (often children) are victims because they are unfortunate enough to live with someone who cooks meth; and that victims of methamphetamine abuse, whether they are innocent bystanders, cooks, or users, can be costly to treat.

Children are the most likely to be affected by fires and toxic inhalation of chemicals because they remain indoors while the noxious chemicals are being 'cooked.'⁴² Inhalation of the toxic chemicals has led to health issues for children including increased levels of agitation and even induction of seizures.⁴² In local news, a 20 month old living in Wayne County died after

accidentally ingesting drain cleaner that was left in a cup on the table. The drain cleaner was an ingredient the child's relatives were allegedly using as an ingredient to 'cook' methamphetamine.⁴³

Federal Efforts to Control the Production/Abuse of Meth

As early as the 1980's, methamphetamine abuse had become a nationwide problem.²⁷ The abuse became more prevalent in the 90's and early part of this century, prompting Congress to enact the Combat Methamphetamine Epidemic Act (CMEA) in 2005.⁸ This law introduced a federal limitation on the purchase of PSE with the hope that limiting the sale of PSE would lead to a decrease in the production and abuse of methamphetamine. The CMEA requires the sale of PSE be limited to 3.6 grams per person per 24 hour period, and also limits each individual to purchases of 9 grams of PSE in a 30 day period. In order to ensure that a person does not exceed the limit, each individual who buys PSE must produce a valid state ID and the transaction must be recorded either in a log book or electronically.⁸ The CMEA, which was introduced in 2005 and became fully implemented on September 30, 2006, seems to have had an initial positive impact on reducing the number of meth labs throughout the U.S.⁸

National Trends in the Number of Meth Labs

The El Paso Intelligence Center (EPIC) collects data on the number of methamphetamine laboratory incidents throughout the US. EPIC uses data collected from the Clandestine Laboratory Seizure System (CLSS) which is a system for states to document the number of labs and materials for making methamphetamine that are seized each year. These data can be used to analyze the success of federal legislation, or legislation from individual states. Tracking these seizures from year to year, and comparing the number of labs before and after certain legislations

have been enacted, will give in impression of whether that legislation was effective.

Additionally, tracking the number of methamphetamine labs several years after legislation was enacted would allow one to see if that legislation remained effective over time.

According to data from CLSS, the CMEA appeared successful in deterring methamphetamine production in the United States as the number of methamphetamine laboratory incidents decreased from approximately 18,500 in 2004 to a low of 6,200 in 2007.²⁸ Unfortunately, this trend seems to be reversing itself as the following years reported a steady rise in the number of labs up to just over 10,000 in 2010.²⁸ If the federal law has only been able to temporarily stymie efforts to produce illicit methamphetamine, have individual states had more luck?

Number of Methamphetamine Lab Incidents by State

Given the costs to family members, the community, and society at large, many states have enacted various laws that limit the sale of PSE. For example, Oregon, Mississippi, and several counties in Missouri require that consumers obtain a prescription from their physician in order to purchase PSE.^{20,21} Mississippi and Missouri have only recently enacted their laws (2010); the data has not yet been collected and analyzed to determine if their prescription-only policies have been successful. Oregon has required prescriptions for PSE for several years beginning on April 5, 2006.²⁰ The number of labs in Oregon subsequently dropped from 191 in 2005 to a low of 9 in 2010.²⁸

Other states have implemented regulations to reduce the abuse of methamphetamine, but have had not shown success in reducing the number of lab incidents. This might be due to the lack of monitoring to ensure that each individual does not exceed the federal limit of PSE

purchases. Most states still use log books to record transactions, which only limits the amount of PSE an individual can buy at a single pharmacy; it does not prevent that person from getting PSE from several different pharmacies. Some states, such as Kentucky, Arkansas, and Oklahoma electronically monitor PSE sales in order to better ensure that consumers are not exceeding the federally allowable limit of PSE by making purchases at several different pharmacies.^{17,22,23}

Despite the electronic monitoring of PSE, these states have not demonstrated a reduction in their number of meth labs discovered by law enforcement. The number of statewide meth labs in Kentucky rose from 428 in 2008 (the first full year following the implementation of the electronic monitoring) to 1060 labs in 2010.¹⁸ Arkansas and Oklahoma have experienced similar results as Kentucky; a drop in methamphetamine labs following implementation of CMEA, followed by a subsequent increase in labs despite electronic monitoring. The number of meth lab incidents and important legislations dates for the following states; Arkansas, Kentucky, Oklahoma, Oregon, and South Carolina; have been highlighted in figures 1 through 7. Data from South Carolina has been used to act as a control, as South Carolina does not impose any limits or regulations above and beyond the CMEA.

Important Dates and Legislation from 2004

In 2004, two states initiated laws attempting to discourage the use of PSE for the purpose of acting as a precursor to methamphetamine, thus reducing the amount of methamphetamine abuse and subsequent costs to health care, law enforcement, and the environment. Oklahoma's HB 2176, which required that PSE-containing products could only be purchased at a pharmacy after showing valid ID and the pharmacist logged the entry, became active law on June 6, 2004.²⁹ Similarly, Oregon's Board of Pharmacy issued a regulation with nearly the exact same restrictions as Oklahoma, although there was not a requirement to keep a log of the sales.³⁰ A

literature search did not produce data on the number of methamphetamine labs for these states from 2003, so no before and after comparison was able to be made following these regulations.

Important Dates and Legislation from 2005

In 2005, Arkansas' Board of Pharmacy adopted Act 256 effective March of that year which changed the status of PSE to a schedule V drug* which effectively limited the number of PSE medications that could be sold to an individual at one time.³¹ Consequently, the number of labs in Arkansas was reduced from 828 in 2004 to 490 in 2005. In addition, Oregon's Board of Pharmacy strengthened its restriction from the previous year to include a provision requiring that pharmacies maintain a log of all PSE sales beginning May 14, 2005.²⁰

2005 also marked the first full year that Oklahoma's and Oregon's original restrictions were in place. Consequently, both states saw a marked decline in the number of methamphetamine laboratory incidents from 2004 to 2005; from 467 to 191 for Oregon and from 699 to 240 for Oklahoma.²⁸ The three states that had not enacted legislation between 2004 and 2005 (Kentucky, Mississippi, and South Carolina) also showed a decline in their number of methamphetamine labs during this period, although the decline is much less impressive (see Figure 1, page 35).

Important Dates and Legislation from 2006

2006 marked the year that the CMEA went into effect (September).⁸ The number of labs decreased nationally from over 13,000 in 2005 to less than 8,500 in 2006. Oregon's

* A scheduled drug is one that has been determined by the FDA and or DEA to have the potential for abuse.⁴⁹ Schedule I drugs are considered to have very high abuse potential and are not available by prescription in the U.S. Schedule II – V are available by prescription and are subject to stricter prescribing controls compared to non-scheduled drugs. The categories of abuse potential rank from schedule I drugs having the greatest potential for abuse, to schedule V having the least.⁴⁹

House Bill 2485, which restricts PSE to prescription-only status, went into effect on July 1 of that year.²⁰ The number of labs in Oregon decreased considerably from 191 in 2005 to 51 in 2006 (see Figure 1). In addition to the reduction in the number of reported meth labs, the state of Oregon experienced an overall decrease in reported number of crimes in 2006. The crime rate for Oregon decreased by 4.9% 2006, versus relatively modest decreases in crime of 0.1% in 2005 and 0.6% in 2004.⁵⁷ The significance of this is unknown, as a correlation between the drop in number of discovered meth labs and a drop in the number of reported crimes cannot be made at this time.

Oklahoma and Arkansas also noticed decreases in the number of labs, but this followed a national trend and it is unclear whether this decrease was due to their individual regulations or the new federal regulation.

Important Dates and Legislation from 2007

2007 was the first year that any state adopted an electronic monitoring system to monitor PSE sales. The intention of electronic monitoring is to better enable those states to limit individual PSE sales to only those allowed by the federal or state law. Electronic monitoring allows 'real time' monitoring of PSE sales. This prevents an individual from exceeding the state and federal imposed daily and monthly limits at the point of sale. Kentucky began using an electronic monitoring system in accordance with Senate Bill 88 which became effective on April 5, 2007.¹⁷ Oklahoma began electronic monitoring in August of the same year.²³ Laboratory declines were seen in both states, as well as declines in Oregon, Arkansas, Mississippi (which did not have additional controls on PSE prior to 2010) and South Carolina (the control state). Once again, the state of Oregon reported a decrease in overall crime; a 3.1% drop from the year before.⁵⁷

Important Dates and Legislation from 2008

Arkansas implemented an electronic monitoring system on May 15, 2008 in its effort to further reduce methamphetamine abuse.²² Despite this, Arkansas experienced a modest rise in the number of labs, a trend that was seen throughout the country as well as in Kentucky, Oklahoma, Mississippi, and South Carolina. The only state mentioned in this report that experienced a decline in the number of labs (albeit a small one) was Oregon (Figure 1), which is also the only state in the country that had a prescription-only law at this time. In addition, Oregon again reported a decrease in crime, down 3.9% when compared to statistics from 2007.⁵⁷

Important Dates and Legislation from 2009

In 2009, the trend is similar to the year before, with the same five states of Arkansas, Kentucky, Oklahoma, Mississippi and South Carolina experiencing an increase in the number of methamphetamine labs. This occurred despite the electronic monitoring in Kentucky, Oklahoma and Arkansas. In fact, the number of methamphetamine labs nationally rose from about 7,500 in 2008 to over 10,000 in 2009.²⁸ Oregon, however, experienced a continuing decline in the number of labs without a subsequent increase in the number of labs in neighboring states.²⁸

Important Dates and Legislation from 2010

Mississippi's prescription-only law became effective July 1, 2010.²¹ It is difficult to say whether this has had an impact on the number of meth labs in Mississippi to date, because the number of reported labs in 2010 is nearly identical to those reported in 2009. However, the number of labs in Mississippi had increased from 159 in 2007 to 691 in 2010; this number might have continued to increase if not for the new prescription regulation. The number of labs in Kentucky rose by over one-third compared to the previous year (see Figure 1, page 35).

The information contained in Figure 1 offers some insight as to whether other states, as well as Kentucky, have been successful in deterring the production of methamphetamine. It would appear, according to the data from EPIC concerning the number of meth labs, that legislation typically has an immediate effect followed by a rebound after several years. The only state that does not follow this pattern is Oregon, a state which only allows the sale of PSE by prescription. Mississippi also only allows PSE to be sold with a prescription, but unfortunately there is a lack of data for comparing the number of meth labs before and after the law because the law was put in effect in 2010. Another means of determining whether the incidence of methamphetamine abuse is on the rise or decline would be to examine hospital data. This may be a better indicator of the actual level of abuse because people might be better at hiding meth labs, are producing smaller levels of methamphetamine; thus better evading detection, or could be getting their methamphetamine from another state.

Admissions Data Related to Methamphetamine Abuse

Hospital admissions related to amphetamine abuse were identified using data from the Healthcare Cost Utilization Project (HCUP). HCUP is a family of databases sponsored by the Agency for Healthcare Research and Quality (AHRQ).⁵⁰ In order to capture all of the relevant data specific to amphetamine abuse, a literature search was conducted to see if this type of research had been conducted previously. A study by Cunningham and Liu compared hospital admissions related to methamphetamine abuse over time.⁴⁴ In order to simplify their search, they used a set of standardized codes; the International Classification of Diseases 9th revision (ICD9). ICD codes are used to classify any number of health conditions including diseases, injuries, symptoms, behavioral disorders, poisonings, etc...⁵⁴ The ICD codes are periodically updated by the World Health Organization (WHO) in order to facilitate the tracking of statistics related to

morbidity and mortality.⁵⁴ ICD codes are also used by insurance companies for the purposes of billing information. Cunningham and Liu used a set of ICD9 codes related to amphetamine abuse, as there is not currently an ICD9 code distinguishing other amphetamines from methamphetamine. Methamphetamine is a type of amphetamine, but amphetamine drugs are used in a number of ADHD treatments as well as several weight loss drugs; thus possibly skewing the results. However, Cunningham and Liu were able to determine that most hospital admissions related to amphetamine abuse were actually the result of a methamphetamine overdose.⁴⁴ Therefore, this study will make a similar assumption; the ICD9 codes specific to amphetamines will act as a good indicator of the actual number of hospital admissions related to methamphetamine abuse.

Similar to the study by Cunningham and Liu, the research for this paper used the ICD9 codes 304.4 (amphetamine and other psychostimulant dependence), 305.7 (amphetamine or related acting sympathomimetic abuse), 969.7 (psychostimulant poisoning), and E854.2 (accidental psychostimulant poisoning).

The data were retrieved from the HCUP database for Kentucky, South Carolina, and Oregon during the years 2001, 2006, and 2008. South Carolina was chosen to act as a ‘control’ as the laws of this state concerning PSE sales are no more stringent than the federal requirements. Oregon was chosen because it has a state law requiring that any person must have a prescription in order to purchase a product containing PSE.²⁰ These years were chosen both for availability of data as well as providing data prior to and after state and federal legislation limiting the sale of pseudoephedrine products. The federal government limited the sale of PSE to 3.6 grams per 24 hours per person and 9 grams per 30 days per person beginning in 2006.⁸ Oregon began limiting PSE sales to prescription-only beginning in July, 2006 (the 2006 data

should partially reflect the implementation of that law) and Kentucky began keeping electronic records of transactions in April 2007. Therefore, the 2008 data would reflect the first full year following the implementation of the electronic monitoring. Unfortunately, the data for 2010 were not able to be retrieved. This would have been helpful to determine whether or not there was a ‘rebound’ in methamphetamine abuse similar to the initial decline and eventual rise in the number of meth labs that were discovered by law enforcement immediately following the implementation of Senate Bill 88.

Based on the data concerning the number of meth labs in the U.S., it might be expected that Oregon had the fewest number of hospital admissions due to methamphetamine abuse, while Kentucky had the most. The results of the data, which can be found in Tables 1 through 3, suggest that the opposite is true. Oregon’s total methamphetamine-related hospital admissions for the three years analyzed were 4 times greater than that of Kentucky and 6 times greater than South Carolina (Table 1). This seems to suggest that the number of meth labs in a particular state, and the amount of methamphetamine abuse by the citizens of that state, are not necessarily correlated. There are several possible explanations for this phenomenon.

Table 1: Methamphetamine Related Hospital Admissions

	2001	2006	2008	Total
Kentucky	226	148	155	529
Oregon	349	1020	730	2,099
South Carolina	100	63	191	354
Total	675	1,231	1,076	2,982

Heroin addicts who come to an emergency room for treatment of a non-fatal overdose have claimed their overdose was the result of taking a higher than normal amount of heroin, the heroin was stronger than usual, they used heroin after a period of sobriety, or some combination of these.⁵⁵ Perhaps the meth users in Oregon use it less frequently due to the lack of availability; when they do use it is following a period of abstinence and they are more likely to overdose as a result. This hypothesis is supported by a study of 137 patients who underwent a 28 day opiate detoxification program. At the end of the program, participants were labeled as still tolerant (patients who failed to complete any portion of the detoxification), reduced tolerance (patients who left the program early), and lost tolerance (patients who successfully completed the program).⁵⁶ In this study, those who successfully completed the program were more likely to die from an opiate overdose.⁵⁶ Those who stayed beyond the initial 28 days of treatment were more likely to die of an opiate overdose than those who left the program immediately following the initial 28 day period.⁵⁶ Kentuckians may have fewer trips to the hospital related to methamphetamine abuse because they are more likely to be chronic users with sustained levels of tolerance; thus protecting them from acute overdoses.

The median cost of treating a methamphetamine overdose in an inpatient setting has approximately doubled for each of the states analyzed between 2001 and 2008 (Table 2) despite a relatively stable median length of stay (Table 3). Oregon has been successful in reducing the number of meth labs, which has possible led to a reduction in overall crime, as mentioned earlier.⁵⁷ However, as the cost of treating meth abuse increases, and the number of hospital admissions in Oregon is much higher than that of Kentucky or South Carolina, has Oregon traded one expense for another?

Table 2: Median Hospital Charge per Admission Related to Methamphetamine Admissions

	2001	2006	2008
Kentucky	4,845	8,070	10,960
Oregon	5,002	9,694	11,423
South Carolina	6,275	10,904	12,702

Table 3: Median Length of Stay per Methamphetamine Related Admission

	2001	2006	2008
Kentucky	3	3	4
Oregon	2	3	3
South Carolina	3	3	3

Another possible explanation for the discrepancy in the number of hospital admissions versus the number of meth labs is that meth abusers in Oregon are able to continue using meth despite the laws that reduce the availability of the precursor PSE. A review of the literature as well as an internet search has lead to several methods by which abusers of meth have been able to bypass the CMEA, electronic monitoring, and other state legislation.

Meth from Mexico

Following the CMEA, the United States had a marked decrease in the number of methamphetamine laboratories. Unfortunately, the decline in labs in this country was met with an immediate increase in the production and exportation of methamphetamine from Mexico.⁴⁵ In fact, by one estimate from the DEA, 80% of methamphetamine used in the United States in 2007 came from a Mexican-based drug cartel.⁴⁵ It would appear that as long as PSE is available in

Mexico, the drug cartels there can continue to use PSE to create large batches of meth. As long as meth is being produced in Mexico and transported across the border, there will unlikely be a shortage of supply here in Kentucky, regardless of the federal and state legislation designed to limit abuse.

According to the National Drug Intelligence Center (NDIC), Mexican officials implemented a ban on the importation of ephedrine and PSE in 2008.⁴⁶ This led to zero commercial imports of PSE and ephedrine into Mexico beginning in 2008, which resulted in a subsequent decline in the production of methamphetamine by Mexican cartels during that same year. Unfortunately, methamphetamine production was on the rise in the United States during that same year as ‘cookers’ discovered ways to obtain more PSE and how to make smaller batches of methamphetamine using the ‘shake and bake’ method (see page 24). Similar to the production of methamphetamine here in the U.S., Mexican cartels quickly learned how to circumvent the ban on PSE imports and have begun diverting large supplies of PSE from other countries in South America.⁴⁶ Despite a nationwide ban on the importation of PSE, Mexican drug cartels are once again producing large supplies of methamphetamine and exporting it to this country.

Smurfing

Another method that has become popular throughout the country is ‘smurfing’ PSE. This term was originally used to describe an individual breaking up a large transaction with a bank into several small ones in order to avoid raising any red flags with the IRS.⁴⁶ Concerning PSE, smurfing is a means by which individuals purchase the daily limit they are allowed by the federal government at one pharmacy, and then going to another pharmacy and doing the same.⁴⁶ This

method is not successful in states such as Kentucky that employ electronic monitoring. However, Kentucky is contiguous to seven states that do not use electronic monitoring; an individual from Kentucky could still purchase large quantities of PSE from sources in these other states.

Stooges

A new method of procuring extra quantities of PSE, particularly in states that employ electronic monitoring systems, is to use ‘stooges.’ A stooge is someone who has been paid by another person to purchase their daily limit of PSE.⁴⁷ Utilizing this method, a single person could obtain several times the daily or monthly limit in spite of electronic monitoring systems. If electronic monitoring becomes more popular in other states, possibly through federal regulation, this method of obtaining PSE may become more popular. However, cooks may have a difficult time finding an adequate number of stooges throughout the month, as a stooge would reach their 30-day limit of PSE rather quickly.

Ephedrine

Even if there was a national legislation to make all PSE products available by prescription only, and if Mexico was unable to procure shipments of PSE from other countries in order to produce methamphetamine, a problem remains because ephedrine is still available over the internet. A simple internet search using the word ephedrine on google.com will result in numerous websites that allow individuals to buy products containing ephedrine. In the absence of PSE, it is reasonable to believe that methamphetamine could still be produced in large quantities until federal legislation restricts the ability to make purchases of the product over the internet.

However, ‘cookers’ might be wary of making large internet purchases of PSE or ephedrine because there is no guarantee that the products purchased online are the same as the product advertised. For example, a bottle of ephedrine purchased over the internet might contain nothing more than sugar pills. PSE products purchased in the U.S. are regulated by the FDA and it is reasonable to assume that commercial PSE products purchased here will not be contaminated or adulterated (unlike ephedrine products that are not legally made or regulated in the U.S.); this is something that ‘cookers’ undoubtedly realize.

The Shake and Bake

Recently, a new method for making methamphetamine known as a “shake and bake” has become more prevalent.⁴ The shake and bake method of producing methamphetamine requires only an empty 2 liter bottle, a few PSE pills, and some common household chemicals.⁴ The amount of PSE required to make meth using this method is less than the 3.6 grams an individual is allowed to purchase in one 24 hour period under the current federal guidelines.⁸ This method is highly dangerous because the process of making meth is even more likely to lead to explosions as it requires the cooker to literally shake a bottle full of highly reactive ingredients.⁴ This new method requires that the ingredients be shaken appropriately and the cap be screwed on “just right” in order to ensure the product is made correctly without resulting in an explosion.

This method has not been researched for this paper; a statement cannot be made as to the amount of methamphetamine that a single ‘shake and bake’ can produce, or whether that amount is sufficient to satisfy a typically abuser. It is possible that this method yields only a limited supply of methamphetamine and cannot be expected to replace the more traditional labs for the chronic abuser. If this method does produce sufficient quantities of meth each month with less

than 9 total grams of PSE, even a nationwide electronic monitoring program might not have an effect on reducing the abuse of this drug.

Alternatives to PSE for the Treatment of Nasal Congestion

Federal and state laws have been issued in order to reduce the availability of the key ingredient in the illegal manufacturing of methamphetamine, PSE. These laws, particularly ones in which PSE is allowed to be sold by prescription only, reduce the availability of PSE to consumers. This begs the question: are there viable alternatives to PSE readily available to patients who require nasal decongestants?

Following national legislation to limit the sale of PSE, many producers of cold medications switched from PSE as the main ingredient to phenylephrine (PE).⁸ Sales of phenylephrine, the primary ingredient in cough and cold medicines such as Sudafed PE, are not regulated by the states or national government, as PE has no known abuse potential. PE also works differently than PSE and has a much lower bioavailability of 38% (bioavailability is the measure of the amount of a drug that reaches systemic circulation following ingestion), compared to nearly 100% for PSE.¹² As a result of having a different mechanism of action and a markedly lower bioavailability, PE has been shown to be inferior to PSE in treating symptoms of nasal congestion and has even failed to show superiority over placebo in treating nasal congestion in numerous clinical trials.^{10,11}

Despite the poor performance of PE in clinical trials, cold and allergy sufferers still have the option of using nasal sprays to alleviate their symptoms. Xylometazoline, the active ingredient found in Afrin, is a nasal decongestant that has been proven to significantly reduce nasal congestion in people with the common cold.¹³ Additionally, there is no current method of

converting the decongestants found in nasal sprays into harmful or illicit drugs such as methamphetamine. Unfortunately, nasal sprays can only be safely used for 3 to 5 days before they result in rebound congestion, leading to worse nasal suffering than the patient would have experienced if they had not used the spray at all.⁹ For this reason, nasal sprays are poor options for chronic allergy and sinus sufferers. Given the lack of other oral decongestants available on the market, cold and allergy sufferers with chronic and persistent symptoms have few, if any, viable options other than PSE for the treatment of their symptoms.

How Will Those Who Use PSE as it is Intended be Affected by a Prescription-Only Law?

Many Kentuckians suffer from nasal congestion; whether in the form of seasonal allergies, chronic allergies, or bouts of the common cold. According to one estimate, Louisville, KY has been ranked as the second worst city to live in for allergy sufferers.²⁴ And according to PollenTec, a company that produces special window screens that allow airflow while preventing pollen and other allergens from entering the home, Lexington has the highest pollen count of any city in the country.²⁵ For many Kentuckians, the ability to control symptoms might be greatly reduced if they are unable to purchase effective over the counter medications such as PSE.

A prescription-only PSE regulation might result in only a minimal additional cost to Kentuckians, as most physicians would be willing to prescribe PSE without requiring an additional visit to the doctor's office.⁴⁷ If this is the case, then it is possible that making PSE a prescription-only product might cause an inconvenience without a marked increase in money spent on physician visits. However, the median household income for Kentucky as of 2008 is \$41,000 which is \$11,000 less than the national average²⁶. In addition, 17% of Kentuckians have an income level below the poverty line, as compared with 13% nationally²⁶. Given this

information, can Kentuckians afford to treat their nasal congestion symptoms if PSE availability is restricted to those who have prescriptions from their physicians?

Despite the additional costs to the individual for the treatment of their allergies, there is a potential for a great deal of savings to the state of Kentucky if the prevalence of methamphetamine abuse could be limited. The estimated cost to the taxpayers of Kentucky in 2009 related to methamphetamine abuse, including investigations, cleaning meth lab sites, arresting individuals, housing those who have been arrested, lab analysis, and man-hours, totaled more than 30 million dollars¹⁹. There is also the concern that methamphetamine abuse is reducing our safety because of the amount of time police officers must devote to the crimes of manufacturing and abuse; approximately 35,000 man-hours were devoted to methamphetamine related crimes in 2010.¹⁹ These costs, in addition to the costs to hospitalize victims of methamphetamine abuse, which includes abusers as well as innocent victims who are injured in meth lab explosions, have prompted debates on whether to change PSE from a restricted OTC product to a prescription only medication.

Finally, there is some evidence that PSE itself might warrant a prescription only status. PSE, even if used as intended, increases heart rate and blood pressure.⁹ Elevations in blood pressure can lead to numerous medical complications including damage to blood vessels that supply the heart, brain, kidneys, and eyes.⁵² Approximately 30% of U.S. adults have high blood pressure and should not take PSE without consulting their physician.^{9,51} Many of these people do not know they have high blood pressure; if they had to see their physician in order to obtain a prescription for PSE, the elevated blood pressure would possibly be discovered in the doctor's office. In addition to issues with high blood pressure, PSE is not approved for use in children under the age of 4.⁹ Despite this recommendation from the FDA and the American Pediatric

Society, children aged 2 and under consume the greatest amount of PSE containing products of any age range among children.⁵³ Children in this age range are at the highest risk for toxicity from the PSE.⁵³

Limitations

The data concerning hospital admissions fails to capture emergency room visits that do not result in an admission to the hospital. Ideally, the data would reflect all emergency room visits, whether or not they resulted in an admission. The emergency department data is available for this research; however, the data was not able to be collected in the time allotted for completion of this paper. The hospital admission data is also limited in that only three years were evaluated. The data from 2001 is well before the implementation of the CMEA or other state specific regulations concerning PSE sales and distribution. 2008 is not the most recent year for which data are available (2010 data are available) but due to time constraints it was the most recent year available for analysis in this research. A further analysis of this research should compare data over a greater number of years in order to detect trends, and should include the most recent year for which data is available.

Another limitation is the data on meth labs discovered in Kentucky. Are the numbers a true reflection of the number of labs, or has law enforcement become more efficient at discovering labs over the last few years? In addition, with the advent of 'mobile meth labs,' it is difficult to determine whether the increase in meth labs is a reflection of the number of individuals abusing meth. Mobile meth labs typically produce small amounts of methamphetamine compared with the more 'traditional' labs that can yield much greater amounts. If the number of labs increase, but the yield from each lab decreases, how has the

overall production of meth changed? A further limitation is the large amount of meth that comes from Mexico, estimated at 80% of the total meth used in the U.S.⁴⁵ Given this statistic, is it even reasonable to assume that the number of labs in a given state is correlated to the amount of meth that is used in that state? Finally, the numbers of meth labs from the Louisville Metro Police Department and from the DEA's website reflect the total number of 'incidents' rather than the total number of labs. For example, if a law enforcement agency responds to a home that has 5 meth labs within the residence, the incident number is one. Therefore the true number of meth labs is probably much higher than what is actually reported.

Another limitation is the use of data from a state that is not demographically similar to Kentucky. Oregon cannot necessarily be directly compared to Kentucky as it is in a different region of the country and consists of a different makeup of citizens concerning education, income, population, and other pertinent statistics.²⁶ Ideally, Mississippi would have been a better comparator, but as PSE has been prescription-only since 2010 in MS, versus 2006 in Oregon, the data for MS is lacking.

Conclusion

Given the conflicting evidence concerning the number of meth labs, the number of hospital admissions, and the numerous ways in which an individual could produce and obtain illicit methamphetamine, it is difficult to predict the consequences of implementing a prescription-only PSE law in Kentucky. Oregon appears to have had some success as it has a markedly reduced number of meth labs compared to before its prescription-only law, and the overall crime rates in Oregon have been reduced following the same law. The greater number of hospital admissions in Oregon is discouraging and suggests a possible unintended consequence

of reducing the immediate availability of methamphetamine to addicts; a decrease in tolerance followed by an overdose. Time will tell whether Oregon has been successful in deterring methamphetamine consumption, but early indicators are promising. If Kentucky can experience a similar decrease in the number of meth labs and a consequent decrease in overall crime, then changing PSE to prescription-only will have an overall positive impact on the citizens of Kentucky.

Discussion

The efforts by Kentucky's legislature to reduce the prevalence of methamphetamine abuse and production have so far been shown to be ineffective. Following federal and state laws, Kentucky has seen a decrease in the number of methamphetamine labs, only to see those numbers steadily climb several years afterwards. Only Oregon, which instituted a prescription-only law in 2006, has seen a steady and lasting decrease in its number of methamphetamine labs. However, hospital admissions for methamphetamine abuse in Oregon have been much higher than similar hospital admissions in Kentucky. Oregon may have outsourced its production of methamphetamine, but there is not clear evidence that use of meth has declined.

Further research is needed to determine all the pros and cons of a PSE prescription-only law. One area of research that might be interesting to pursue is the adverse health consequences of the lay person using PSE for its intended purpose without having consulted a doctor beforehand. For example, does OTC use of PSE lead to an increased incidence of hypertension? If so, what are the consequences of the increased hypertension? Are there additional costs to healthcare? Can PSE induced hypertension eventually lead to organ dysfunction such as kidney

damage? If so, at what rate and at what cost to the healthcare system? Answers to these questions can help decision makers weigh all the options when considering the status of PSE.

Changing the availability of PSE to prescription-only may help reduce production and consumption of meth in Kentucky in the short-term, but like previous laws may have little to no long-term impact. When considering different ways to reduce drug abuse in Kentucky, it is important to consider changes that will have an immediate impact as well as policies and regulations that will prevent drug abuse in the future. In order to accomplish this, it is necessary to consider the root causes of drug abuse. Some questions to consider are: what makes a person use methamphetamine in the first place? What characteristics, if any, do drug abusers have in common with each other? Finally, what can we do to ensure that people are less likely to abuse drugs, regardless of how cheap and available they may be?

According to self-reporting statistics from 2009, college graduates abuse drugs at a lower rate than those who have graduated from high school or have dropped out (6.1% versus 8.8% versus 10.6%).³⁴ The same survey showed that people who were employed full time were less likely to use illicit drugs versus those who were unemployed (8% versus 17%). The Bureau of Labor Statistics has shown that in 2009, the level of income rose proportionately with education level, while the rate of unemployment was inversely proportional to education.³⁵ Kentuckians have a lower than average level of education, lower than average salaries, and a higher than average propensity to abuse drugs.²⁶ The best way to prevent methamphetamine abuse in Kentucky, or any form of drug abuse for that matter, would be to enhance our education system.

Investing in the education of the youth of Kentucky might prove to be a better deterrent to drug abuse than any law concerning the distribution of PSE. A prudent policy might be to

limit PSE to prescription only and ask legislators to encourage federal legislation to do the same. If Kentuckians are unable to get PSE without a prescription from this or any other state, we might be able to better control the abuse of this drug and the myriad of problems that abuse leads to. However, to have a lasting impact on drug abuse in general, Kentuckians need to be willing to invest more money in the education system, which would potentially lead to a decrease in all forms of drug abuse.

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Figure 1

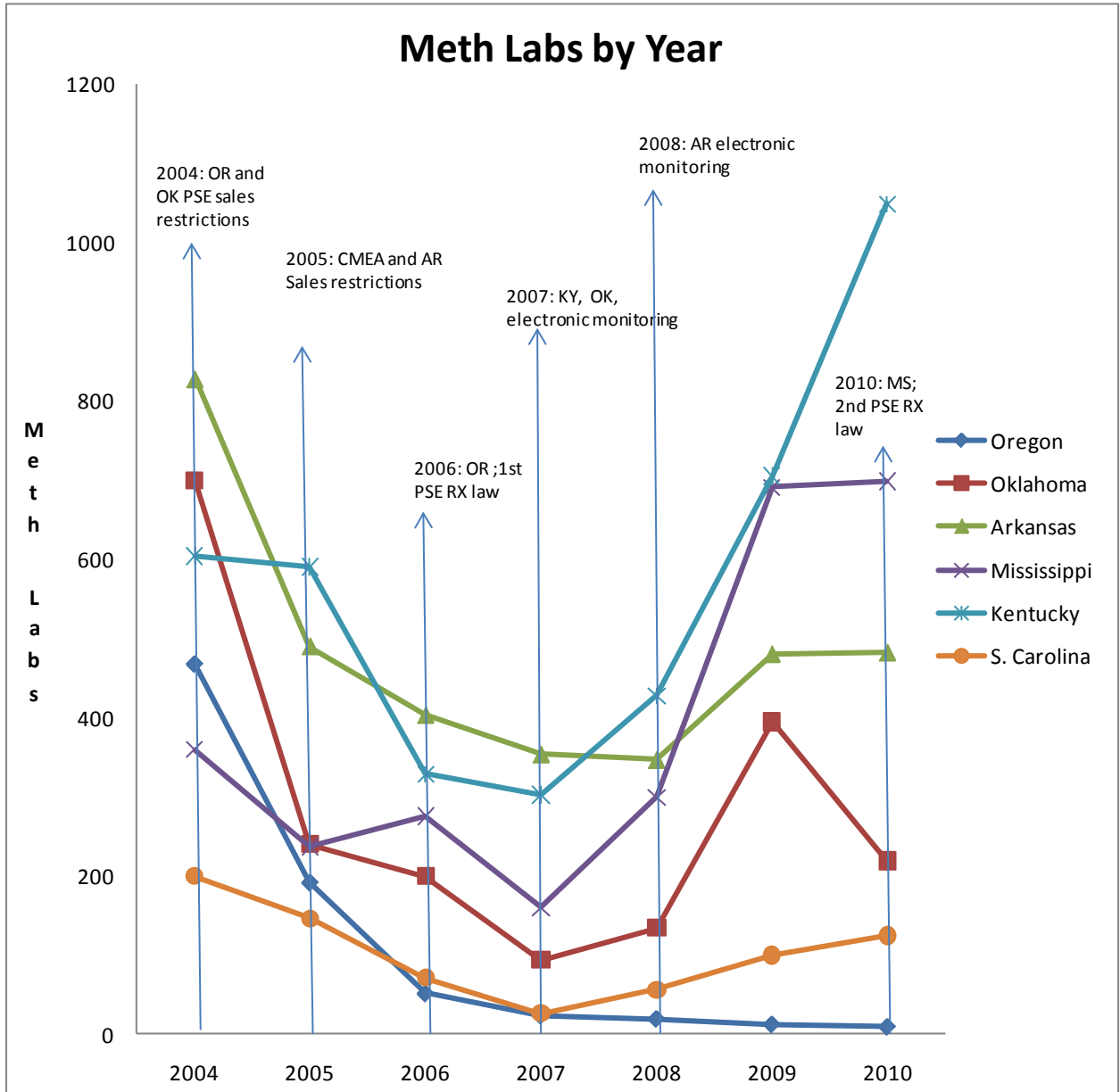
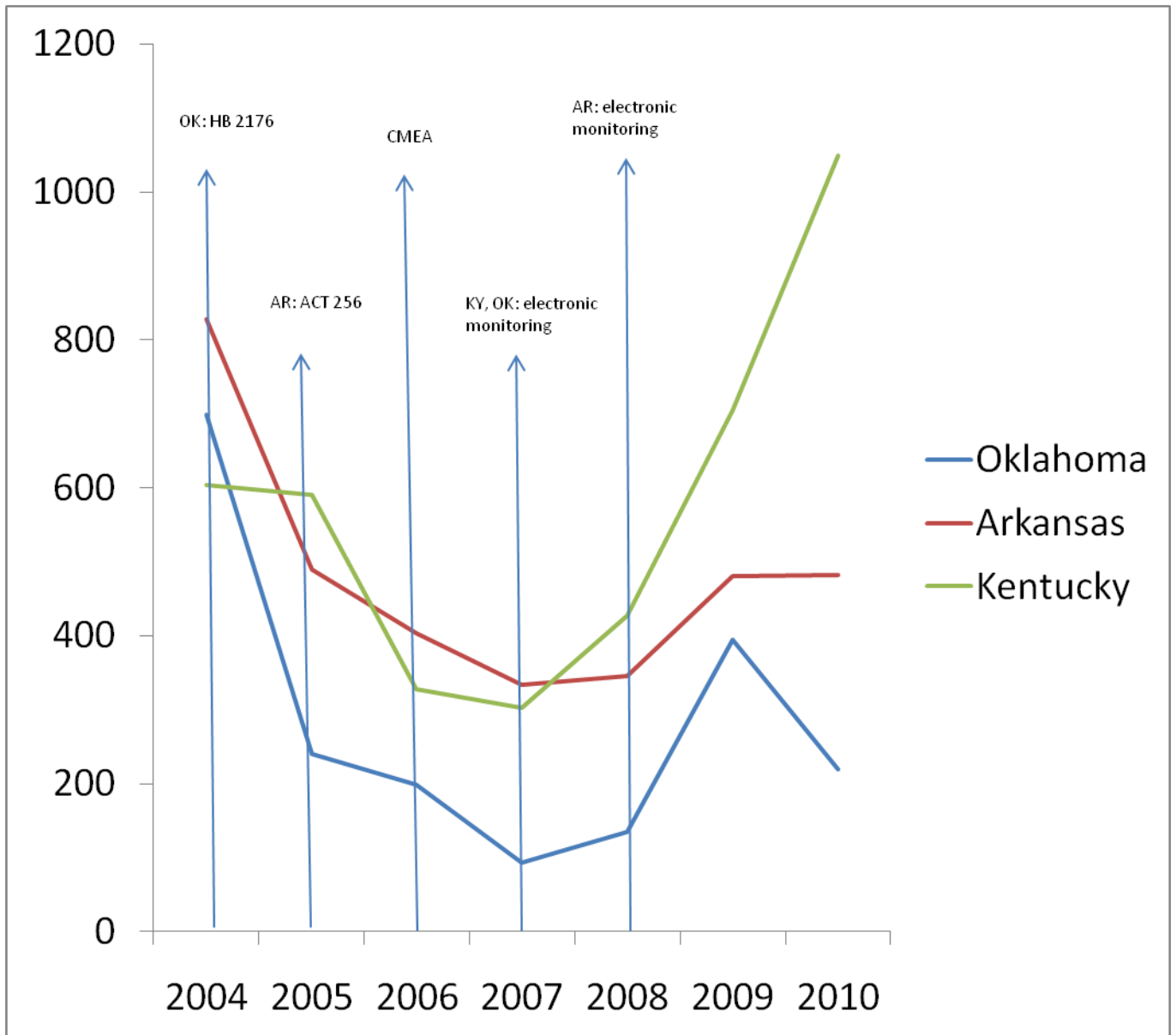
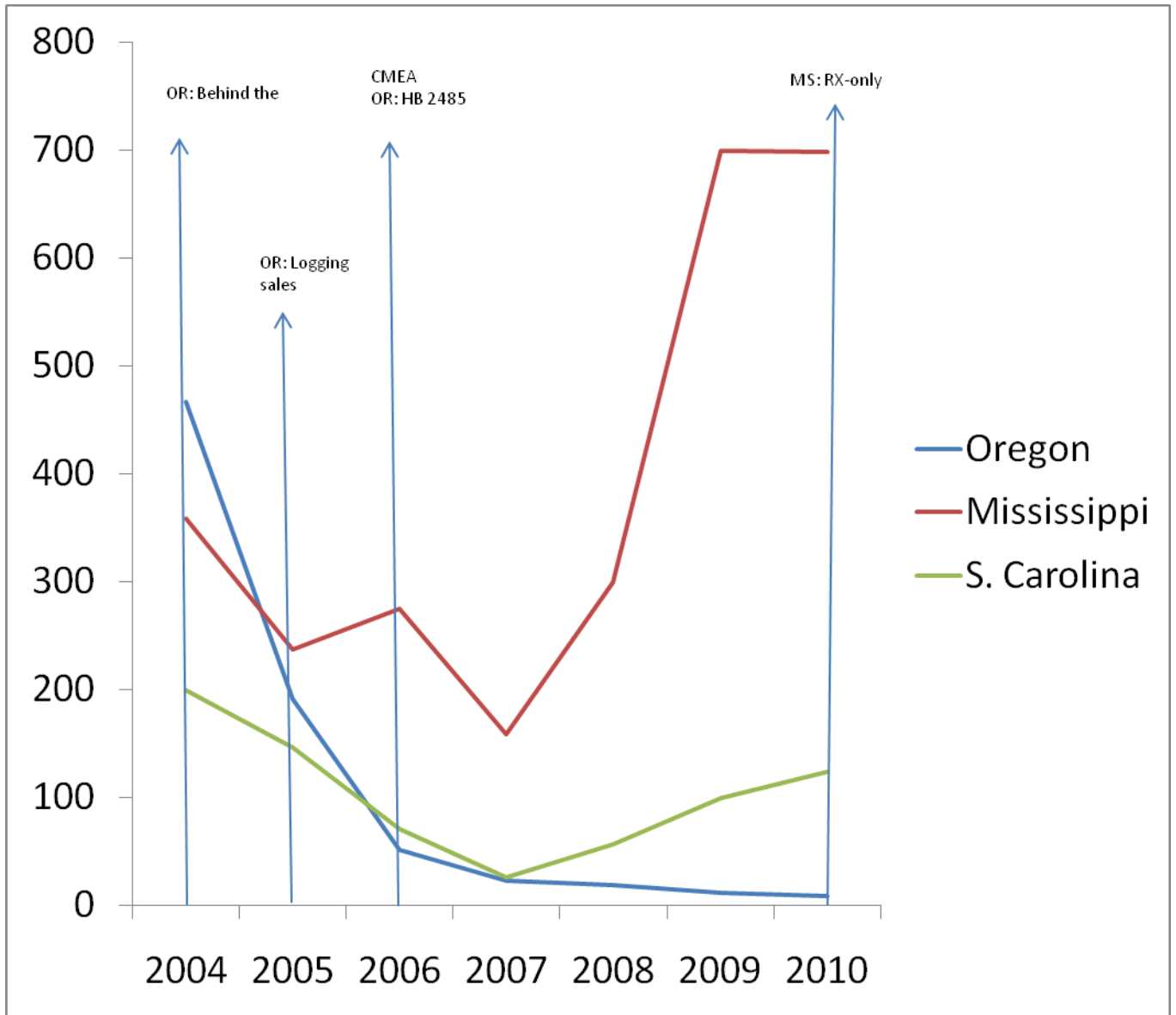


Figure 2: Electronic Monitoring States



Number of meth lab incidents by year

Figure 3: Prescription-only states with control state (S. Carolina)



Number of meth lab incidents by year