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Changing over-the-counter ephedrine and pseudoephedrine products to prescription only: Impacts on methamphetamine clandestine laboratory seizures☆

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ABSTRACT

Background: Clandestine laboratory operators commonly extract ephedrine and pseudoephedrine—precursor chemicals used to synthesize methamphetamine—from over-the-counter cold/allergy/sinus products. To prevent this activity, two states, Oregon in 07/2006 and Mississippi in 07/2010, implemented regulations classifying ephedrine and pseudoephedrine as Schedule III substances, making products containing them available by prescription only. Using simple pre-regulation versus post-regulation comparisons, reports claim that the regulations have substantially reduced clandestine laboratory seizures (an indicator of laboratory prevalence) in both states, motivating efforts to implement similar regulation nationally. This study uses ARIMA-intervention time-series analysis to more rigorously evaluate the regulations' impacts on laboratory seizures.

Methods: Monthly counts of methamphetamine clandestine laboratory seizures were extracted from the Clandestine Laboratory Seizure System (2000—early 2011) for Oregon, Mississippi and selected nearby states (for quasi-control).

Findings: Seizures in Oregon and nearby western states largely bottomed out months before Oregon's regulation, and changed little thereafter. No significant impact for Oregon's regulation was found. Mississippi and nearby states generally had elevated seizures before Mississippi's regulation. Mississippi experienced a regulation-associated drop of 28.9 seizures (50.2%) in the series level ($p < 0.01$), while nearby states exhibited no comparable decline.

Conclusions: Oregon's regulation encountered a floor effect, making any sizable impact infeasible. Mississippi, however, realized a substantial impact, suggesting that laboratories, if sufficiently extant, can be meaningfully impacted by prescription precursor regulation. It follows that national prescription precursor regulation would have little impact in western states with low indicated laboratory prevalence, but may be of significant use in regions facing higher indicated prevalence.

1. Introduction

Clandestine laboratory operators commonly extract ephedrine and pseudoephedrine—precursor chemicals used in the illicit synthesis of methamphetamine—from over-the-counter (OTC) cold/sinus/allergy products (Cunningham and Liu, 2003, 2005). To prevent this activity, two states to date, Oregon in 07/2006 and Mississippi in 07/2010, have implemented regulations that classify ephedrine and pseudoephedrine as Schedule III substances, making products containing them available by prescription only (Oregon, 2005 Law Chapter 706; Mississippi, 2010 Law Chapter 303).

Critics argue that such prescription precursor regulation increases costs to the healthcare system by requiring consumers to visit a doctor before treating a common cold or allergies; poses particular problems for lower income consumers, as they have

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less access to medical care (and thus prescriptions); and creates additional work for doctors—a group already challenged by patient demand (cf. CHPA, 2005).

Advocates contend that such regulation is nevertheless worthwhile because it has the potential for reducing methamphetamine clandestine laboratories (Rannazzisi, 2010). Reducing laboratories would be of public health import not only because they produce illicit methamphetamine, but also because they can result in the injury/death of persons, often innocents, co-located with the laboratories, and they produce toxic waste that is dumped haphazardly in communities (Blostein et al., 2009; Burgess et al., 1996; Centers for Disease Control, 2000; Farst et al., 2007; Grant et al., 2010; Melnikova et al., 2011; Santos et al., 2005; Spann et al., 2006; Thrasher et al., 2009).

Multiple government reports have asserted that Oregon and Mississippi's prescription precursor regulations have, in fact, reduced clandestine laboratory seizures (an indicator of laboratory prevalence). For example, the Drug Enforcement Administration (DEA) reports that Oregon's regulation has been associated with a dramatic and sustained decline in the number of methamphetamine laboratories seized in that state (Rannazzisi, 2010). In testimony before the US Congress, the Oregon Attorney General described the impact of Oregon's regulation on clandestine laboratories as "astounding" (Kroger, 2010). And both the National Drug Intelligence Center (NDIC) (NDIC, 2011a,b) and the Office of National Drug Control Policy (ONDCP) (ONDCP, 2011) have reported that clandestine laboratory seizures in Oregon and Mississippi dropped in association with the states' prescription precursor regulations.

In light of such assertions, efforts are under way to make OTC ephedrine and pseudoephedrine products available by prescription-only in several other US states; for example, California (California SB 315, 2011), Nevada (Nevada SB 203, 2011), Kentucky (Kentucky SB 45, 2011) and Tennessee (Tennessee SB 0561/HB 0181, 2011). And federal legislation has been proposed which would require a prescription for pseudoephedrine products nationwide (Wyden, 2010).

This said, government reports on Oregon and Mississippi's prescription precursor regulations have used a simple analytic approach to assessing the regulations' effectiveness. Specifically, they selected time periods before and after each regulation, found that seizures during the post-regulation periods were lower in number, and concluded consequently that the regulations were effective (NDIC, 2011a,b; ONDCP, 2011). This type of approach is prone to error because it does not take into account time series analysis issues such as trend (including local trend), drift, serial correlation, seasonality, outliers, and the nature of impacts (e.g., whether the impacts are gradual or abrupt; Box and Jenkins, 1970; Box and Tiao, 1975; Cook and Campbell, 1979; Liu, 2006; McCleary and Hay, 1980; Shadish et al., 2002). In a systematic review, Ramsay et al. (2003) re-analyzed 33 health-related time series intervention studies that failed to address one or more of the issues just noted. All 33 studies claimed that the interventions had significant effects, but Ramsay et al.'s re-analyses, which used more appropriate time series procedures, found that about half of the studies showed no significant intervention effects.

There are studies that have addressed trend, serial correlation, seasonality, etc. in the course of determining how the regulation of bulk forms of ephedrine and pseudoephedrine impact various methamphetamine problems/indicators—methamphetamine hospital admissions, arrests, treatment admissions, route of administration, purity, and price (Callaghan et al., 2009; Cunningham and Liu, 2003, 2005, 2008; Cunningham et al., 2008, 2009, 2010a; cf. McKetin et al., 2011). But the studies' applicability to prescription precursor regulation is questionable, as bulk-precursor regulation may not generalize to interventions that target OTC products.

To assess the possible impact of prescription precursor regulation on clandestine laboratory seizures in Oregon and Mississippi, this study uses Autoregressive Integrated Moving Average (ARIMA)-intervention time series analysis with quasi-control series—an accepted, relatively rigorous form of analysis (Cook and Campbell, 1979; Shadish et al., 2002). Time series were constructed using data from the DEA's Clandestine Laboratory Seizure System (CLSS) between January 2000 and the beginning of 2011 (April for Oregon and May for Mississippi).

1.1. Store-based OTC product regulations

Prior to their prescription regulation efforts, Oregon and Mississippi attempted to control OTC ephedrine and pseudoephedrine products by regulating how stores could sell the products, a less restrictive approach. For historical completeness, this study also examines the impacts of the two states' store regulations on laboratory seizures, as well as federal store regulations implemented in 2006.

Effective 01/2002, Oregon made it unlawful to distribute more than nine grams of ephedrine or pseudoephedrine to anyone other than certain exempted individuals/organizations (e.g., physicians/pharmacists/wholesalers; Oregon, 2001 Law Chapter 615). In 11/2004, Oregon required that (1) single-entity pseudoephedrine products be placed behind a counter and sold only from a pharmacy, (2) products containing pseudoephedrine in combination with another active ingredient be sold only by a pharmacy and/or non-prescription drug outlet, and (3) purchasers show photo identification (Oregon Board of Pharmacy, 2004a,b). In 05/2005, Oregon required that (1) all pseudoephedrine products be kept in a prescription area or locked storage space within a pharmacy and sold only from a pharmacy, and (2) sellers make a logbook entry for each sale (Oregon Board of Pharmacy, 2005a,b). The 01/2002, 11/2004 and 05/2005 interventions will be referred to here as Oregon's Phases 1, 2 and 3 store regulations, respectively.

In 07/2005, Mississippi implemented a 6 g daily ephedrine/pseudoephedrine purchase limit and a 9 g monthly purchase limit on ephedrine/pseudoephedrine products, and required that a package containing ephedrine/pseudoephedrine be limited to 3 g or less of the substances. Single ingredient ephedrine/pseudoephedrine products were required to be placed in a locked display case or behind a counter where the public is not permitted. Products containing ephedrine or pseudoephedrine in combination with another active ingredient had to be placed (1) behind a counter, (2) within 30 ft. of an establishment's cashiers, and (3) in a locked display case or under video surveillance. Photo identification was required of purchasers (Mississippi, 2005 Law Chapter 309).

In 04/2006, the federal Combat Methamphetamine Epidemic Act (CMEA) required that (1) daily sales of ephedrine/pseudoephedrine base be limited to 3.6 g per customer, (2) products be sold in blister packs with no more than two dosage units per blister, and (3) sales be limited to 9 g total per month. Starting September 30, 2006 (in effect, 10/2006), the CMEA required that (1) products be placed behind the counter or in a locked cabinet, (2) purchasers provide photo identification, and (3) sellers record purchaser name/address and product details in a logbook (DEA, 2006). (Following nationwide implementation of the CMEA, some states enacted legislation matching it (e.g., Mississippi, 2009 Law Chapter 540). For the purposes of the present study, this matching legislation does not constitute an intervention and is not discussed further here.)

2. Methods

All US states report clandestine laboratory seizures to CLSS, including data on seizure location and date, and estimated laboratory capacity. Laboratories in