An Analysis of the Economic Impact of Requiring Prescriptions for Pseudoephedrine Products

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March 4, 2013

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Executive Summary

With any public policy that restricts access to a product that is good for some people but misused by others there are inherent distortions, costs, and loss of consumer welfare. Ideally, any such policy should minimize the costs to non-targeted populations while effectively restricting access only to those who misuse the product. But achieving this goal is far from simple. This assessment holds true for the regulation of pseudoephedrine (PSE), the active ingredient in many popular and effective cold and allergy products that also has the unfortunate distinction of being a key component in manufacturing the illicit drug methamphetamine (meth).

Despite 2006 implementation of federal law that required stores to keep all cold and allergy medicines containing PSE behind the counter and to check purchasers' identification against a new monthly purchase limit, PSE diversion to meth production remains a demonstrable problem. Given policymakers' increasing interest in stricter state and/or federal regulation of PSE products, it is critical to remember that not all proposed measures are equally beneficial or effective. Some have more severe trade-offs than others. A policy decision based solely on a concern about the diversion of PSE medicines to meth production is shortsighted because it only considers one side of the issue—the thousands of meth cooks and their domestic meth labs—and not the 18 million families who legitimately need PSE medicines for relief from colds and allergies.

One idea that is being discussed among some policymakers—requiring all PSE medicines to be available by prescription only—would force high social and economic costs on consumers. As this report details, the estimated unintended consequences of a prescription-only PSE policy include the following costs and burdens:

- Extra doctor visits, contributing $59 million in additional costs to the government, consumers, and private insurance companies in the first year following the policy's implementation;
- More absenteeism and lost work productivity, when the common cold already costs this nation an estimated $25 billion annually in lost productivity;
- Higher prices for PSE medicines due to the overall cost difference between a prescription-only product and an over-the-counter one;
- Increased health insurance premiums due to additional doctor visits and higher PSE drug costs;
- An estimated loss of $219.2 million in state tax revenues over ten years.

On top of creating financial burdens, a prescription-only PSE policy would not be 100 percent effective at eliminating PSE diversion because it does not address theft and fraudulent prescriptions for these medicines. In fact, many prescription drugs are heavily abused, despite their prescription status, to the extent that the U.S. Centers for Disease Control has labeled prescription drug abuse a "public health epidemic." According to the 2011 National Drug Threat Assessment, deaths from prescription drug overdoses outnumber deaths due to cocaine, heroin, and meth combined.

The benefits of a prescription-only policy for PSE medicines do not seem worth the costs, especially when there are other policy options at hand.

Introduction

In addition to being an active ingredient in many cold and allergy products, pseudoephedrine (PSE) has the unfortunate distinction of being a key component in manufacturing methamphetamine (meth). In an effort to curb meth production and use, some lawmakers are contemplating stricter federal regulation of cold and allergy medicines containing PSE. In addition, two states have passed legislation mandating that patients must obtain a prescription from their doctor for these products. While motivated by good intentions, such a move is not without appreciable costs. In this paper, I detail the most significant of these consequences, examining in particular the unintended economic effects of legislation mandating a prescription-only rule for PSE.

The paper is divided into two parts. Part one provides context for the issue by giving an overview of the legislative environment, which includes activity at both the federal and state levels. The second part of the paper describes the estimated economic cost of a national prescription-only policy for PSE products and the indirect effects—both from public health and economic standpoints—associated with such a policy.

Part 1: Background on Policy Efforts to Curb PSE Diversion

Meth abuse has long been an issue for U.S. drug enforcement, increasing throughout the 1990s and peaking in the mid-2000s.[1] The diversion of over-the-counter medicines containing PSE to the production of meth has been a concern of advocates and policymakers, leading Congress to pass the Combat Methamphetamine Epidemic Act of 2005. This law requires stores to keep all PSE products in a locked cabinet or behind the counter and to check purchasers' identification to ensure that no single customer exceeds the monthly nine-gram limit established in the legislation, all while maintaining nonprescription access.[2]

Despite these restrictions, meth producers have continued purchasing and misusing PSE medicines through devious means, including using fake IDs, buying from multiple stores, and stealing from wholesalers or pharmacies. Relatively recently, meth cooks are also employing a significantly smaller-scale (but volatile) "one-pot" method of meth production.

While meth use continues to adversely affect many communities, the overall rate of use has declined in recent years. According to the National Survey on Drug Use and Health, "The number and percentage of persons aged 12 or older who were current users of methamphetamine in 2010 (353,000

[1] Dana Hunt, Sarah Kuck, Linda Truitt, "Methamphetamine Use: Lessons Learned," Abt Associates, Contract No. 99-C-008 (January 31, 2006), www.ncjrs.gov/pdffiles1/nij/grants/209730.pdf.
[2] U.S. Drug Enforcement Administration (DEA), "General Information Regarding the Combat Methamphetamine Epidemic Act of 2005 [Title VII of Public Law 109-177]," May 2006, www.deadiversion.usdoj.gov/meth/cma2005.htm.

or 0.1 percent) were similar to those from 2007 through 2009, but lower than those from 2002 through 2006."[3]

Since the behind-the-counter component of the Combat Methamphetamine Epidemic Act took effect on September 30, 2006, the number of current meth users has remained relatively constant, but below the level observed prior to enactment. In addition, while the number of new meth users has declined significantly since 2007,[4] there has been a recent uptick in the number of meth labs after an initial decline following passage of the law.[5]

Though the federal Combat Methamphetamine Epidemic Act seems to have impacted meth use, many believe that the restrictions the law imposed were insufficient. As a result, policymakers, in conjunction with manufacturers and distributors of PSE medicines, have proposed and undertaken other measures to reduce PSE diversion to meth production.

Many states have imposed retail sales restrictions for PSE, ephedrine, and phenylpropanolamine sales beyond those required by the Combat Methamphetamine Epidemic Act. For example, ten states have further reduced the total amount of PSE medicines an individual can purchase. Eight states will not sell PSE medicines to anyone convicted of a meth-related crime. Sixteen states only sell PSE medicines at pharmacies. Twenty-six states have put in place an electronic sales blocking technology that captures in real time data mandated by federal law. This system, the National Precursor Log Exchange in twenty-five states, allows retailers to block the sale to any purchaser who has exceeded his or her legal limit, at the point of sale. It also provides information to law enforcement to track suspect activity.

However, not all proposed measures are equally beneficial or effective. The aforementioned measures largely target criminals and do not unduly compromise general consumers' access to their medicines of choice. A problematic policy change that assuredly compromises consumer access—on which the remainder of this report focuses—is a requirement that medicines containing PSE be made available by prescription only. Mississippi and Oregon have already enacted prescription-only legislation, while several other states are weighing the idea.[6]

Given some lawmakers interest in pursuing prescription-only policies at the state and possibly the federal level, it is important to understand any foreseeable unintended effects this policy would produce. As the following section of this report demonstrates, requiring prescriptions for PSE products should not be undertaken lightly.

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[3] *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658 (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011).
[4] Ibid.
[5] Senate Caucus on International Narcotics Control, letter to Government Accountability Office Comptroller General Gene Dodaro, April 29, 2011, www.drugcaucus.senate.gov/Mexico-Report-Final-5-2011.pdf.
[6] Office of National Drug Control Policy, "Controlling Precursor Chemicals," www.whitehouse.gov/ondcp/precursor-chemicals.

Part 2: Costs Associated with Requiring Prescriptions for PSE Medicines

There are inherent problems with any policy that restricts access to products that many rely on for cold and allergy relief but others misuse. Requiring a prescription for PSE medicines based solely on a concern about PSE diversion and meth production is shortsighted because of costs that legitimate consumers of PSE medicines would be forced to bear. Further, it would do little to impede the flow of meth into the hands of criminals and addicts, as a majority of meth is imported from Mexico. According to the U.S. Drug Enforcement Agency, Mexican meth accounts for 80 percent of the meth sold in the United States.[7]

This section looks in depth at the types of costs a prescription-only policy would likely introduce. These costs must be weighed against the benefit of potentially reducing illicit use.

The primary and legitimate use of PSE is for medicines to treat congestion from colds, allergies, and hay fever.[8] Restricting access to PSE medicines would negatively impact those who suffer from these ailments and need a PSE product for relief. This is not an insignificant population—a reported 18 million families in the United States use medicines containing PSE to treat these symptoms.[9] The U.S. Centers for Disease Control found that in 2010 nearly 17 million adults suffered from hay fever,[10] while the National Institutes of Health reports an estimated 1 billion cases of the common cold per year.[11]

A full analysis of the impact of a prescription-only policy must take into account both the direct effect—namely, the burden placed on those who continue to use PSE medicines despite the restricted access—and the indirect effect, or the "hidden" burden imposed on consumers who stop using PSE medicines as a result of the higher cost and reduced access.

Direct Effects of a Prescription-Only Policy

The primary direct economic burden of making PSE medicines prescription-only arises from the extra doctor visits this policy change would require. When people see a doctor to obtain a prescription for one of these products, costs increase for insurers, government health care programs, and patients.

In 2011, Avalere Health conducted an analysis of the cost of these extra doctor visits. Avalere's model yielded an estimated 579,315 additional doctor visits in the first year after implementation of the policy. Using a per-visit estimate for private insurance, Medicare, and Medicaid of $94, $76, and $70 per

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[7] DEA, *Speaking Out against Drug Legalization* (2010), 3, www.justice.gov/dea/pr/multimedia-library/publications/speaking_out.pdf.
[8] National Institutes of Health MedlinePlus, "Pseudoephedrine," www.nlm.nih.gov/medlineplus/druginfo/meds/a682619.html.
[9] SymphonyIRI 2009 consumer household panel.
[10] U.S. Centers for Disease Control and Prevention, "Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2011," *Vital and Health Statistics*, Series 10, no. 256, Table 3, www.cdc.gov/nchs/data/series/sr_10/sr10_256.pdf.
[11] National Institutes of Health, "Understanding a Common Cold Virus," *NIH Research Matters*, April 13, 2009, www.nih.gov/researchmatters/april2009/04132009coldvirus.htm.

physician visit, respectively, Avalere estimated $32.4 million in additional costs for private and public payers. With an estimated $26.6 million in consumers' out-of-pocket expenses—co-pays as well as costs incurred by uninsured patients—Avalere's total cost estimate for the first year was $59 million.[12]

A prescription-only policy for PSE medicines would also result in more absenteeism and lost work productivity. Already, lost productivity due to the common cold is estimated to cost nearly $25 billion annually, including decreased at-work productivity ($16.6 billion), missed worked due to an individual's illness ($8 billion), and missed work due to caretaker responsibilities ($230 million).[13] A prescription-only policy for PSE medicines would only expand this loss of productivity as people would have to miss more work or school for additional doctor visits or go without a medicine that they previously could have gotten over-the-counter.

In addition to these costs, another economic burden of a prescription-only policy would be higher drug prices that the policy would induce. Avalere estimates that such a policy would increase drug prices by 35 percent, resulting in higher expenditures for private health insurance companies and government health care programs, which for the most part do not currently cover PSE medicines. Added to the increase in costs associated with physician visits, higher drug prices would in turn lead health insurance companies to charge higher premiums, which would affect all insured people, even those not requiring PSE medicines. As Avalere describes, "Prescription drugs typically face more labeling, handling, storage, and dispensing requirements relative to OTC products. Each of these supplemental requirements results in additional activities and costs for manufacturers and pharmacies, driving the price of the product upward and resulting in higher costs to consumers and their health plans."[14]

On the government side, beyond the increase in costs for government health care programs associated with physician visits and coverage of PSE medicines, state governments would suffer an estimated loss of $219.2 million in tax revenues over ten years if PSE medicines were no longer sold over-the-counter.[15]

Indirect Effects of a Prescription-Only Policy

The direct negative economic impacts outlined above are just one measurement of how consumers are adversely impacted by restricted access to the medicine of their choice. Policymakers should also factor in the indirect consequences when making policy decisions. On top of the illness or allergies from which they seek relief, consumers who legitimately use PSE medicines would also face significant indirect effects if these medicines were available only by prescription.

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[12] Avalere Health, "Managing Access to Pseudoephedrine: Potential Impacts of a Prescription-Only Policy versus Real-Time Stop Sale Technology," December 2011, 19.
[13] Thomas J. Bramley, Debra Lerner, and Matthew Sarnes, "Productivity Losses Related to the Common Cold," *Journal of Occupational and Environmental Medicine* 44, no. 9 (September 2002).
[14] Avalere Health, "Managing Access to Pseudoephedrine: Potential Impacts of a Prescription-Only Policy versus Real-Time Stop Sale Technology," 15.
[15] Ibid., 17.

According to a 2010 Asthma and Allergy Foundation of America survey of cold, allergy, and flu sufferers, a majority of those surveyed were not convinced that the alternative provides the same level of relief as the drugs that use PSE as the primary ingredient. Respondents in this survey noted that requiring a prescription of individuals who are ill and in need of their preferred decongestants is an unnecessary burden.[16]

Under a prescription requirement, some people would elect not to see a physician to get a prescription, opting instead to buy a non-PSE cold or allergy medicine. These consumers would bear the burden of being driven off of a preferred product they know to be helpful and onto one they do not prefer, which may not adequately address their needs. Other people may choose to suffer through their symptoms without treatment, neither seeing a doctor for a prescription nor buying a less-preferred alternative. Booz & Co. recently released a study of the seven most popular over-the-counter medicines (including cold and allergy medicines) and found that if these over-the-counter medicines were not available, 60 million people would simply not seek treatment.[17]

In economics, the effect of a policy that drives consumers to change their behavior is known as excess burden. Excess burden is often discussed in the context of taxes, but in a sense, the burden of a prescription-only policy for a nonprescription product is analogous to the burden of a tax. A tax affects both those who pay the tax and those who alter their behavior to avoid paying the tax. Similarly, a prescription-only policy affects both those who bear the burden of obtaining a prescription and those who alter their behavior because of the restriction.

As I explain with my American Enterprise Institute colleague Alan Viard, "Excess burden measures the extent to which a tax [or policy change, in the case of PSE] interferes with the taxpayer's [or consumer's] freedom to choose his or her preferred behavior . . . In other words, the excess burden arises because the tax changes the incentives confronting consumers."[18]

Using the example of a soda tax, we illustrate why excess burden is a problem: "The tax gives consumers an artificial incentive to avoid purchasing soda, because their tax liability goes down when they buy fewer cartons. Unfortunately, responding to this incentive prevents mutually beneficial transactions between consumers and producers from taking place."[19] While the consumers and producers may be different in the context of PSE medicines, a prescription-only policy would prevent mutually beneficial transactions from occurring in much the same way a tax would.

Avalere estimates that PSE utilization would decrease 83 percent under a national prescription-only policy.[20] The loss of consumer welfare among legitimate PSE users in this group is a large and

[16] Asthma and Allergy Foundation of America and Harris Interactive, "Pseudoephedrine Awareness Study," 2010.
[17] Booz & Co., "The Value of OTC Medicine to the United States," January 2012.
[18] Alex M. Brill and Alan D. Viard, *The Real Tax Burden: More Than Dollars and Cents* (Washington, DC: AEI Press, 2011), 4, 8.
[19] Ibid., 8.
[20] Avalere Health, "Managing Access to Pseudoephedrine: Potential Impacts of a Prescription-Only Policy versus Real-Time Stop Sale Technology," 18–19.

important cost to consider, above and beyond both the costs imposed directly on consumers who obtain prescriptions for PSE medicines and the costs endured broadly by the health care sector.

Conclusion

Meth addiction is a serious problem with devastating consequences for individuals, families, and communities. In addition to law enforcement efforts, policy measures to curb meth production are entirely appropriate and necessary. Federal legislation in 2005 has been helpful in stemming the growth in meth production and abuse, but the general consensus is that more could be done in the policy realm. But policies to address domestic meth production, including restricting access to PSE medicines, must consider all foreseeable consequences.

In this paper, I have offered a prime example of the importance of a holistic assessment of policy proposals for addressing meth abuse: making PSE medicines prescription-only is potentially more burdensome than beneficial. Two considerations in particular are vital. First, policymakers must bear in mind that requiring prescriptions would not be 100 percent effective at curbing PSE diversion. Many prescription drugs are heavily abused, despite their prescription status, to the extent that the U.S. Centers for Disease Control has labeled prescription drug abuse a "public health epidemic." In fact, according to the 2011 National Drug Threat Assessment, deaths from prescription drug overdoses outnumber deaths due to cocaine, heroin, and meth combined.[21] Second, and perhaps more important, making PSE medicines available by prescription only would have significant economic and societal costs. Clearly, these two outcomes must be taken into account in any objective evaluation of the overall effects of such a policy.

[21] U.S. National Drug Intelligence Center, "National Drug Threat Assessment," August 2011, www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf.

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