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On Behalf of the Consumer Healthcare Products Association
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Thank you for the opportunity to testify today. My name is Linda Suydam and I am President of the Consumer Healthcare products Association, the trade association representing the manufacturers of over-the-counter (OTC) medicines. Before coming to CHPA, I spent 21 years with the Food and Drug Administration, including serving as senior associate commissioner.

Senator Feinstein and Senator Grassley, it is an honor to appear before you today. The two of you have been leaders on the issue of methamphetamine abuse for a number of years and we applaud the efforts you have taken to date to address this horrible situation.

As we look for new ways to fight the diversion of nonprescription medicines containing pseudoephedrine (PSE) into meth production, I want to express our industry's commitment to working with you to rid our nation of the scourge of meth labs. Our goal is to stop illegal pseudoephedrine sales while maintaining over-the-counter access for legitimate consumers who rely on these medicines.

I understand you are exploring the viability of the Oregon model today, and I want to address that issue, both by noting some of the issues involved in the Oregon approach, but more importantly, by offering you a different solution to the meth lab problem that creates a federal framework for a national electronic tracking system. By enhancing the existing framework of the Combat Methamphetamine Epidemic Act (CMEA), such a system will more effectively and comprehensively address the problem head on. Let me first frame the issue from our perspective, then address some of the issues we see in Oregon, and then explain to you why a federal requirement that PSE products be sold only if electronically tracked is the right and comprehensive solution to eliminating meth labs nationally.

SCOPE OF THE ISSUE

Let me first address PSE products in general, and the scope of the issue in particular. The OTC industry in the United States accounts for roughly $30 billion in sales annually. Of that, about $4.1 billion is in the cough and cold category. Sales of PSE-containing products are about $600 million.

Maintaining access to non-prescription pseudoephedrine is important because pseudoephedrine is unique and for many consumers it is the ingredient that works best for them. Despite legal restrictions that limit PSE sales quantities, require PSE to be sold only from behind the counter, and require consumers to sign a sales logbook, 15 million Americans per year still choose these medicines over other products for effective relief from allergies and colds.

While there are other decongestants available over-the-counter, pseudoephedrine is unique. Approved by the U.S. Food and Drug Administration for nonprescription use in 1976, PSE is a safe and effective active ingredient for the relief of congestion associated with colds and allergies. It is a key ingredient in leading cold and allergy medicines like Sudafed, Claritin-D, Zyrtec-D, and a number of other brands and store label medicines. . PSE is pharmacologically different from other decongestants and, even with sales limits and location restrictions placed on PSE in the last several years; it remains the nonprescription oral decongestant of choice for over 15 million Americans each year.

To ensure that consumers could still have access to an unrestricted oral OTC decongestant, manufacturers of cold and allergy medicines reformulated many products by substituting phenylephrine (PE), an alternative oral decongestant also approved by FDA for use in OTC medicines. Millions of consumers, however, still choose PSE as their decongestant because it works better for them. .

It is also important to note that phenylephrine is metabolized more quickly than PSE and cannot be formulated in a long-lasting dose (12 or 24 hour), so popular medicines with long-lasting doses like Claritin-D, Zyrtec-D, and Sudafed must use PSE. Unlike PE, which is only available in conventional formulations to be taken every 4 hours, PSE is available as 12-hour and 24-hour sustained-release tablets which are taken only once per 12 hours or 24 hours, respectively. As with all sustained-release formulations, this reduces the so-called "pill burden", increasing consumer convenience and reducing the risk of medication errors.

From a regulatory point of view, all sustained-release PSE formulations represent advanced drug development products which were approved individually by FDA through New Drug Applications in the 1980s and 1990s.

The Scope of the Problem

Contrary to some reports, the vast majority of PSE medicines are sold for their intended use. A comparison of meth labs and PSE sales data shows no correlation between sales in states with many meth labs compared to states with very few labs. In other words and despite undocumented assertions, the diversion of PSE into meth labs is such a small portion of overall sales that it is not measurable in sales patterns between states with and without meth labs.

According the Drug Enforcement Administration, the majority of meth is imported into the United States as a finished product. Some meth, however, is produced domestically by “meth cooks” who manufacture meth by combining a number of easily obtainable ingredients, often including OTC cough/cold and allergy medicines containing PSE.

To prevent the criminal diversion of PSE to the illegal production of methamphetamine, the CMEA, which was signed into law in 2006, requires all PSE-containing OTCs to be secured behind a sales counter, limits purchases to 3.6 grams per day and 9 grams per 30 days, and requires a purchaser’s signature in a logbook that is accessible by law enforcement.

The CMEA and similar state laws reduced meth labs nationally by over 65 percent from their peak in 2003 to a low in 2007. In the last couple of years, however, meth lab incidents in the hardest-hit states started increasing because criminals are exploiting the inability of the current system to block illegal sales before they happen. Many meth cooks are getting around sales limits by "smurfing" – accumulating illegal amounts of PSE by buying legal quantities at multiple stores.

The meth lab problem, however, remains confined to a relatively small number of states. In 2009, 78% of nation's reported meth labs were in just 10 states, covering 20% of the U.S. population.

As I will discuss in further detail below, today we are calling on Congress to amend the Combat Methamphetamine Epidemic Act to require that all over-the-counter pseudoephedrine sales be tracked through a nationwide electronic tracking system that can block illegal sales and help law enforcement identify meth cooks.

10 states already have taken this step, passing legislation requiring retailers to use a statewide electronic tracking system for pseudoephedrine sales. We are working with retailers in 8 of these states by funding the National Precursor Log Exchange, or the NPLEx system, which allows them to comply with these new laws.

Will the Oregon Approach Solve the Problem?

While 10 states have concluded that electronic tracking strikes the right balance, Oregon adopted a prescription mandate.

Oregon has seen meth labs drop 98% from 587 in 2001 to 10 labs in 2009. But it's easy to draw the wrong conclusion from these numbers, because during the same period Washington State, which did not have a prescription mandate, saw meth labs drop 97% from 1,480 to 39 labs. The fact is that the meth lab problem has dramatically abated in many States in the West -- without a prescription mandate.

Meth Lab Incidents* in Western States

	2001	2002	2003	2004	2005	2006	2007	2008	2009	
Arizona	312	253	140	122	75	41	15	10	11	96%
California	1883	1743	1287	764	470	353	286	346	181	90%
Idaho	131	119	91	42	21	16	16	8	8	94%
Nevada	259	105	131	79	52	35	14	6	9	97%
Oregon	587	525	419	472	189	55	22	21	10	98%
Utah	162	121	85	72	54	15	5	7	3	98%
Washington	1480	1443	1011	947	532	206	238	137	39	97%

* DEA *El Paso Intelligence Center (EPIC) National Clandestine Laboratory Database*

When contrasted with electronic tracking, prescription mandates simply fall short as a solution for addressing meth labs. They impose new costs on consumers and the healthcare system,

while offering none of the law enforcement benefits of electronic tracking. Prescriptions are a healthcare function, not an effective law enforcement mechanism, as shown by the widespread and growing diversion and abuse of prescription medicines.

Under a prescription mandate,

- Consumers bear new costs for repeated doctor visits and prescriptions.
- Consumers without insurance are even harder hit.
- Healthcare payors will either bear new costs or leave consumers on their own to cover all the costs associated with acquiring PSE through a prescription.
- Consumers lose access to needed medicines when pharmacies aren't open.
- Current nonprescription sales limits would no longer apply, so meth cooks who can obtain a prescription could purchase unlimited amounts of PSE.
- There is no system for real-time blocking of illegal sales.
- There is no system to block sales across state lines or even identify meth cooks who are crossing state lines.

Requiring a prescription for PSE purchases means that doctors would have to play a law enforcement role to prevent doctor-shopping meth cooks from obtaining a prescription and by seeing patients unnecessarily with complaints including seasonal allergies and the common cold, which is valuable time better spent on patients who actually need a doctor's attention.

Cash-strapped state governments would face a heavy burden if they were required to absorb additional Medicaid costs, as well as lose sales tax revenues generated by PSE products due to prescription tax exemptions in many states.

In addition to the strain placed on consumers, providers and state governments, the simple fact is that moving PSE to prescription status only would create new and more complicated law enforcement challenges.

We all know the terrible toll that prescription drug abuse takes on our population. Meth cooks will use the same loopholes in the prescription system that others exploit to get their hands on prescription drugs.

There many different prescription monitoring programs in the states, they don't interface with one another, and none offers the functionality of the NPLEx system.

The bottom line is that a multi-state approach to electronic PSE sales tracking offers far more for law enforcement than a prescription approach, with none of the prescription downsides for consumers and the healthcare system.

A Better Solution – National E-Tracking

As noted above, we are today asking Congress to require that all over-the-counter pseudoephedrine sales be tracked through an electronic system – basically we are asking that

the current, largely paper system be modernized to provide a system that will work seamlessly across all states. This can be done within the framework created by CMEA – simply shifting today's logbook requirements to an electronic tracking requirement that will block excessive sales to potential abusers, and provide law enforcement a valuable tool to pursue criminals operating these dangerous and illegal meth labs.

The idea of an electronic tracking system is neither experimental nor costly -- since enactment of the CMEA in 2006, 10 states have looked at ways to address this problem and have enacted laws requiring electronic tracking of PSE sales, Oklahoma, Arkansas, Kentucky, Louisiana, Illinois, Missouri, Kansas, Washington, Alabama and Washington. Electronic tracking is a way to link all log-books electronically – store by store, county by county and even state by state – so that an individual can be stopped from buying above the legal limit if they already have made a purchase at a different location.

Oklahoma, Arkansas, and Kentucky led the way in implementing electronic tracking systems. As an industry, when we saw that the technology was available to run systems like these, and heard reports from law enforcement that they are a huge advance over the current system, we became convinced that electronic tracking strikes the right balance between preserving access for legitimate purchasers of PSE-containing medicines while blocking meth cooks from accessing illegal quantities of the product.

It also became clear that the most significant barrier to getting electronic tracking systems off the ground was the lack of state funds. In 2008, our member companies came together to explore how they could offer an industry-funded system to states with meth lab problems. Following an RFP process in the fall of 2008, our member companies executed contracts with Appriss, Inc., to develop and deploy a multi-state, real time electronic tracking system now known as the National Precursor Log Exchange (NPLEx).

Further supporting the development of the NPLEx system, last year the National Sheriffs Association called for the use of a multi-state electronic tracking system to more effectively enforce current law and fight domestic meth production. Law enforcement officials in many States including the Louisiana State Police, the Illinois State Police, the California Sheriffs Association, the Kansas Sheriffs Association and the Washington Association of Sheriffs and Police Chiefs are calling for the implementation of electronic tracking systems.

NPLEx soon will be operational in 8 of the 10 states that require electronic tracking of PSE sales, Kentucky, Louisiana, Illinois, Missouri, Kansas, Washington, Alabama and Washington.
Through cutting edge technology, NPLEx is the only multi-state system for controlling drug dispensing and offers robust functionality that is simply not available in the prescription drug arena. Key features of NPLEx include:

- Effective enforcement of PSE sales limits through real-time blocking of illegal sales.
- Seamless connectivity from all stores in every NPLEx state, working across state lines.
- Unified logging of purchase records already required by law.

- Identification of meth cooks for law enforcement.
- Secure data storage legally accessible only by law enforcement.
- Faster sales transactions for retailers and consumers.
- A safety override that allows and records a sale made under duress.
- No new burdens on legitimate consumers.
- No access charges for retailers, pharmacists, or law enforcement.

The multi-state NPLEx system is just now being deployed, but states that have been using electronic tracking are seeing the results.

- Electronic tracking systems block thousands of attempted purchases.
- Reported meth labs are increasing as electronic tracking helps law enforcement find previously-undiscovered labs.
- Electronic tracking leads to 70 percent of meth lab busts in key Kentucky counties.
- In a Florida pilot project, electronic tracking reduced illegal sales by over 90 percent.

We all recognize how powerful meth addiction is, and that it needs a full-scale, comprehensive approach, including education and treatment. We believe that this comprehensive approach includes the use of an effective electronic tracking system to keep PSE out of the hands of meth cooks. That is why we have offered the NPLEx system and advocated for its adoption in the states.

Although the meth lab problem is confined to a relatively small number of states, we also believe that a comprehensive, national electronic tracking system will help ensure no state border is a barrier to effective enforcement of the CMEA.

That is why we are calling on Congress to pass legislation requiring the use of electronic PSE sales tracking nationwide, our member companies are committed to a nationwide deployment of the NPLEx system to respond to such a requirement, and I am pleased to say that leading retailers also support our call for Congressional action.

Conclusion

As one who spent 21 years of my career at FDA prior to my current position, I know first-hand the rigor used in determining the safety and effectiveness of a medication before allowing it to be sold to the public without a doctor's supervision. I believe strongly that the placement of a medicine on prescription status should remain a medical question, rather than a law enforcement issue. This is especially true when, as is the case with pseudoephedrine, we have an alternative and better mechanism to meet law enforcement needs without placing new burdens on consumers.

As an industry, we look forward to working with you on federal legislation to enable the nationwide deployment of NPLEx to provide one, unified system.

Thank you again for the opportunity to testify today.