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March 31, 2021

The Honorable Rachel Prusak  
Chair, Oregon House Committee on Health Care  
900 Court St. NE, H-489  
Salem, OR 97301

**RE: HB 2648 - Related to Pseudoephedrine Containing Medications - SUPPORT**

Dear Chairwoman Prusak:

On behalf of the Consumer Healthcare Products Association (CHPA), the national trade association representing the leading manufacturers of over-the-counter (OTC) medications, dietary supplements, and consumer medical devices, I'm writing to express strong support for HB 2648. The legislation proposes to allow pharmacists or pharmacy technicians to sell medications containing pseudoephedrine (PSE) without a prescription to any individual over the age of 18. HB 2648 brings the State of Oregon in line with every other state in the country, by providing increased access to affordable medications for consumers, limiting unnecessary visits to already overloaded doctor's offices, and allowing consumers to purchase some of the most effective and popular cold and allergy decongestants on the market today.

**What Is Pseudoephedrine (PSE)?**

PSE is a safe and effective active ingredient found in some of the most popular cold and allergy medications on the market today. It is one of only two orally ingested decongestants approved by the Food and Drug Administration (FDA) for over-the-counter (OTC) sale and has been available without a doctor's prescription in the United States since 1976. PSE can be found in medications such as Sudafed, Zyrtec-D, Allegra-D, Claritin-D, Mucinex-D, and many others. Unlike other decongestants, PSE comes in extended release tablets, allowing for 12- and 24-hour periods of congestion relief. For many Americans, it is the only decongestant that works, and the only one that get them through the night and through the workday without having to take additional doses of medicine.

**How Is PSE Regulated?**

In 1976, the FDA made PSE containing medications available for OTC sale. Manufacturers could package PSE containing medications with few restrictions, retailers could sell as much product as they would like, and consumers could purchase as much PSE as they needed in dealing with annual cold and allergy seasons.

In 2006, President Bush signed the Combat Meth Epidemic Act (CMEA). The act placed medications containing PSE where customers do not have direct access to them ("behind the counter"), limited daily (3.6 grams) and monthly (9 grams) allowable purchase limits for consumers, required individuals to present identification to purchase PSE containing medications, and made retailers keep personal information about customers who purchase PSE for at least two years after the purchase on a paper or electronic log.

That same year, the State of Oregon became the first state in the country to categorize PSE as a Schedule III controlled substance, requiring consumers to obtain a doctor's prescription for



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the purchase PSE containing medications. Oregon is the only state in the Union with this regulation. All 49 other states allow consumers to purchase PSE containing medications without having to take time off work and endure the expense of a visit to a physician.

### **Why Is PSE Regulated?**

While PSE is a safe and effective decongestant when used as directed, it can also be diverted by criminals from its intended use and in the illegal manufacture of methamphetamine. As methamphetamine use and domestic production of the drug increased rapidly in the United States at the turn of the century, some states and the federal government began to restrict the sale of PSE since it is a precursor to methamphetamine. According to the Drug Enforcement Administration, “meth labs” peaked in 2004 when 23,703 meth lab incidents were reported. Meth labs have declined steadily since that time and are now at their lowest level (890 in 2019) in 19 years.<sup>1</sup>

### **States Have Rejected Prescription-Only Policies for PSE**

Since Oregon’s adoption of a prescription-only policy for PSE in 2006, only the state of Mississippi followed suit in adopting the same prohibition. That law, adopted in 2010, was recently repealed. Starting in January of 2022, the State of Oregon will be the only jurisdiction in the country (state or local) that will require consumers to obtain a doctor’s prescription for the purchase of FDA approved medications containing PSE.

The vast majority of states – including Oregon neighbors Washington, Idaho, and Nevada - have instead chosen to regulate PSE medications by adopting a real-time, stop-sale, system that blocks the illegal sale of PSE at the point-of-sale and across state lines. This system, known nationally as the National Precursor Log Exchange (NPLEx), is mandated by 36 states nationwide. Two other states (California and New York) allow its use voluntarily and greater than 80% of pharmacies in those states are utilizing the technology. In still other states, many retailers voluntarily use the system as their means to comply with federal requirements. According to the National Association of Drug Diversion Investigators (NADDI), the NPLEx system blocked 1.9 million boxes from being illegally sold nationwide in 2020 alone. That accounts for over 5.1 million grams of PSE kept from being illegally obtained.

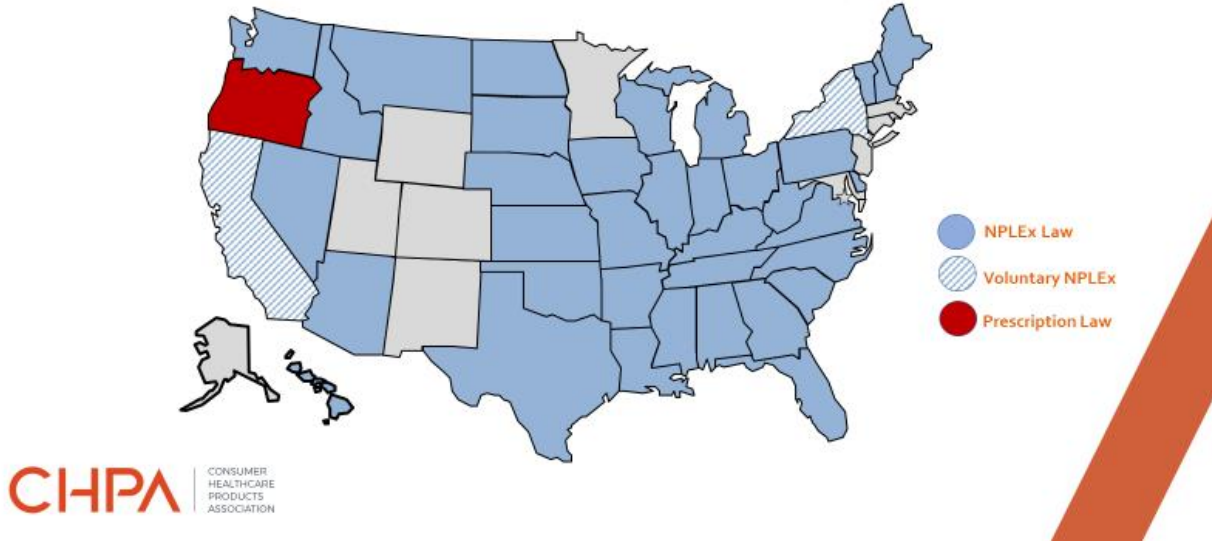
NPLEx is provided free-of-charge to any state that mandates its use. Pasted below is a map of the United States indicating state specific PSE regulation. As the map indicates, only the State of Oregon requires a doctor’s prescription for the purchase of PSE containing medication.

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<sup>1</sup> Drug Enforcement Administration National Drug Threat Assessment, March 2021. [2020 National Drug Threat Assessment \(NDTA\) \(dea.gov\)](#)

## State Reject Prescription Policies for PSE

36 states have adopted NPLEx at no cost to taxpayers



### Prescription-Only Policy for PSE Does Not Work

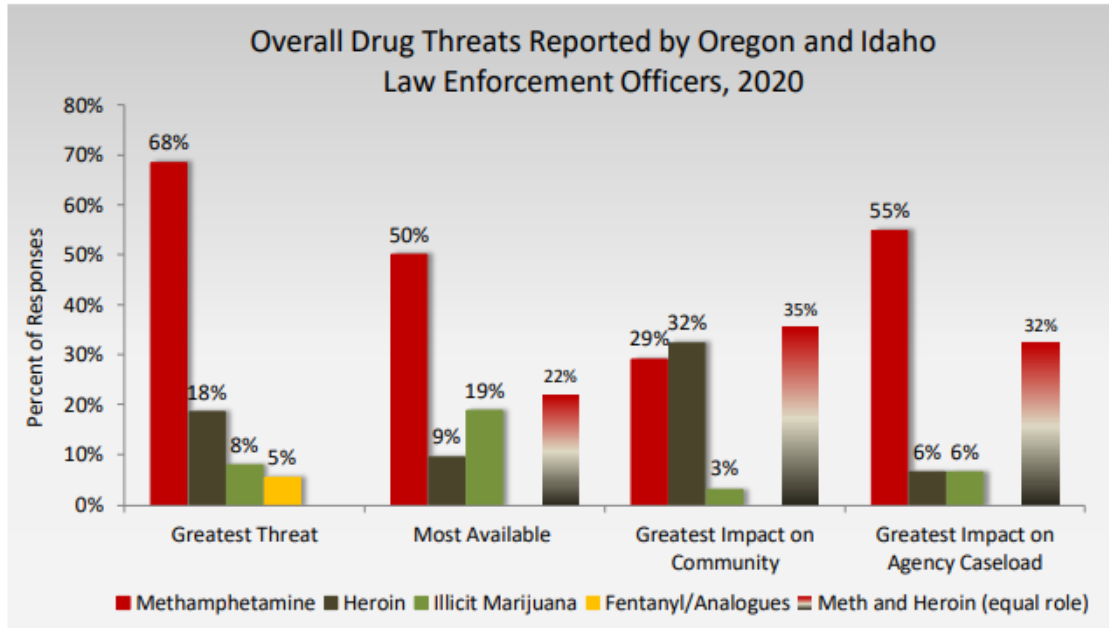
Prescription policy, be it a prescription from a medical doctor or even a pharmacist, is not an effective tool for the prevention of drug diversion. Prescriptions are intended to serve health care professionals in monitoring side effects related to medicine use, and adherence to dosage intake once medicine is dispensed. They are not meant to police diversion of medicine from its intended use. The current prescription drug abuse problem in Oregon and around the country is testament to this fact.

While the regulation of PSE was well intentioned, Oregon's own prescription-only law has done little to impact the methamphetamine problem in the region. In fact, according to the Oregon-Idaho High Intensity Drug Trafficking Area's 2020 Drug Threat Assessment, methamphetamine remains the region's greatest drug threat, is the most readily available illicit drug in the state, and has had the greatest impact on caseloads for law enforcement (see image below). The prescription for PSE law has had little to no impact on the rate of abuse of methamphetamine as a whole, and while domestic meth production in Oregon has dropped dramatically (from 192 labs seized in 2005 to 1 in 2019), Idaho experienced similar low production as only 4 labs were seized between 2014 and 2019.<sup>2</sup> Idaho, however, does NOT require a prescription for PSE. As the National Alliance for Model State Drug Laws pointed out in its 2015 study of the methamphetamine landscape, Oregon's drop in meth labs were not unique. Similar decreases in the number of meth lab incidents occurred in surrounding states, lab incidents were reduced prior to the passage of the prescription-only law, and the decline in meth labs was due more to outside sources of supply than to the passage of the

<sup>2</sup> [THREAT ASSESSMENT & STRATEGY – Oregon-Idaho High Intensity Drug Trafficking Area \(oidhida.org\)](https://www.oidhida.org/THREAT_ASSESSMENT_STRATEGY)

PSE prescription legislation.<sup>3</sup> The National Association of State Controlled Substance Authorities came to similar conclusions when they examined the law as well.<sup>4</sup>

**Figure 2.**



Note: The response category *Meth and Heroin (equal role)* was not an available option for the survey question on greatest drug threat. Total survey responses=38 (49% response rate). Source: 2020 Oregon-Idaho HIDTA Drug Threat Survey.

### Prescription Laws Penalize Law Abiding Citizens

Congestion related to the common cold and allergies can severely hamper the quality of life for the individual suffering from the ailment. Allergies in particular can cause sneezing, itching of the nose and eyes, stuffy and runny nose, and even swollen and watery eyes. Congestion can prevent individuals from getting a full night's sleep and adversely impacts productivity in the workplace. In some cases, lack of treatment for allergies can develop into more serious illnesses like asthma. Treatment of respiratory ailments has become a much greater concern in light of the recent COVID-19 pandemic. Unfortunately, residents and visitors to Oregon are prevented from addressing congestion with one of the most effective and affordable over-the-counter solutions available today. In fact, according to NADDI, 40,221 Oregonians crossed state lines in 2020 alone to purchase just under 100,000 boxes of PSE containing medications. Despite a national lockdown due to the COVID-19 pandemic, cold and allergy suffering Oregonians took on the risk of the drive just to gain congestion relief.

### Pharmacist Prescription Is Still Prescription

<sup>3</sup> National Alliance for Model State Drug Laws (NAMDSL). Pseudoephedrine Prescription Laws in Oregon and Mississippi. A Study of the Current Methamphetamine Landscape. Carnevale Associates, LLC. June 30, 2015.

<sup>4</sup> "Impact of State Laws Regulating Pseudoephedrine on Methamphetamine Production and Abuse A White Paper of the National Association of State Controlled Substance Authorities"  
<http://nascsa.org/PDF/pseudoephedrineWhitepaper4.18.16.pdf>



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Some proponents of the existing prescription only law for PSE suggest a pharmacist prescription as a middle ground compromise. In the end, however, a prescription requirement is a prescription requirement. There really is no difference. Shifting liability from a medical doctor to a pharmacist will only cause pharmacies to choose not to sell PSE products from behind-the-counter. Therefore, law abiding consumers will continue to lack the access to these medications that are afforded residents of 49 other states.

Unlike PSE purchases made without a prescription, PSE dispensing via a prescription have no daily or monthly purchase limits. As a result, criminals can obtain as much PSE as they desire, thus increasing the risk of diversion for illicit purposes.

### **Conclusion**

In recent years, consumers have taken an exceedingly greater interest and responsibility for their own health. The COVID-19 pandemic has only exacerbated that trend. Readily available over-the-counter medications play a critical role in the wellness regiment of millions of Americans – including thousands of cold and allergy suffering families in the State of Oregon.

Unfortunately, the existing prescription requirement for PSE containing medications has a negative impact on this positive public health trend. Oregon is the only state in America that does not allow PSE containing medications to be sold without a doctor's prescription. This policy hurts families that can least afford it without any unique peripheral benefit to the state or its law enforcement.

HB 2648 would repeal this law and bring it in line with the rest of the United States. Additionally, it would install the NPLEx system to govern all sales of PSE just as it is in 36 other states.

Thank you for the opportunity to comment on this important legislation. Feel free to contact me directly with any follow up questions you may have.

Sincerely,

A handwritten signature in blue ink that reads 'Carlos I. Gutiérrez'.

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Cc: Members of the House Committee on Health Care