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GOVERNOR

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TESTIMONY ON SENATE BILL 2474
A BILL FOR AN ACT RELATING TO PSEUDOEPHEDRINE
by
Jodie F. Maesaka-Hirata, Director
Department of Public Safety

Senate Committee on Health
Senator Josh Green M.D., Chair
Senator Clarence K. Nishihara, Vice Chair

Monday, February 13, 2012, 1:15 PM
State Capitol, Conference Room 229

Chair Green, Vice Chair Nishihara, and Members of the Committee:

The Department of Public Safety (PSD) supports Senate Bill 2474 that proposes to make pseudoephedrine and pseudoephedrine containing products a Schedule V controlled substance.

The Legislature passed Act 184 in 2008 that mandated that all retail distributors selling products, mixtures, or preparations containing pseudoephedrine must electronically report all retail sales data to the Narcotics Enforcement Division (NED) on a monthly basis. Pseudoephedrine control and tracking has been very successful in Hawaii in reducing the amount of clandestine laboratories manufacturing methamphetamine, commonly referred to as "ICE." NED formed a partnership with the Western States Information Network (WSIN/RISS) whose mission is to support law enforcement efforts

nationwide to combat illegal drug trafficking, identity theft, human trafficking, violent crime, terrorist activity, and to promote officer safety in Alaska, California, Hawaii, Oregon, Washington, as well as Canada and Guam to host the pseudoephedrine tracking database.

The electronic tracking log is an impressive first step for the State to attempt to track retail pseudoephedrine sales and decrease the production of methamphetamine (ICE). This tracking system has a few shortcomings, unlike Hawaii's electronic prescription monitoring program a system that reports all controlled substance prescription data monthly, the pseudoephedrine tracking program does not report information relating to persons purchasing just under the 3 grams per day or a 9 gram a month limits. Presently, most of the sales of pseudoephedrine containing products are sold at pharmacies and that many of the non-pharmacy retail distributors no longer carry pseudoephedrine containing products and are now selling over the counter "pseudoephedrine PE" products that cannot be utilized to manufacture methamphetamine.

PSD would like to recommend an amendment to Senate Bill 2474 Section 2, page 3 lines 5 through 11 to read as follows:

"(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers[.-] <u>that contain pseudoephedrine and pseudoephedrine containing products.</u>"

PSD finds that Section 3 of Senate Bill 2474 is unnecessary and request that it be deleted from the bill. If Pseudoephedrine is made a schedule V controlled substance, all dispensers of the drug are mandated to electronically report all dispensations through the department's electronic prescription accountability system delineated under Chapter 329, Part VIII, Hawaii Revised Statutes.

PSD is recommending that subsection 4 of Section 329-64(a) on page 9 lines 14 through 22 be deleted. This would delete the exemption for the sale of over the counter pseudoephedrine and pseudoephedrine containing products.

PSD is also recommending that Senate Bill 2474 repeal Sections 329-73 Pseudoephedrine permit, 329-74 Unlawful transport of pseudoephedrine and 392-75 Sales of products, mixtures, or preparations containing pseudoephedrine; reporting requirement for wholesalers. All of these sections will not be necessary if pseudoephedrine is made a schedule V controlled substance.

Senate Bill 2474 enacted would allow pharmacies to report all sales on Hawaii's electronic prescription monitoring program, saving on the reporting of data on two separate systems as well as allow the Narcotics Enforcement Division the ability to track the dispensing of this controlled substance.

For these reasons the department supports passage of Senate Bill 2474 with the proposed amendments.

Thank you for the opportunity to testify on this matter.

HDMA
Healthcare Distribution Management Association

February 13, 2012

The Honorable Sen. Josh Green, M.D.
Chair, Senate Committee on Health
Hawaii State Capitol, Room 229
415 S. Beretania Street
Honolulu, HI 96813

Re: S.B. 2474 and S.B. 2361 (PSE Schedule V controlled substance)

Dear Senator Green:

On behalf of its nine full-service wholesale drug distributor members doing business in Hawaii including two with facilities in state, the Healthcare Distribution Management Association (HDMA) respectfully submits the following comments for your consideration regarding S.B. 2474 and S.B. 2361. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 200,000 pharmacies, hospitals, nursing homes, physician offices and clinics nationwide.

As an advocate for the safe, reliable, and efficient distribution of the nation's healthcare products supply, HDMA shares the objective of S.B. 2474 and S.B. 2361 in preventing precursor chemicals, such as pseudoephedrine, from being purchased in excess or stolen at the pharmacy level and being abused. However, without additional clarifying language S.B. 2474 and S.B. 2361 will have a significant, negative impact on legitimate drug distribution that we believe may be unintended. Classifying products that contain pseudoephedrine as a Schedule V controlled substance will require distributors located in Hawaii to place an overwhelming volume of over-the-counter products containing pseudoephedrine in cages within secure warehouses. Schedule V designation would significantly change current inventory practices and safeguards.

Drug distribution centers are highly regulated, secure, restricted access facilities that must pass regular inspections conducted by both the DEA and the Hawaii Board of Pharmacy. Distribution facilities that are currently licensed to distribute other controlled substances are subject to multiple security and recordkeeping procedures that include: (1) employee screening; (2) restricted access; (3) alarm systems; (4) self-locking and self-closing doors; and (5) inventory control systems.

As a result, DEA registered controlled substance distributors meet the objectives of S.B. 2474 and S.B. 2361 —storing products in a secure, restricted access, highly monitored location with strict recordkeeping requirements. These facilities have not been a source of pseudoephedrine diversion. Therefore, HDMA respectfully asks you to consider adding the following language exempting distributors from the additional storage and handling burdens triggered by S.B. 2474 and S.B. 2361:

"This section does not apply to wholesale drug distributors licensed and regulated by the Hawaii Board of Pharmacy and registered with the United States Drug Enforcement Administration, and exempts them from storage, reporting, recordkeeping or physical security control requirements for controlled substances containing pseudoephedrine."

Thirteen states, including Oregon and Mississippi, that have passed legislation or regulations classifying pseudoephedrine as either a Schedule III or V controlled substance have included similar language for

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wholesale drug distributors. These states recognize that subjecting wholesale distributors to any additional requirements in terms of storage or recordkeeping would be duplicative in light of the strict controls that are already imposed at both the federal and state level.

If you have any questions or need additional information, please do not hesitate to contact me at 703-885-0214.

Sincerely,

Elizabeth A. Lankford

Elizabeth A. Lankford
Manager, State Government Affairs
Healthcare Distribution Management Association

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TO: COMMITTEE ON HEALTH

Senator Josh Green, M.D., Chair

Senator Clarence K. Nishihara, Vice Chair

DATE: Monday, February 13, 2012

TIME: 1:15 p.m.

PLACE: Conference Room 229

FROM: Hawaii Food Industry Association - Lauren Zirbel, Executive Director

RE: SB 2361 RELATING TO PSEUDOEPHEDRINE and SB 2474 RELATING TO HEALTH

Chairs & Committee Members:

In opposition.

We estimate that upwards to 100,000 citizens and tourists in Hawaii would be required to visit a doctor if a prescription were required to purchase pseudoephedrine products. **This would exacerbate current provider shortages through resulting physician office visits.**

We estimate sales of pseudoephedrine in Hawaii to be around 250,000 packages.

Most meth is imported into the U.S. as a finished product. Approximately 20% is sourced from the U.S., with 80% from "superlabs" and less than 20% from small labs.

Electronic Tracking of PSE Sales Presents a Real Solution for Combating Meth Abuse. **E-logs provide real-time approval or denial of PSE purchases at the point-of-sale, creating no access barriers for the 18 million American households that purchase non-prescription cold and allergy medicines to treat their symptoms.**

E-logs enable law enforcement to track real-time activity and search histories, thus identifying "smurfing" operations and labs that might otherwise go undetected. For example, electronic tracking led to 70% of meth lab busts in key Kentucky counties, and reduced illegal sales by more than 90% in a Florida pilot. 19 states have enacted laws that require electronic tracking of PSE sales: Kentucky, Illinois, Louisiana, Iowa, Missouri, Florida, Alabama, S. Carolina, Kansas, Washington, N. Dakota, Nebraska, Indiana, Tennessee, N. Carolina, Michigan, Texas, Oklahoma, and Arkansas. Nationwide, the NPLEx system blocked over 850,000 boxes, accounting for over 2 million grams of pseudoephedrine in 2011 alone.

A prescription-only policy would fail to limit PSE sales, curb meth use, or enable meth lab detection. **In fact, Oregon (a prescription only state) had more meth related deaths in 2010 than they did prior to their Rx law passage**. And Mississippi, another Rx state, ranked 10th in the country in meth labs just last year – more than Texas, Florida, New York, and California!

Law enforcement officials have testified before members of Congress about the effectiveness of e-logs, and communicated their concerns that a prescription-only policy would fail to limit PSE sales or enable meth lab detection.

Federal law currently limits all PSE-containing OTCs to behind the counter, with sales per customer of no more than 3.6 grams per day and 9 grams per 30 days, and requires purchasers to show ID and sign a logbook.

Electronic tracking allows retailers to block illegal sales and enhances law enforcement's suppression and investigative efforts. **Establishing a multistate electronic tracking system for medicines that contain PSE will prevent smurfing across different retailers, even across state lines, and provide a highly efficient law enforcement tool. At the same time, it will create no new barriers for the millions of cold and allergy sufferers looking for relief.**

E-tracking can also be combined with a state's meth conviction records. Oklahoma became the first state to enact a law prohibiting sales of PSE to individuals with meth convictions. State officials used their tracking system to identify individuals who had been blocked from making illegal pseudoephedrine purchases and discovered that as many as 60 percent of those being blocked had prior criminal records, many for drug charges. Now Oklahoma will deny any sales of pseudoephedrine to those individuals, even within otherwise legal quantity limits.

What is the Downside of Rx pseudephedrine?

Unfortunately, reducing or cutting off supply does not guarantee a reduction in demand or use. Mexico, for example, banned pseudoephedrine nearly three years ago. Yet the country is once again the "primary source of methamphetamine" in the U.S., according to the Justice Department's National Drug Intelligence Center's 2010 threat assessment. In fact, Oklahoma estimates that 70 percent of the meth in their state is from Mexico, in a potent, smokeable form called "ice."

Despite extreme actions taken by the Mexican government, drug traffickers and meth cooks have simply found alternative ingredients to use, such as phenylacetic acid, or they illegally smuggle pseudoephedrine to keep meth production viable and profitable.

What is the cost to consumers and taxpayers?

- If only half of the estimated 16 million Americans who use pseudoephedrine each year went to a doctor once a year to obtain a prescription for pseudoephedrine, this would **add three quarters of a billion dollars in healthcare costs** for office visits alone.

- Restricting access to pseudoephedrine products would also decrease sales tax revenues in many states, as over-the-counter medications are subject to sales tax while prescription medications are not.

- Medicaid programs and state employee health and retiree insurance plans would likely face an average of $11.5 million in added costs for increased provider visits and provision of prescription pseudoephedrine.

The Good News:

The OTC industry offering to pay for this system! The Consumer Healthcare Products Association (CHPA)—the trade association representing U.S. manufacturers of nonprescription medicines—supports a multistate electronic tracking system in retail outlets that will monitor all over-the-counter (OTC) PSE purchases in real-time to prevent criminals from exceeding legal limits. Providing an enforcement mechanism for the purchase limits is the best way to curb the diversion of PSE for meth production. States have been passing laws requiring such systems, but in some cases, the laws do not take effect unless funding for them is provided. States began asking for industry support, and industry agreed to help.

Thank you for the opportunity to provide this testimony.

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February 13, 2012

To: Senate Committee on Health
Senator Josh Green, M.D., Chair
Senator Clarence K. Nishihara, Vice Chair

By: Richard C. Botti
On Behalf of LISH

Re: SB 2361 Relating to Pseudoephedrine
SB 2474 Placing Pseudoephedrine as a schedule V drug.
SB 2228 Establishing a tracking system for Pseudoephedrine products.

Chairs & Committee Members:

SB 2361 and SB 2474 proposed addressing the crystal meth issue by punishing tens of thousands of law abiding consumers having cold, flu, and or allergy issues by requiring them to make a Dr. appointment, pay a co-pay fee, and then pay a Rx co-fee.

While it may make sense to those closely related to the meth problem, it doesn't make sense to those that are law abiding citizens that have an immediate problem with their cold, flu, and/or allergy, and know what the solution is to their problem.

Every year at this time, many of us experience an epidemic of URI (Upper Respiratory Infection) where antibiotics are next to useless. Shaking the URI can take well over a month, and can reoccur as soon as the weather get damp and cold again. We have learned to think in advance and make sure we have an adequate supply of pseudoephedrine products on hand, as they are the only products that help control the symptoms. It is a family illness, not just a one person issue. This measure will avoid requiring each of us to go to the doctor, doubling, tripling, or quadrupling the cost and inconvenience, when self diagnosis is a no brainer.

The attached chart best explains what Electronic Tracking will do.

We propose the Legislature address the concerns of meth labs with electronic Tracking.

We not believe anyone that is so possessed to try crystal meth should be placed ahead of honest law abiding citizens by creating major inconvenience, unnecessary cost, and unnecessary suffering. We should not put the criminal element against the needs of the majority.

A former President of your Senate once said to me: "Dick, there are always choices!". This has become a common quote in our household. The vast majority of your constituents make good choices. Those that make poor choices generally are not your constituents, and don't care much about anything in the community. So, why punish us?

We support SB 2228, because it makes sense to go after the problem, not the symptom. The attached chart explains Electronic Tracking, and it won't cost the State.

Electronic-tracking (E-tracking) is the best solution to reducing the production of methamphetamine.		
Electronic Tracking is the Right Solution	**Rx is Too Costly and More Effective Alternatives Exist**	**PSE is Important**
HEADLINE: •1 E-tracking is the best solution to reducing meth labs. It is the only solution that will block illegal sales in real time and prevent meth cooks from buying illegal amounts of PSE.	HEADLINE: •2 A prescription mandate would be very expensive for the healthcare system and would not effectively solve the problem.	HEADLINE: •3 Pseudoephedrine is a unique and important decongestant relied on by over 16 million cold, allergy, and sinus sufferers.
KEY FACTS: •4 E-tracking is a "real-time" system that allows the retailer to refuse an illegal sale, based on purchases made anywhere in the state. E-tracking is the only system that can provide real-time stop-sale across multiple states. •5 Twelve of the 14 states that have taken action to fight illegal PSE sales have rejected prescription mandates and chosen a better solution—electronic stop sale e tracking. •6 E-tracking has a proven track record and blocks thousands of attempted purchases. o1 In the four states that have fully implementing this system, e-tracking technology blocks nearly 40,000 grams of illegal pseudoephedrine sales per month. o2 E-tracking in a Florida pilot project reduced illegal sales by over 90%.	KEY FACTS: •7 If PSE is made Rx, o3 Illegal sales would not be blocked; o4 Current sales limits would not apply; and o5 Lose ability to track illegal purchases across state lines. •8 Making PSE Rx only will: o6 burden millions of consumers with significantly higher costs to get needed medication, o7 force consumers to go to the expense and inconvenience of unnecessary doctor visits, o8 prevent consumers from quickly treating a common cold or chronic allergies with their preferred medicine, and o9 trigger Medicaid coverage, driving up state-budget costs. •9 Supply does not impact demand. Mexico banned PSE nearly three years ago but the country is once again the primary source of methamphetamine in the US, according to the Justice Department's national Drug intelligence Center's 2010 threat assessment.	KEY FACTS: •1 16 million American consumers take pseudoephedrine each year. •2 PSE is pharmacologically different than other decongestants and for some people, is the only oral decongestant that works for them •3 PSE is the only decongestant available for 12 hour and 24 hour relief •4 In a recent nationwide survey, a majority of consumers: o1 oppose an Rx mandate (63%) and o2 think e-tracking was a better solution than an Rx program.