SB40

Measure Title:	**RELATING TO PSEUDOEPHEDRINE.**
Report Title:	**Pseudoephedrine; Prescription Drugs**
Description:	**Reclassifies pseudoephedrine as a schedule III drug which may only be dispensed with a prescription; makes conforming amendments.**
Companion:	
Package:	**None**
Current Referral:	**HTH/CPN, JDL**

NEIL ABERCROMBIE
GOVERNOR

JODIE MAESAKA-HIRATA
INTERIM DIRECTOR

Deputy Director of
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STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
919 Ala Moana Blvd. 4th Floor
Honolulu, Hawaii 96813

No. _____

TESTIMONY ON SENATE BILL 40
A BILL FOR AN ACT RELATING TO PSEUDOEPHEDRINE
by
Jodie Maesaka-Hirata, Interim Director
Department of Public Safety

Committee on Commerce and Consumer Protection
Senator Rosalyn H. Baker, Chair
Senator Brian T. Taniguchi, Vice Chair

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

Thursday, February 10, 2011, 8:30 AM
State Capitol, Room 229

Chairs Baker and Green, Vice Chairs Taniguchi and Nishihara, and Members of the Committees:

The Department of Public Safety (PSD) supports Senate Bill 40 that proposes to make pseudoephedrine and pseudoephedrine containing products, a Schedule III controlled substance. In 2008, the Legislature passed Act 184 that mandated that all retail distributors selling products, mixtures, or preparations containing pseudoephedrine electronically report all retail sales data to PSD's Narcotics Enforcement Division (NED) on monthly bases. Pseudoephedrine control and tracking has been very successful in Hawaii in reducing the amount of clandestine laboratories manufacturing methamphetamine / 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, to promote officer safety in Alaska, California, Hawaii, Oregon, Washington, as well as Canada and Guam, and to host the pseudoephedrine tracking database.

The electronic tracking log was a great 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 this system that reports all controlled substance prescription data the pseudoephedrine tracking program does not report information relating to persons purchasing just under the 3 grams a day or 9 gram a month limits. Presently, most of the sales of pseudoephedrine containing products is sold at pharmacies, and 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.

Senate Bill 40 if 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 NED to monitor all sales ever those just under the existing State and Federal 3 grams a day or 9 gram a month limits.

For these reasons, PSD strongly supports passage of Senate Bill 40.

Thank you for the opportunity to testify on this matter.

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February 10, 2011

Senate Committee on Commerce & Consumer Protection
Senator Roslyn H. Baker, Chair
Senator Brian T. Taniguchi, Vice Chair

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

By: Richard C. Botti or Lauren Zirbel
On Behalf of LISH, and the Consumer Healthcare Products Association

Re: SB 40 RELATING TO PSEUDOEPHEDRINE
SB 586 RELATING TO PSEUDOEPHEDRINE

Chairs & Committee Members:

In opposition to SB 40 and SB 586

This measure would prohibit consumers from purchasing over-the-counter (OTC) cold and allergy medicines containing pseudoephedrine (PSE), and instead require them to see their physician for a prescription in order to purchase these products at a pharmacy.

PSE, a safe and effective active ingredient found in leading cold and allergy medicines to provide congestion relief, can be used to illegally manufacture methamphetamine. As a result, some policymakers and law enforcement officials are seeking to require a doctor's prescription to obtain PSE-containing medicines, even though the vast majority of these medicines are sold to law-abiding consumers.

Since 2006 federal law and some state laws have moved all PSE-containing medicines behind a sales counter, limited purchases to 3.6 grams per day and 9 grams per 30 days, and required a purchaser's signature in a logbook that is accessible by law enforcement. These laws reduced meth labs nationally by more than 65 percent from their peak in 2003 to a low in 2007.

We encourage policy makers to weigh the legitimate need of allergy sufferers who will face unnecessary doctor visits with co-pays, prescription drug co-pays, difficulty finding a doctor when traveling, in the evenings, and in rural areas; against the law enforcement need to reduce meth labs. According to the U.S. DEA, no meth labs have been found in Hawaii since 2006.

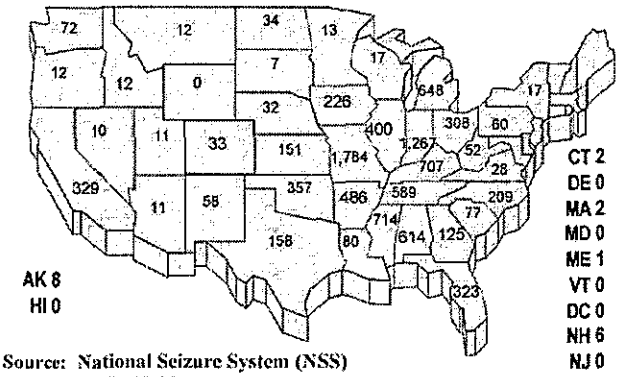
We propose that the current law is working, and this trade-off is not only not necessary, but will create far too great a cost increase to the thousands of legitimate PSE purchasers.

The following pages provide a more detailed information we wish to offer.

Maps of Methamphetamine Lab Incidents

NOTE: These maps include all meth incidents, including labs, "dumpsites" or "chemical and glassware" seizures.

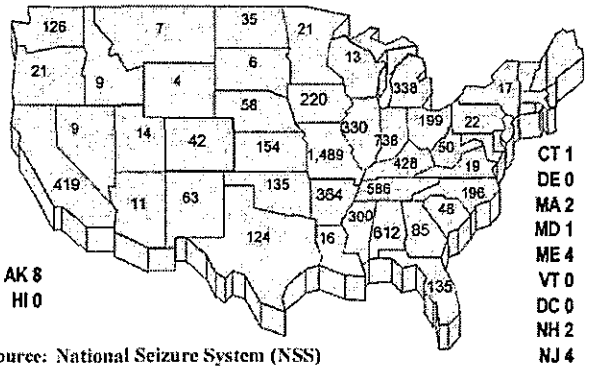
Total of All Meth Clandestine Laboratory Incidents
Including Labs, Dumpsites, Chem/Glass/Equipment
Calendar Year 2009



Source: National Seizure System (NSS)
Total: 10,064
Dates: 1/1/2009 to 12/31/2009

Map last updated September 2010

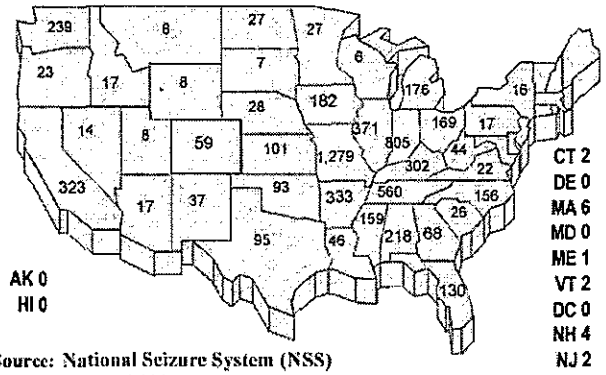
Total of All Meth Clandestine Laboratory Incidents
Including Labs, Dumpsites, Chem/Glass/Equipment
Calendar Year 2008



Source: National Seizure System (NSS)
Total: 7,485
Dates: 1/1/2008 to 12/31/2008

Map last updated September 2010

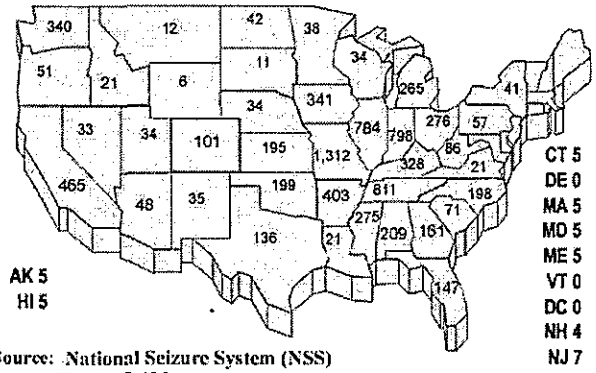
Total of All Meth Clandestine Laboratory Incidents
Including Labs, Dumpsites, Chem/Glass/Equipment
Calendar Year 2007



Source: National Seizure System (NSS)
Total: 6,233
Dates: 1/1/2007 to 12/31/2007

Map last updated September 2010

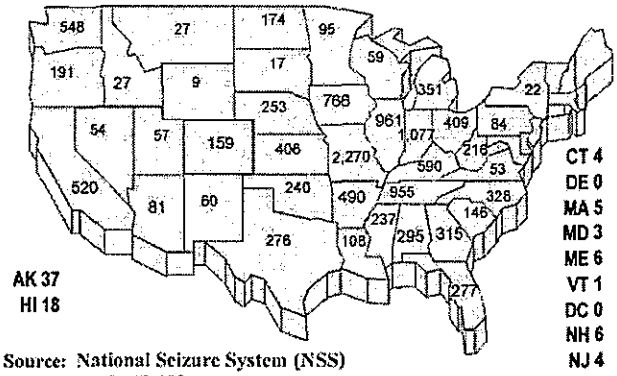
Total of All Meth Clandestine Laboratory Incidents
Including Labs, Dumpsites, Chem/Glass/Equipment
Calendar Year 2006



Source: National Seizure System (NSS)
Total: 8,486
Dates: 1/1/2006 to 12/31/2006

Map last updated September 2010

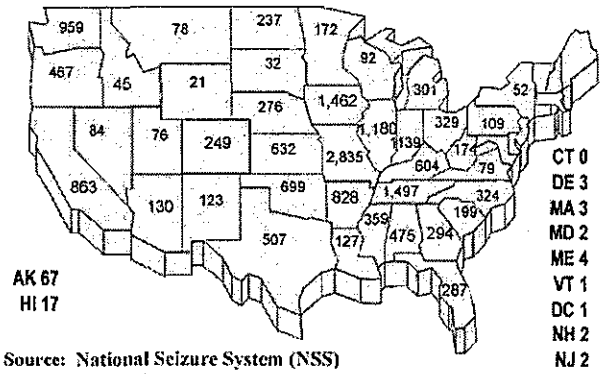
Total of All Meth Clandestine Laboratory Incidents
Including Labs, Dumpsites, Chem/Glass/Equipment
Calendar Year 2005



Source: National Seizure System (NSS)
Total: 13,403
Dates: 1/1/2005 to 12/31/2005

Map last updated September 2010

Total of All Meth Clandestine Laboratory Incidents
Including Labs, Dumpsites, Chem/Glass/Equipment
Calendar Year 2004



Source: National Seizure System (NSS)
Total: 18,581
Dates: 01/01/2004 - 12/31/2004

Map last updated September 2010

Presented with Testimony in opposition to SB 40 and SB 586 by Consumer Healthcare Products Assn.

Preserving Access to Pseudoephedrine:

Strengthening Our Nation's Effort to Stop Illegal Sales Is the Right Solution, Not Mandating Prescription Access for Cold and Allergy Medicines

The Issue: Illegal Meth Production

Pseudoephedrine (PSE), a safe and effective active ingredient found in leading cold and allergy medicines to provide congestion relief, can be used to illegally manufacture methamphetamine. As a result, some policymakers and law enforcement officials are seeking to require a doctor's prescription to obtain PSE-containing medicines, even though the vast majority of these medicines are sold to law-abiding consumers.

Since 2006 federal law and some state laws have moved all PSE-containing medicines behind a sales counter, limited purchases to 3.6 grams per day and 9 grams per 30 days, and required a purchaser's signature in a logbook that is accessible by law enforcement. These laws reduced meth labs nationally by more than 65 percent from their peak in 2003 to a low in 2007.

But meth lab incidents in some states started increasing because criminals have identified ways to skirt these sales limits by "smurfing" – when criminals move from store to store to purchase illegal amounts of PSE to be used for the production of meth. Furthermore, meth cooks have deployed news ways to make smaller quantities of meth in more frequent batches, such as the one-pot, or "shake and bake," method.

The Solution: Preventing Illegal Sales

Twelve states have gone a step further and enacted laws requiring electronic stop sale systems, or e-tracking, of PSE sales. Electronic tracking unifies the logbooks that were previously kept in each individual store, preventing criminals from skirting the limits by visiting multiple stores.

Electronic blocking technology:

- Stops meth crimes before they happen by blocking illegal sales
- Blocks 40,000 grams of PSE sales in Illinois, Iowa, Kentucky and Louisiana alone each month
- Provides law enforcement with a record of purchase attempts and helps them identify meth cooks and ultimately, meth labs. The National Sheriffs Association passed a resolution in 2009 calling for implementation of just this type of multi-state system.

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.

A unified electronic tracking system combined with a national meth registry system would block illegal pseudoephedrine sales, identify meth cooks and keep them out of the system, while allowing legitimate consumers to treat their healthcare needs.

How Much PSE is Diverted for Meth Manufacture?

An estimated 16 million Americans purchase pseudoephedrine each year, with sales being proportionate to a states' population and having no correlation with the number of meth lab incidents. While estimate that the diversion rate is high have no factual basis, there is plenty of evidence that diversion is actually very low.

What we know about sales:

- In 2009 alone there were over 50 million packages of pseudoephedrine sold (not including WalMart) and about 10,000 meth labs reported in the US.
- A Kentucky report calculated approximately 2.2% of pseudoephedrine sold in that state in 2009 would be needed to fuel meth production in the 491 labs for which law enforcement estimated lab capacity.
- Just under 500,000 people purchased OTC medicines with pseudoephedrine over the past year in Kentucky. Less than 2% of purchasers bought more than 38 grams over the year, or roughly a dozen packages.

The Downside of Rx

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.

When a state goes prescription-only, consumers and, yes, meth cooks simply go to neighboring states to purchase pseudoephedrine medicines. When Mississippi went prescription-only in July 2010, Louisiana saw a 259 percent increase in pseudoephedrine sales; Tennessee saw a 349 percent increase in sales; and Alabama saw a 222 percent increase.

The rise in prescription drug abuse also reinforces the fact that scheduling a drug is not a guarantee of preventing abuse. In fact, illicit use of prescription drugs is the fastest growing category of drug abuse. There are no limits to how much pseudoephedrine an individual can buy with prescription.

There are also costs 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.

A Stronger, Smarter, Lasting Solution

As an industry, we are calling on Congress to amend the Combat Methamphetamine Epidemic Act to require that all pseudoephedrine sales be tracked through a nationwide electronic tracking system and that all convicted meth offenders be prohibited from purchasing cold and allergy medicines containing pseudoephedrine.

Mandating prescription-only sale of these common cold medicines, as some have proposed, would be ineffective and burdensome – on legitimate consumers, the healthcare system and law enforcement.

We must use proven technology to target meth abusers and protect legitimate access to medicines containing pseudoephedrine that many cold and allergy sufferers depend on for relief. We are committed to our nation's continued fight against meth and believe this is the right, comprehensive, and common sense solution.

HAWAII FOOD INDUSTRY ASSOCIATION (HFIA)
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Honolulu, HI 96813
Fax : 808-791-0702
Telephone : 808-533-1292

DATE: Thursday February 10, 2011 TIME: 8:30 a.m. PLACE: CR 229

TO: COMMITTEE ON COMMERCE AND CONSUMER PROTECTION

Senator Rosalyn H. Baker, Chair; Senator Brian T. Taniguchi, Vice Chair

COMMITTEE ON HEALTH

Senator Josh Green, M.D., Chair; Senator Clarence K. Nishihara, Vice Chair

FROM: Hawaii Food Industry Association - Lauren Zirbel, Government Relations

RE: SB 40 and SB 586 RELATING TO PSEUDOEPHEDRINE

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 exacerbating current provider shortages through the 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 19 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 would 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. Ten states have enacted laws that require electronic tracking of PSE sales: Alabama, Arkansas, Illinois, Iowa, Kansas, Kentucky, Louisiana, Missouri, Oklahoma, and Washington.

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.

The following is a draft of Model Pseudoephedrine Electronic Tracking Legislation.

Model Pseudoephedrine Electronic Tracking Legislation

(a) (1)A retailer shall not sell to the same person, and a person shall not purchase, products containing more than three and six tenths (3.6) grams per day or more than nine (9) grams per thirty day period of ephedrine or pseudoephedrine base, or their salts, isomers, or salts of isomers. The limits shall apply to the total amount of base ephedrine and pseudoephedrine contained in the products, and not the overall weight of the products. (2) Nonprescription products containing pseudoephedrine or ephedrine shall be maintained behind the counter or in a locked case where the customer does not have direct access.

(b) The retailer shall require any person purchasing a nonprescription product that contains pseudoephedrine or ephedrine to present valid government issued photo identification at the point of sale. The retailer shall record the name and address of the purchaser; name and quantity of product purchased; date and time purchased; and purchaser identification type and number, such as driver license state and number, and require the purchaser's signature in a logbook.

(c) Beginning January 1, 2012, a retailer shall, before completing a sale under this section, electronically submit the required information to the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI). Absent negligence, wantonness, recklessness, or deliberate misconduct, any retailer utilizing the electronic sales tracking system in accordance with this subdivision shall not be civilly liable as a result of any act or omission in carrying out the duties required by this subsection and shall be immune from liability to any third party unless the retailer has violated any provision of this subsection in relation to a claim brought for such violation.

(d) If a retailer selling a nonprescription product containing pseudoephedrine or ephedrine experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirement, the retailer shall maintain a written log or an alternative electronic recordkeeping mechanism until such time as the retailer is able to comply with the electronic sales tracking requirement.

(e) NADDI shall forward state transaction records in NPLEx to the appropriate state agency weekly, and provide real-time access to NPLEx information through the NPLEx online portal to law enforcement in the state as authorized by the agency.

(f) This system shall be capable of generating a stop sale alert, which shall be a notification that completion of the sale would result in the seller or purchaser violating the quantity limits set forth in this section. The seller shall not complete the sale if the system generates a stop sale alert. The system shall contain an override function that

may be used by a dispenser of ephedrine or pseudoephedrine who has a reasonable fear of imminent bodily harm if they do not complete a sale. Each instance in which the override function is utilized shall be logged by the system.

(g) A violation of any provision of this section is a Class A misdemeanor, punishable by fine only. If a product is dispensed in violation of subsection (a), the owner or operator of the wholesale or retail establishment dispensing
the product shall be in violation of subsection (a).

(h) This section does not apply to a person who obtains the product pursuant to a valid prescription.

(i) This section shall supersede any local laws or ordinances regulating sales of products containing pseudoephedrine or ephedrine.

To: Committee on Commerce and Consumer Protection 2/7/2011
Committee on Health
From: Patrick Adams, Rph
Re: SB 40 and SB 586

Honorable Baker and Committee Members,

In opposition to: SB 40 and SB586

I am a Board of Pharmacy member and Director of Pharmacy for Foodland and don't think it is the best interested of the people of Hawaii for psuedoephredrine to be a CIII medication. The general public will incur an unnecessary cost to obtain a medication that is safe for self-use. Every sale will result in a physician visit but the basis of the physician visit appears to be for record keeping purposes. Psuedoephedrine does not meet the requirements as set forth by the Durham-Humphrey Amendment of 1951 as a legend medication since Psuedophedrine is not considered too dangerous for use unless under the supervision of a physician. Historical evidence has shown that psuedoephedrine is safe for consumer use as an OTC medication therefore the issue appears to be the abuse potential as drug substrate. I believe a change of psuedoephedrine status puts additional workload on an already stressed system of prescription providers and a financial burden on the Hawaii citizens. In addition I don't believe this will change the abuse or the ability to manufacturer Methamphetamine to a greater degree than we have already seen since changing pseudoephedrine to a behind the counter sale.

I agree that the abuse potential for psuedoephrine is of concern but as a substrate of a dangerous medication not as the medication is sold to the general public. This abuse potential has made the control of the medication an important part of public safety and I believe the present system controls and limits the sale of psuedoepphrine without the financial burden to the public and to the health system. Since the record keeping is the real purpose in changing psuedoephedrine to a CIII, I have two possible solutions that would fulfill the record keeping need without requiring a physician visit:

1. The present law requires a consumer to request psuedoephedrine from a pharmacy. The pharmacy collects the consumers information, checks the psuedoephedrine log to insure the consumer is within buying limits, dispenses the medication and collects a signature. Pharmacies could be required to file this information in a database that would be forwarded to the NED for inspection to insure consumers are not using multiple pharmacies.

Or

2. Change Psuedoephedrine to a CV medication but allow the pharmacist to dispense without a prescription on a signature log that we presently are using. This would forward the records to NED through the Control Medication Log that the NED already receives but would take the prescription requirement away. This is how many states have controlled medications like paregoric and codeine cough

medicine. Specifically Washington State controls codeine cough medicine in this way.

Since 1951 when legend medications were established things have changed and we are starting to see some issues with the two classification medication system. We will continue to see these reclassification issues in the future as we did with emergency conception and we should be looking ahead to solutions that fit better into contemporary times. I believe there is a need to address the danger and abuse potential of medications and put into place a system that addresses the safety of the consumer as well as their ability to pay. Hawaii citizens make most psuedoephedrine sales legally with legal intent. Many of these citizens will be denied this medication if they are required a physicians visit to obtain it due to financial limitations. This includes our children and our parents. I would ask the committee to look for a different solution in regard to psuedoephedrine.

Sincerely,

Patrick L Adams, Rph
Foodland Supermarkets Ltd
808-640-1848

HDMA
Healthcare Distribution Management Association

Healthcare Distribution Management Association (HDMA)
Testimony on S.B. 40
Classifying Pseudoephedrine as a Schedule III Controlled Substance
Hawaii Senate Commerce & Consumer Protection, Judiciary & Labor, and Health Committees
Joint Hearing
February 10, 2011

My name is Sergio Santiviago, Associate Director for State Government Affairs with the Healthcare Distribution Management Association (HDMA), and on behalf of our four full-service wholesale drug distributor members with facilities located in Hawaii, I am respectfully submitting the following testimony on S.B.40.

Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 165,000 pharmacies, hospitals, nursing homes, physician offices and clinics in every state in the nation. In fact, 85% of all prescription medicines in this country go through a distribution facility on the way from the manufacturer to the pharmacy/provider setting.

As a strong advocate for the safe, reliable, and efficient distribution of the nation's healthcare products, HDMA applauds the goal of preventing precursor chemicals used for manufacturing methamphetamine and other illegal substances—such as pseudoephedrine (PSE)—from being purchased in large quantities or stolen at the pharmacy level for such purposes. However, without additional clarifying language, S.B. 40 will have a significant, negative impact on legitimate drug distribution that we believe may be unintended.

Specifically, classifying products containing PSE as Schedule III controlled substances would substantially change current inventory practices and safeguards for distributors in Hawaii by triggering federal Drug Enforcement Administration (DEA) regulations requiring that, in effect, the large volume of over-the-counter (OTC) products containing pseudoephedrine be stored in smaller cages and/or vaults located within already-secure warehouses (see 21 C.F.R. §1301.72(b)). These DEA requirements were not created with the intent of securing the typically large quantities of OTCs on-hand in a facility, but rather the comparatively much smaller quantities of controlled substances that are commonly stored within it.

Whether storing controlled substances, prescription or OTC drugs—or typically all of them—licensed and registered drug distribution centers are highly regulated and secure facilities that must comply with strict federal and state regulatory requirements, and pass regular DEA and Hawaii Board of Pharmacy inspections. If a facility is—as most are—licensed to distribute controlled substances, prescription and OTC drugs, it must comply with federal requirements for storing controlled substances—even while appropriately storing non-controlled substance drugs within the facility, but outside of the vaults or cages reserved for controlled substances.

Federal regulations concerning storage of controlled substances mandate multiple and specific security procedures, such as (1) employee screening; (2) restricted access; (3) alarm systems; (4) self-locking and closing doors; (5) detailed, tamper-protected, recordkeeping; and (6) inventory control systems. Thus, DEA-registered wholesale drug distributors already meet the objectives of S.B. 40—storing drug products in highly secure facilities with limited opportunities for access, even if not all drug products being warehoused are schedule I–V controlled substances. As a result of these strict requirements, these facilities have not been a source of pseudoephedrine diversion.

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Therefore, HDMA respectfully asks you to consider adding the following language as a new subsection to the bill, exempting distributors from the additional (and unnecessary) storage and handling burdens triggered by S.B. 40:

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

Twelve states passing similar legislation or regulations classifying pseudoephedrine as either a Schedule III-V controlled substance have included this specific exemption from the additional storage and handling requirements as described above for wholesale drug distributors. These states recognize that to require DEA-registered wholesale distributors' compliance with unnecessary, expensive, and otherwise inapplicable security burdens fails to contribute towards the goal of reducing illegal access to PSEs.

Thank you in advance for your consideration of our comments, and if you have any questions, need additional information, or are interested in touring the operations at an in-state distribution facility, please do not hesitate to contact me at 703.885.0231.

HDMA respectfully recommends adding the following language to Section 1 of S.B.40, amending HRS 329.18(b)(7) by creating a new subsection "(A):"

(7) Pseudoephedrine.

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

Enacted PSE Controlled Substance Scheduling Requirements
2/2/2011

State/Bill No.	Status	Exemption Summary
Arkansas SB 109	Signed by Governor 2/22/05	Places PSE products under Sch. V. **In-state distributors selling only to pharmacy are exempt.**
Illinois HB 4300	Signed by governor 5/25/06	Places PSE products under Sch. V. **Allows that persons registered with the DEA shall not be required to meet the physical security control requirements (such as cage or vault) for Sch. V controlled substances containing PSE.**
Iowa SF 169	Signed by governor 3/22/05	Places PSE products under Sch V. Distributors included in exemption list: **A vendor who holds a permit issued by the board and who sells, transfers, or otherwise furnishes a precursor substance to a practitioner or a pharmacy as defined in section 155A.3.**
Louisiana HB 890	Effective 8/15/09	Places PSE products under Sch V. Wholesalers licensed by the state and DEA are **exempt** from the storage, reporting, record keeping, and physical security requirements for controlled dangerous substances for nonprescription products containing ephedrine, pseudoephedrine, and phenylpropanolamine which are not listed in another schedule.
Minnesota HF 1	Signed by governor 6/02/05, SF 51 provisions incorporated into HF 1 (*Omnibus public safety finance bill*.)	Places PSE products under Sch. V. **Includes distributor storage exemption.**

Enacted PSE Controlled Substance Scheduling Requirements
2/2/2011

State/Bill No.	Status	Exemption Summary
Missouri SB 10	Signed by governor 6/15/05	Places PSE products under Sch. V. **Requires Board to promulgate rules regarding distributor storage exemption.** Emergency rule mirrored the federal List 1 Chemical requirements
Mississippi HB 512	Signed by the governor 2/2010, Effective 7/1/2010	Places PSE products under Sch. III. **Includes storage/handling exemption for wholesalers.**
New Mexico HB 211	Signed by governor 3/1/06	Places PSE products under Sch. V. Excludes liquids and liquid gel caps. **Sec 16.19.20.49 allows for distributors who meet DEA security requirements to be exempt from any additional storage/security requirements.**
Oklahoma HB 2176	Final regulations signed 7/11/2004	Places PSE products under Sch. V. **Distributors may apply for a special registration and be exempt from additional security and storage requirements.**
Oregon HB 2485	Signed by governor 8/16/05	Places PSE products under Sch. III, requiring a prescription. Does not exempt liquids. **Board of Pharmacy included distributor storage exemption in regulation.**
West Virginia SB 147	Signed by Governor 5/11/05	Places single ingredient PSE products under Sch V, excluding pediatrics. Does not exempt liquids. **Board of Pharmacy clarified that no additional storage/security or recordkeeping requirements would be placed on distributors.**

Enacted PSE Controlled Substance Scheduling Requirements
2/2/2011

State/Bill No.	Status	Exemption Summary
Wisconsin AB 183	Signed by Governor 6/7/07	Places PSE products under Sch. V. **Includes amendment prohibiting the Board from proposing additional storage requirements for distributors.**

Medicine Buddha and Bodhisattvas
Natural Cancer Wellness Foundation
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COMMITTEE ON COMMERCE AND CONSUMER PROTECTION
Senator Rosalyn H. Baker, Chair
Senator Brian T. Taniguchi, Vice Chair

COMMITTEE ON HEALTH
Senator Josh Green, M.D., Chair
Senator Clarence K. Nishihara, Vice Chair

SB40 & SB586

DATE: Thursday, February 10, 2011
TIME: 8:30 a.m.
PLACE: Conference Room 229
State Capitol
415 South Beretania Street

OPPOSE!

Lets be Honest. True, The legislature finds that Act 193, Session Laws of Hawaii 2005, was enacted to control access to pseudoephedrine - a key ingredient in ICE, Methamphetamine HCL - and a contributor to Hawaii's illegal drug trade.

Pseudoephedrine can be easily used as a precursor in the synthesis and manufacture of ICE, Methamphetamine HCL and should be controlled.

ICE, methamphetamine is bad but pseudoephedrine is good. When introduced in the 1940's it was considered a "cure for the common cold". Pseudoephedrine has been non-prescription OTC for over 60 years with no public harm.

But pseudoephedrine is not a Schedule III drug according to the legal definitions in the Law. Pseudoephedrine is not associated with any mental, emotional or physical dependency.

The State but not the Feds has also limited the distribution of the parent herb, Ephedra, common name, Mormon's Tea. Mormon's can not drink coffee or black tea, I'm guessing that they drank Ephedra since it's called Mormon's Tea. Ephedra has been G.R.A.S. Generally Recognized as Safe. Until the Feds started making up news stories like Marijuana Madness. Works every time. The Big Lie technique.

These are all State Laws because the Federal Government lacks the power to proceed.

You need to find a more successful and legitimate way to control your drug problems other than harming the public health.

If the current laws don't work why would going further down the wrong road faster and more dangerously be any better?

Pseudoephedrine is one of the few medicines for URI that actually works. [not good for men with prostate problems]

Your Old Testament Crime and Punishment isn't working with your drug problem.
Maybe you should try the New Testament Jesus methods of forgiveness, compassion and healing.
That seems to be working better Worldwide.

Hard Drug Laws only benefit the Black Market and the Criminal Industry and their co partners Law Enforcement.

Hard Drug Laws do not benefit Society or the individual only crime and criminal organizations.

If Hard Drug Laws worked you wouldn't be hearing this bill

Because you are hearing this bill, Q.E.D. Hard Drug Laws don't work.

For example, it takes an average of 7 attempts to quit Tobacco, why do you expect the Drug Courts to work on the first one or two tries?

There is no Cinderella story here, the shoe doesn't fit and stronger punishment hasn't worked already.

Harming the public health isn't a successful way of controlling methamphetamine demand, production and use.

When diet pills were prescribed like candy there wasn't any problems from any illegal drug trade and "meth head" crash cases were rare. Those days are gone with the prohibition of diet pills. Smoking is about equal in absorption rate as injection, crack, coke, meth and ice. Wonder what the drug problem would be like of CIA Black Ops had a different funding stream other than illegal cocaine sales. History channel reports that Hitler's went even more crazy when he moved up from cocaine injections [Sherlock Holmes was a cocaine addict (Quick, Watson, the needle.) as was Sigmund Freud.] to methamphetamine. After this change in his drug of choice, his Generals plotted to assassinate him; evidently, he went even too crazy for them, the Nazi command. NOW THAT'S GOT TO BE A VERY BAD DRUG, if it is too mean for even the Nazi command.

Rehab could be enhanced to solve the drug problem.

I suggest you leave BAD ENOUGH alone and not go down the wrong road worse.

Dr. Myron Berney, ND LAc
MahaSiddha MahaSukha