SB2536

Measure Title:
RELATING TO THE I-SAVERX PRESCRIPTION DRUG PROGRAM.

Report Title:
Prescription Drugs; I-SaveRx; Governor; Reimportation

Description:
Directs governor to establish the State of Hawaii's participation in the I-SaveRx prescription drug program to provide residents with increased access to affordable drugs.

Introducer(s):
IGE

Current Referral:
HTH, CPH

TESTIMONY OF THE STATE ATTORNEY GENERAL
TWENTY-FOURTH LEGISLATURE, 2008

ON THE FOLLOWING MEASURE:
S.B. NO. 2536, RELATING TO THE I-SAVERX PRESCRIPTION DRUG PROGRAM.

BEFORE THE:
SENATE COMMITTEE ON HEALTH

DATE: Wednesday, February 13, 2008 **TIME:** 1:15 PM
LOCATION: State Capitol, Room 016
Deliver to: Committee Clerk, Room 215, 1 copies

TESTIFIER(S): Mark J. Bennett, Attorney General
or Cori K. Woo, Deputy Attorney General

Chair Ige and Members of the Committee:

The Attorney General has serious concerns regarding this bill, specifically, the ability of the State to execute its provisions within federal restrictions.

The purpose of the bill is to direct the Governor to establish Hawaii's participation in the I-SaveRx prescription drug program to provide residents with increased access to affordable drugs. Hawaii residents would have access to the I-SaveRx program through an Internet website and a toll-free twenty-four-hour telephone number run by Illinois' pharmacy benefit manager, Pegasus Health Services Limited, which has existing relationships with licensed pharmacies in Canada, the United Kingdom, Australia, and New Zealand.

We have identified several legal problems with this bill concerning FDA requirements and approval.

First, importing a drug into the United States that is unapproved or does not comply with the labeling requirements in the Federal Food, Drug, and Cosmetic Act ("FFDCA") is prohibited under 21 U.S.C. section 331(a), (c), and (d). Under the same section of the FFDCA, the interstate shipment of any prescription drug that lacks required FDA approval is also illegal. Interstate shipment includes importation

such as bringing drugs from a foreign country, like Canada, into the United States.

Second, the drug distribution network for legal prescription drugs in the United States is a "closed" system that involves several players who move drug products from the point of manufacture to the end user, and provides the American public with multiple levels of protection against receiving unsafe, ineffective, or poor quality medications. Even if the drug was manufactured in the United States and approved by the FDA, then shipped to a purchaser in a foreign country and brought back in through Illinois, once it leaves the United States it loses its FDA approval. Therefore, pursuant to 21 U.S.C. section 381(d)(1), it is illegal for any person other than the original manufacturer of a drug to import into the United States a drug that is originally manufactured in the United States and sent to another country. Failure to comply with the applicable federal law would expose any individual involved with this program to both civil and criminal liability pursuant to 21 U.S.C. sections 331, 332, 333, and 381(d)(1) and 18 U.S.C. sections 2 and 371.

The Attorney General would like this Committee to be informed on these issues.

POLICY ADVISORY BOARD FOR ELDER AFFAIRS (PABEA)
NO.1 CAPITOL DISTRICT
150 SOUTH HOTEL STREET, SUITE 406
HONOLULU, HAWAII 96813

TO: SENATE-SGT-AT- ARMS

February 11, 2008
Fax 586-6659

FROM: Bruce McCullough
Legislative Committee, PABEA

FOR: Committee on Health
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

RE: SB 2536 Relating to the I-SaveRx Prescription Drug Program

DATE: Wednesday, February 13, 2008

TIME: 1:15 PM

PLACE: RM 016

I am offering testimony on behalf of PABEA, which is a State appointed Board tasked with advising the Executive Office on Aging (EOA). My testimony does not represent the views of the EOA, but of the board.

PABEA is in strong support of this proposed legislation.

I-SaveRx is a prescription drug reimportation program developed by the State of Illinois that allows Illinois consumers to refill prescriptions for the most common brand-name prescription drugs used to treat chronic illness at affordable prices from pharmacies in Canada and the United Kingdom.

This bill amends Chapter 346 of the Hawaii Revised Statues by inserting a new section to enable Hawaii to participate in the I-Save Rx program that is currently in effect in the State of Illinois as well as several other states that are participating in the program.

Since Illinois implemented the I-Save Rx prescription drug program,, Wisconsin, Missouri, Kansas, and Vermont have joined the program as participating states.

HAWAII ALLIANCE FOR RETIRED AMERICANS (HARA)
AN AFFILIATE OF THE ALLIANCE FOR RETIRED AMERICANS
C/O AFSCME, 888 MILILANI STREET, SUITE 101
HONOLULU, HAWAII 96813

TO: SENATE-SGT-AT- ARMS

FEBRUARY 11, 2008
Fax 586-6659

FROM: Bruce McCullough
HARA Legislative Committee, Chair

FOR: Committee on Health
Senator David Y. Ige, Chair
Senator Carol Fukunaga, Vice Chair

RE: SB 2536 Relating to the I-SaveRx Prescription Drug Program

DATE: Wednesday, February 13, 2008

TIME: 1:15 PM

PLACE: RM 016

I am submitting testimony on behalf of the Hawaii Alliance for Retired Americans (HARA). HARA represents 17,000 retirees. We are a chapter of the National Organization, The Alliance for Retired Americans.

HARA is in strong support of this legislation.

I-SaveRx is a prescription drug reimportation program developed by the State of Illinois that allows Illinois consumers to refill prescriptions for the most common brand-name prescription drugs used to treat chronic illness at affordable prices from pharmacies in Canada and the United Kingdom.

This bill amends Chapter 346 of the Hawaii Revised Statues by inserting a new section to enable Hawaii to participate in the I-Save Rx program that is currently in effect in the State of Illinois as well as several other states that are participating in the program.

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February 11, 2008

TO: Chair David Y. Ige and Members of the Senate Committee on Health

FROM: Pharmaceutical Research and Manufacturers of America
(Norman H. Suzuki)

RE: **SB 2536** Relating to the I-SaveRx Prescription Drug Program

Hearing Date: 2/13/08 at 1:15 p.m.

My name is Norman Suzuki. I am a representative of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which is a trade association of the country's leading research-based pharmaceutical and bio-technology companies, which are in the business of making medicines.

PhRMA respectfully **opposes** passage of **SB 2536** for the reasons set forth in the attached statement.

Thank you for considering this testimony.

Statement PhRMA

In Opposition to Hawaii Senate Bill 2536

February 11, 2008

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes Hawaii Senate Bill 2536 (SB 2536) because it would likely jeopardize the health and well-being of patients and compromise the integrity of the prescription drug supply in the United States.

SB 2536 would allow the State of Hawaii and its residents to join an illegal importation website called "I-SaveRx" which is currently utilized by a limited number of states as a way to facilitate the distribution of potentially unsafe and illegal drugs to state residents from foreign pharmacies.

PhRMA and its member companies realize the importance of providing patients with access to life-sustaining and cost-effective pharmaceuticals. However, PhRMA urges Hawaii legislators to consider the safety and liability concerns associated with importing and facilitating the importation of pharmaceuticals from abroad.

Patient Safety Is Jeopardized

On January 11th, 2007, the National Association of Boards of Pharmacy (NABP) released a press statement entitled, *2006 Unprecedented Year of Increased Fake Drug Production, Introduction into U.S. Drug Supply.* In its press release, the NABP states that "one of Canada's largest internet pharmacies is selling counterfeit versions of Lipitor, Crestor, Celebrex and seven other drugs." Additionally, the NABP discussed the 2005 case in the United Kingdom where 10,000 packs of Lipitor were found to have been mixed with counterfeit packs and at least 2,500 of these used by patients before it was determined that they were counterfeit.

Internet pharmacies that claim to be Canadian, Irish, or British may have no ties at all to Canada, Ireland, or the United Kingdom. Many internet pharmacies actually based in these countries obtain their drugs from third-world sources such as India, Thailand, and the Philippines. Furthermore, the Canadian equivalent of the US FDA is not designed to provide oversight on products that merely pass through Canada destined for patients in the US. Patient health is further jeopardized when licensed pharmacists are replaced by questionable internet sites.

The US Food and Drug Administration (FDA) estimates that approximately 1% or less of drugs in the United States are tainted or counterfeit.[1] Assuming that is accurate, that means approximately 3,500,000 U.S. prescriptions may be potentially affected by counterfeit drugs each year.[2] Recent discoveries in counterfeit drugs in the United States have included AIDS/HIV therapy, over-the-counter pain medications, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, cardiac drugs, antihistamines, and many more. [3] The use of counterfeit drugs can cause harm in variety of ways including ingesting the wrong drug which means the patient is not being treated for their condition; getting the wrong concentration or dose which can result in death; taking a drug with no active ingredients which means the patient's condition is not being treated; and ingesting dangerous materials used to make the fake drugs. [4]

In a May 20, 2005, letter to Governor Kenny Guinn of Nevada, the FDA stated that importation of foreign drugs is illegal and outlined numerous safety concerns. In this letter, FDA Associate Commissioner for Policy and

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[1] Bryan A. Liang, *Over the Virtual and Geographic Borders: Understanding Importation and Counterfeit Drugs* , 36 Cal. W. Int'l L.J. , 11 (2005), citing Paul M. Rudolph& Ilisa B.G. Bernstein, *Counterfeit Drugs*, 350 New Eng. J. Med. 1384 (2004).
[2] Id. at 11.
[3] Id.
[4] Id at 11-12.

Planning Randall W. Lutter indicated, "We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by the FDA."[5]

Legal Concerns and Potential Liability for Public Entities

In addition to safety concerns, the FDA indicates that states and/or other entities that encourage, act, or even cause illegal importation run afoul of the Federal Food, Drug, and Cosmetic Act ("FDCA")[6]. FDCA violations have already triggered Department of Justice enforcement actions. As a practical matter, FDA believes that, "it is extremely unlikely that any program in [a state or municipality] could ensure that all of the applicable legal requirements are met." The administration and costs to a state associated with attempting to create and maintain a program that could oversee the distribution of foreign drugs to its residents, often on an individual basis, would likely be so substantial that a state would be unable to adequately protect against all possible civil and criminal violations.

Under most state laws, if a state provides Canadian and other foreign drugs directly or facilitates their distribution, such as through contracting with foreign pharmacies, importing directly or participating in a website (such as I-Save-Rx) that will provide imported drugs to state residents, the following causes of action may apply: negligence; strict liability/breach of implied warranty of merchantability; failure to warn; and fraud or misrepresentation. Moreover, states may be liable for these state-based actions.

Importation Savings are Negligible and FDA Approved Drugs are Available at Low Cost or No Cost

On September 19th, 2006, the Illinois Auditor General released his state-sponsored audit of I-SaveRx after 19 months in operation. Rather than saving the state of Illinois a windfall from importing prescription drugs, the Auditor General found that I-SaveRx instead cost Illinois taxpayers over $1 million and reached only 4,000 people. While importation was hailed by some as a means to save money, analysis of actual data continues to show that this is not the case.

PhRMA and the biopharmaceutical industry are committed to working with the FDA and other agencies to keep America's drug supply safe. We are equally committed to ensuring that every American has access to quality medicines. In April 2005, PhRMA established the Partnership for Prescription Assistance (www.pparx.com) which offers a single point of access to more than 475 public and private patient assistance programs, including more than 180 programs offered by pharmaceutical companies. PPARx brings together America's pharmaceutical companies, doctors, other health care providers, patient advocacy organizations, and community groups to help qualifying patients who lack prescription coverage get the medicines they need through the public or private program that is right for them. Many will get them free or nearly free. Since its inception, PPARx has matched over 4 million Americans nationally to patient assistance program. In Hawaii alone, nearly 9,000 residents have been matched to at least one patient assistance program.

In addition, PhRMA sponsors www.BuySafeDrugs.info which provides information on safe, legal way that patients can save on prescription medications, educates patients on the risks of importing medicines, and explains why legalizing importation is bad public policy.

It is for all these reasons, PhRMA respectfully urges Legislators in Hawaii to oppose SB 2536.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines. Industry wide research and investment reached a record $51.3 billion in 2005.

[5] Randall W. Lutter, FDA Associate Commissioner, Letter to Nevada Governor Kenny Guinn, May 20, 2005.

[6] William K. Hubbard, FDA Associate Commissioner for Policy and Planning, Letter to CA Deputy Attorney General, August 25, 2003.

LINDA LINGLE
GOVERNOR

LILLIAN B. KOLLER, ESQ.
DIRECTOR

HENRY OLIVA
DEPUTY DIRECTOR

STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES
P. O. Box 339
Honolulu, Hawaii 96809-0339

February 13, 2007

MEMORANDUM

TO: Honorable David Y. Ige, Chair
Senate Committee on Health

FROM: Lillian B. Koller, Director

SUBJECT: S.B. 2536 – RELATING TO THE I-SAVERX PRESCRIPTION DRUG PROGRAM
Hearing: Wednesday, February 13, 2008, 1:15 a.m.
Conference Room 016, State Capitol

PURPOSE:

The purpose of this bill is to direct the Governor to establish the State of Hawaii's participation in the I-SaveRx prescription drug program to provide residents with increased access to affordable drugs.

DEPARTMENT'S POSITION: The Department of Human Services appreciates the Legislature's intent to lower the cost of prescription drugs for the citizens of Hawaii but we must oppose this bill because it will require substantial State funds that will clearly adversely impact the priorities in the Executive Supplemental Budget.

The Department needs to point out that the State of Hawaii would be prohibited from utilizing Federal Medicaid matching funds to purchase prescription drugs from the I-SaveRx Prescription Drug Program because these drugs are purchased from Canada and Europe. The U.S. Food and

Drug Administration (FDA) considers imported prescription drugs as unapproved new drugs, and Federal Medicaid rules clearly indicate that only FDA approved drugs can be prescribed. Therefore, this bill will require a substantial appropriation of State general funds to pay for the drugs purchased from the I-SaveRx Prescription Drug program and the State will not receive Federal Medicaid matching funds.

Inasmuch as these options will require additional substantial State appropriations, the Department opposes this bill and respectfully requests that such funding not adversely impact nor replace the priorities in the Executive Supplemental Budget.

The Department defers to the Department of the Attorney General as to the legality of this bill.

Thank you for the opportunity to comment on this bill.