TESTIMONY OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
THIRTIETH LEGISLATURE, 2020

ON THE FOLLOWING MEASURE:
H.B. NO. 1608, H.D. 1, RELATING TO PRESCRIPTION DRUGS.

BEFORE THE:
HOUSE COMMITTEE ON CONSUMER PROTECTION AND COMMERCE

DATE: Wednesday, February 5, 2020 **TIME:** 2:00 p.m.

LOCATION: State Capitol, Room 329

TESTIFIER(S): Clare E. Connors, Attorney General, or
Andrea J. Armitage, Deputy Attorney General

Chair Takumi and Members of the Committee:

The Department of the Attorney General provides the following comments.

The purpose of this bill is to require the Department of Health (DOH) to administer a program for the wholesale importation of prescription drugs that will meet the requirements of federal law. This program would import prescription drugs from Canada, while ensuring safety and cost savings to Hawaii's consumers.

The measure requires the DOH to either become a licensed wholesaler, or to license an entity to become a wholesaler, for the purpose of seeking federal certification and approval to import prescription drugs from Canada.

We note that DOH does not currently have this expertise or experience. With regard to DOH becoming a licensed wholesaler, the requirements to become a wholesale prescription drug distributor are detailed and complex, and do not appear to contemplate a state agency being the applicant. See: https://cca.hawaii.gov/pvl/files/2019/06/Require-Instruct-App-for-Wholesale-Prescrip-Drug-Dist_12.16R.pdf.

In addition, the National Academy for State Health Policy recently published model prescription drug importation legislation that is very similar to this bill. https://nashp.org/wp-content/uploads/2019/12/Wholesale-Importation-Act-Dec-19-2019.pdf. It provides for state agencies to contract with licensed wholesalers for the

importation of prescription drugs that will provide savings to the states' consumers. Based on the foregoing, the Committee might consider deleting the option of DOH becoming a licensed wholesaler. (Section 1, page 1, lines 15-17.)

Wholesale importation of prescription drug programs for states is a relatively recent innovation nationally. The U.S. Department of Health and Human Services published proposed rules to regulate these programs on December 23, 2019 (our testimony to the Health Committee stated the date was December 18, 2019, which was in error). The rules are not yet final. The deadline for comments is March 9, 2020. The proposed rules can be found at: https://www.federalregister.gov/documents/2019/12/23/2019-27474/importation-of-prescription-drugs. Another alternative to consider might be to pass legislation after these rules become final to ensure that Hawaii law comports with federal regulations.

Thank you for the opportunity to share these comments.

DAVID Y. IGE
GOVERNOR

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Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committee on Consumer Protection and Commerce
Wednesday, February 5, 2020
2:00 p.m.
State Capitol, Conference Room 329

On the following measure:
H.B. 1608, H.D. 1, RELATING TO PRESCRIPTION DRUGS

Chair Takumi and Members of the Committee:

My name is Catherine Awakuni Colón, and I am the Director of the Department of Commerce and Consumer Affairs (DCCA or Department). The Department offers comments on this bill.

The purpose of this bill is to authorize the Department of Health to implement a program for wholesale importation of prescription drugs, effective July 1, 2050.

The Department did not testify on H.B. 1608 in the Committee on Health hearing because it was unaware that testimony would point to the DCCA as a possible alternative agency to administer the proposed Wholesale Importation of Prescription Drugs Act. Respectfully, the proposal to place regulatory authority over the Wholesale Importation of Prescription Drugs Act with the DCCA, as referenced in the committee report of the Committee on Health, is unwarranted.

The Department notes that Hawaii Revised Statutes chapter 328 (Food, Drugs, and Cosmetics) is replete with regulatory oversight of drugs, including, but not limited to:

- Section 328-14 (Drugs or devices deemed adulterated when)

- Section 328-15 (Drugs or devices deemed misbranded when; prescriptions excepted, when)
- Section 328-16 (Drugs limited to dispensing on prescription)
- Section 328-16.5 (Prescription labeling)
- Section 328-17 (New drugs, regulation of sale; etc.; exceptions)
- Section 328-17.5 (Principal labeler responsibility under recall of drug)
- Section 328-17.6 (Out-of-state prescriptions)
- Section 328-17.7 (Record of prescriptions)
- Section 328-17.8 (Electronic prescription information)
- Section 328-92 (Drug product and biological product selection)
- Section 328-94 (Prescription record)
- Section 328-96 (Hawaii list of equivalent generic drug products and interchangeable biological products)
- Section 328-119 (Minimum requirements for the storage and handling of prescription drugs)
- Section 328-120 (Recordkeeping)
- Section 328-121 (Written policies and procedures)
- Section 328-122 (Responsible persons)
- Section 328-123 (Salvaging and reprocessing).

Although Hawaii Administrative Rules (HAR) section 16-95-30 provides the requirements for the Board of Pharmacy to license a wholesale prescription drug distributor, the Department plays only a minor, ministerial role in evaluating an applicant for licensure. See HAR section 16-95-30, a copy of which is attached.

H.D. 1 establishes a state mechanism to implement a proposed rule (21 Code of Federal Regulations Part 1 and Part 251) pursuant to the Federal Food, Drug and Cosmetics Act (52 Stat. 1040; 21 United States Code sections 301-395). The current deadline to submit comments on the proposed rule is March 9, 2020. The Department recommends that the Committee defer this measure to ensure the state law is not inconsistent with the final federal rule.

Thank you for the opportunity to testify on this bill.

(E) State pharmacy law, chapter 461, HRS, and chapter 16-95 HAR;
(F) Prescription files and;
(G) Drug Facts and Comparison or other current drug information guide; and

(7) An attestation that, at a minimum, the pharmacy possesses the following technical equipment and supplies:
(A) Class A prescription balance or a balance of greater sensitivity and appropriate weights;
(B) Mortar and pestle (glass or porcelain);
(C) Refrigerator;
(D) Bottles and vials of assorted sizes;
(E) Graduates or other similar measuring device; and
(F) Prescription labels.

(c) No permit shall be issued unless all deficiencies have been corrected and approved by the board.

(d) The board may delegate to its executive officer the authority to issue a permit upon receipt of a completed application and documentation evidencing clear compliance with this section. [Eff 5/16/64; am and ren §16-95-26, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-12, 461-14)

Historical note: The substance of this section is substantially based upon section 16-95-51. [Eff 5/16/64; am 6/11/77; am and ren §16-95-51, 6/22/81; R 12/24/92]

§16-95-27 Repealed. [R 12/24/92]

§16-95-28 Repealed. [R 12/24/92]

§16-95-29 Repealed. [R 12/24/92]

§16-95-30 Wholesale prescription drug distributor license requirements. (a) Application for a wholesale prescription drug distributor license shall be made under oath on a form to be provided by the board. In addition to providing information required by section 16-95-21(b), the applicant shall provide the

following information as it pertains to the applicant including any officer, director, manager, or other persons in charge of wholesale drug distribution, storage, or handling:

(1) Any convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony conviction under federal, state, or local laws;

(3) Each person's past experience in the manufacture or distribution of prescription and controlled drugs;

(4) Any suspension, revocation, disciplinary action, or pending investigation by any federal, state, or local government of any license currently or previously held for the manufacture or distribution of any drugs, including controlled substances;

(5) Verification of at least one year of experience in the distribution or handling of prescription drugs for any person responsible for the distribution of drugs; and

(6) A current list of officers, directors, managers, and other persons in charge of the wholesale distribution, storage, and handling of prescription drugs, including a description of each person's duties and a summary of each person's qualifications.

(b) A map of the facilities shall also be submitted. The map shall identify:

(1) The storage area for drugs;

(2) The storage area for quarantined drugs; and

(3) The placement of the lighting, ventilation, and temperature control equipment.

(c) No license shall be issued prior to receipt of a satisfactory inspection report from the state department of health. At a minimum, the board requests that the department of health shall ensure that:

(1) The facilities are of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) The storage areas are designed to provide adequate ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) A quarantine area is available for prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or whose immediate or sealed outer or sealed secondary containers have been opened;

(4) The facility is maintained in a clean and orderly fashion;

(5) The facility is free from infestation by insects, rodents, birds, or vermin of any kind;
(6) The facility is secure from unauthorized entry;
(7) Access from outside the premises is kept to a minimum and well controlled;
(8) The outside perimeter of the premises is well-lighted;
(9) Entry into areas where prescription drugs are held is limited to authorized personnel;
(10) The facilities are equipped with an alarm system to detect entry after hours;
(11) The facilities are equipped with a security system that will provide suitable protection against theft and diversion;
(12) All prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs adopted by the state department of health.
    (A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in the current United States Pharmacopeia National Formulary and all supplements, to help ensure that its identity, strength, quality, and purity are not adversely affected;
    (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs;
(13) Upon receipt, each outside shipping container of prescription drugs is examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs that are unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;
(14) Each outgoing shipment of prescription drugs is inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs are delivered that have been damaged in storage or held under improper conditions;
(15) Returned, damaged, outdated, deteriorated, mishandled, or adulterated prescription drugs are physically separated from other prescription drugs and stored, in such a way that no

cross-contamination or confusion is possible, until they are destroyed or returned to the supplier;

(16) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used are identified as such, and are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier; and

(17) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug is either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(d) Written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories shall be submitted. Written policies and procedures shall include:

(1) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

(2) A procedure for handling recalls and withdrawals of prescription drugs. The procedures shall be adequate to deal with recalls and withdrawals caused by:

(A) Any action initiated at the request of the department of health, the Food and Drug Administration, or any other federal, state, or local law enforcement or other government agency;

(B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the distributor prepares for, protects against, and handles properly any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or in other emergencies; and

(4) A procedure to ensure that all outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall require written documentation of the disposition of outdated prescription drugs. The documentation shall be maintained for five years after disposition of the outdated drugs. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: §461-4.5)

§16-95-31 Miscellaneous permit. An application for a miscellaneous permit shall be filed at least fifteen days before a board meeting and shall be accompanied by the application fee, which shall not be refunded, and required fees. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-16)

§16-95-32 Criminal conviction. When an applicant or the applicant's personnel has been convicted of a crime related to the pharmacy profession and it is determined that the conviction may be considered under section 831-3.1, HRS, the board may request the following documents from the applicant:

(1) Copies of any court records, judgments, orders, or other documents that state the facts and statutes upon which the applicant was convicted, the judgment of the court with regard to that conviction, the sentence imposed, and the record of compliance with the sentence imposed; and

(2) Affidavits from any parole officer, employer, or other persons who can attest to a firm belief that the applicant has been sufficiently rehabilitated to warrant the public trust. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-21)

§16-95-32.2 Denial or rejection of application. (a) An application for issuance of a license or permit shall be denied when an application is insufficient or incomplete; is not accompanied with the required fees; or when an applicant

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Testimony COMMENTING on HB1608 HD1
RELATING TO PRESCRIPTION DRUGS.

REP. ROY M. TAKUMI, CHAIR
HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE
Hearing Date: February 5, 2020 Room Number: 329

Fiscal Implications: Unknown appropriation amount and 14.0 FTE for new positions are required to implement this measure.

Department Testimony: The Department of Health (DOH) supports the intent of HB1608 which is to address unsustainable prescription drug inflation. A proposed solution is to implement a wholesale prescription drug imporation program. However, this measure will not be meaningfully implemented without appropriations and new staff. For example, although the business model is based on a fee on each prescription, DOH lacks start-up funds.

The department commends the Legislature for introducing bold ideas to curb rising drug prices, and a wholesale prescription drug importation program may be effective. However, the enormity and complexity of the task may be better suited for a newly authorized quasi-public entity like a Prescription Drug Importation Authority rather than a Cabinet-level agency like the Department of Health that is subject to procurement and civil service classifications.

Assuming DOH is the license holder, a basic program that is mandated to be operational within six months of federal approval requires:

- One Program Specialist VI to provide supervision;
- One registered pharmacist to assure clinical and pharmaceutical integrity;
- Five Program Specialist V to conduct purity sampling, inventory management, and logistics;
- One Accountant V to track revenues and expenses;

- One actuary to analyze risk, market, utilization, and consumer trends;
- One Contract Specialist to maintain agreements with health plans, providers, and suppliers;
- One IT Specialist to maintain web sites and other technology assets; and
- Three customer service agents to staff the hotline.

In addition to day-to-day operational expenses, DOH will require funds to lease storage space, some of which must be temperature-controlled and secure, as well as transporation assets.

DOH looks forward to the ongoing conversation to reduce health care and prescription drug costs.

Thank you for the opportunity to testify.

Offered Amendments: N/A.

Testimony of the Board of Pharmacy

Before the
House Committee on Consumer Protection & Commerce
Thursday, February 5, 2020
2:00 p.m.
State Capitol, Conference Room 329

On the following measure:
H.B. 1608, H.D. 1, RELATING TO PRESCRIPTION DRUGS

Chair Takumi and Members of the Committee:

My name is Lee Ann Teshima, and I am the Executive Officer of the Board of Pharmacy (Board). The Board will review this bill at its next publicly scheduled meeting on February 13, 2020.

The purpose of this bill is to authorize the Department of Health to implement a program for wholesale importation of prescription drugs.

Thank you for the opportunity to testify on this bill.

An Independent Licensee of the Blue Cross and Blue Shield Association

February 4, 2020

The Honorable Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair
House Committee on Consumer Protection & Commerce

Re: HB 1608, HD1 – Relating to Prescription Drugs

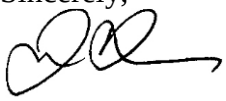
Dear Chair Takumi, Vice Chair Ichiyama, and Committee Members:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 1608, HD1, which authorizes the Department of Health to implement a program for wholesale importation of prescription drugs. Effective 7/1/2050.

HMSA supports the intent of this measure to lower the cost of pharmaceutical drugs for the people of Hawaii. We do believe that any process of importing and testing drugs from outside the country should have federal oversight according to U.S. Food and Drug Administration (FDA) regulations and standards to ensure safety and quality. We look forward to further discussions on how this program could be implemented with the Department of Health.

Thank you for the opportunity to provide testimony on this measure.

Sincerely,



Jennifer Diesman
Senior Vice President Government Relations

AARP Real Possibilities in Hawaii

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HOUSE OF REPRESENTATIVES
Committee on Consumer Protection and Commerce
Wednesday, February 5, 2020
2:00 p.m.
Conference Room 320

To: Representative Roy Takumi, Chair
Re: H.B. HD1 Relating To Prescription Drugs

Dear Chair Takumi, Vice-Chair Ichiyama, and Members of the Committee,

My name is Keali'i Lopez and I am the State Director for AARP Hawai'i. AARP is a membership organization of people age fifty and over, with nearly 145,000 members in Hawai'i. AARP advocates for issues that matter to Hawai'i families, including the high cost of long-term care; access to affordable, quality health care for all generations; and serving as a reliable information source on issues critical to people over the age of fifty.

HB 1608 HD1 directs the State Department of Health to administer a wholesale prescription drug importation program that can import safe prescription drugs from Canadian suppliers which would be less expensive, and provide cost savings to Hawaii's consumers.

AARP Hawaii strongly supports HB 1608 HD1. This is an issue that AARP knows is critically important to all consumers, but especially to the many people over 50 who depend on prescription drugs to keep them healthy and who've been devastated by the price increases we've seen in recent years.

- Drug prices are out of control. Prices of brand-name prescription drugs increased almost 130 times faster than inflation did in 2015 alone.
- Americans depend on their prescription. A recent AARP survey found that 3 of 4 adults age 50+ regularly take at one prescription medication, and over 8 in 10 take at least two drugs. More than half of seniors take four or more drugs.
- High drug prices raise costs for everyone. High drug costs increase health insurance premiums and cost sharing for all people with health coverage. High drug spending also increases the cost for programs such as Medicare and Medicaid, which translates into higher taxes to the general public.

AARP believes that we should reduce barriers to global price competition by allowing for the safe importation of lower-priced drugs from licensed wholesalers and pharmacies operating in Canada. We also believe that strong safety standards must be implemented as any part of this system. Although this is not a complete solution to the problem of high drug costs, safe and legal importation will help put downward pressure on prices and enable consumers to secure additional savings.

AARP fully supports this program which will help lower the high cost of prescription to consumers.

Thank you for the opportunity to testify in support of HB 1608 HD1.

Testimony of Shabbir Imber Safdar
Executive Director, The Partnership
for Safe Medicines
www.safemedicines.org

Dear members of the Committee on Consumer Protection and Commerce:

I am writing to explain my concerns with and opposition to HB 1608, which would establish a wholesale prescription drug importation program in Hawaii. I am Shabbir Imber Safdar, the Executive Director of The Partnership for Safe Medicines, a sixteen-year-old not-for-profit that accepts no corporate members or donations. Our members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients—everyone that touches medicine from the factory floor to the patient.

We take positions almost exclusively on pharmaceutical supply chain safety issues, tightly focusing on policies that reduce the threat of counterfeits in the American drug supply. That includes regulations around pill presses, training and resources for law enforcement to recognize counterfeits drugs and counterfeit drug traffickers, and policies that weaken or strengthen the supply chain.

Biologics, including insulin, cannot be imported.
Under the 2003 Federal law that this state law operates under, biologics including insulin cannot be imported. Many of the non-biologic (small molecule) medicines already have cheaper generic options in the U.S.

Challenges to implementation abound. Previous failed importation experiments resulted in safety violations.
The Partnership for Safe Medicines has studied the policy implications of importation for many years. Looking at all the evidence, we and many other experts, including four former FDA commissioners, have found that it is impossible to implement Canadian drug importation in a way that is safe or will save money.

Illinois, Minnesota, and Maine attempted importation in the past without success. Every program had patient safety problems, and Illinois and Minnesota shuttered their programs when they failed to save enough money to justify the state budget costs.

Hawaii has no access to Canadian medicine supply because this proposal is opposed by Canadian stakeholders.
Canadian medicines are not available to us. Canadians, including the federal government led by Trudeau, healthcare professionals, and patient communities have said they don't want us raiding their drug supply. Widespread drug shortages already plague their country, and because

they import 70 percent of their own medicine, they have no way to increase production to accommodate bulk purchases from U.S. states.

Additionally, the 2003 federal law that governs importation does not allow importation from any country other than Canada.

Americans have been victimized by licensed Canadian drug sellers peddling counterfeit medicines many times before.
As written, HB 1608 suggests that all we have to do is buy from licensed Canadian wholesalers, and we'll be safe, but we cannot outsource our safety to Canada. Hundreds of American medical clinics learned that they had been buying fake cancer medicine from a licensed Canadian wholesaler between 2009 to 2012. In 2005, the FDA found that licensed Canadian pharmacist Andrew Strempler, who supplied thousands of Americans with medicine, was selling counterfeits, too.

Some legislators support drug importation in the spirit of experimentation, theorizing that nothing bad will happen to their constituents if the program does not work. Sadly, that isn't the case. Counterfeiting medicine is a massive world-wide industry valued at $200 billion annually, and while fake handbags and sneakers won't kill you, fake medicine will. This has been the history of the Canadian online pharmacy industry. When Canadian online pharmacies like Strempler's RXNorth found that they were unable to meet American demand about 15 years ago, they turned to cheap foreign-made counterfeit products and passed them off as Canadian. Other pharmacies with names like "CanadaDrugs.com" or "Canada Drug Center" also took this tack, and in some cases, people were killed by tainted medicines or received counterfeits that were supposed to be lifesaving.

Hawaii legislation has many problematic flaws
In addition to the concerns above, there are other flaws in the legislation that are worrisome.

The definition of Canadian suppliers is far too broad to be safe.
According to this proposed law, anyone who can dispense medication in Canada can sell medication wholesale to Hawaii. Pharmacists are not generally experts in shipping bulk quantities of medication internationally, nor do they have to comply with logistics for shipping medication that has specific vibration, temperature, or handling requirements.

In addition, this bill allows anyone with a pharmacy license in any province in Canada to participate in this program. This means that the tiny, poorly funded pharmacy regulator in a tiny

territory with only 40,000 people such as Nunavut could find itself the regulatory authority for Hawaii's 1.42 million residents.

No Track-and-Trace program exists in Canada, therefore compliance is impossible.
The proposed law requires track-and-trace compliance for any medical products before the medicine enters the state. However, there is no track-and-trace system in Canada to rely upon, and Canadian entities cannot be categorized as Trusted Trading Partners under the DSCSA because they do not possess state-issued wholesaler or pharmacy licenses.

No guarantee of savings for consumers in this program.
The proposed law has no guarantee of savings required before implementation. Experts from the London School of Economics have studied parallel trade of medication in Europe across country borders and found that savings are usually consumed by middle men in the supply chain instead of being passed on to consumers.[1]

Lack of record keeping to protect patients upon discovery of counterfeit or substandard medicine.
The proposed legislation does not require recordkeeping of transactions. Such records are critical for identifying affected patients and vendors in the event of an adverse medical event.

No additional resources for law enforcement including the board of pharmacy for increased surveillance.
The proposed legislation requires that the program created involve carefully screening Canadian suppliers and preventing any imported medicine from leaving the state of Hawaii. However, no funding is identified for enforcement of either of these functions for either the Board of Pharmacy or state law enforcement. Nor are there any new criminal penalties created for taking these prohibited products out of the state of Hawaii.

No liability protection for pharmacists dispensing counterfeits to patients.
There is a long history of Canadian operators selling Americans fake medication they claim is Canadian. Should such a vendor succeed under this program, a patient will end up engaging in litigation with the entire supply chain. The pharmacists who dispense this medication on assurance of safety by the state will be left with the legal and financial liability for this harm despite having no ability to vet the vendor in any way.

Requires pharmacies and health care providers to lose money in dispensing these medicines.

[1] "The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis", London School of Economics

Testimony of Shabbir Imber Safdar
Executive Director, The Partnership for Safe Medicines
www.safemedicines.org

HB1608 does not allow pharmacies or health care providers are not allowed to charge patients and health plans any more than the acquisition cost for these medicines. Businesses like pharmacies that have to pay rent, storage, security, staffing, insurance and other expenses can't be expected to lose money on dispensing medication or they will go out of business quickly.

Incomplete auditing requirements provided to the state legislature.
Any new program such as this has the potential to endanger patients and requires significant oversight. However the Annual report to the Governor and the Legislature only requires audit findings to be provided for the first three reporting periods. If patients are being endangered, this law allows the department of health to legally hide this information from the legislature and the Governor.

There are other safer ways to bring down prices.
There isn't an elected official today who doesn't hear from their constituents that health care costs are an issue, and pharmaceutical spending, which is less than 20% of overall healthcare spending, is certainly a piece of the problem. But states are finding other, safer ways to address these costs. Louisiana has negotiated a "Netflix" subscription model, which will allow the state to treat all hepatitis C cases in the state at a fixed cost. West Virginia kicked their PBM out of their Medicaid program and saved $52 million in their first year. Other states are looking at capping co-pays on products like insulin.

HB 1608 sounds like a good idea, but it will feed an existing black market in poorly regulated and counterfeit drugs. Rather than simply fail, the bill will create incentives for Canadian wholesalers to ship counterfeit or substandard medicine into America that will be expensive to detect, and even more expensive for patients if we fail to detect it. Hawaii could help more people access healthcare by funding programs with less risk.

Sincerely,

Shabbir Imber Safdar
Executive Director, Partnership for Safe Medicines

February 4, 2020

TO: Chair Roy M. Takumi
Vice Chair Linda Ichiyama
Members of the House Committee on Consumer Protection & Commerce

FROM: Pharmaceutical Research and Manufacturers of America (PhRMA)
(William Goo)

RE: **HB 1608 HD1** - Relating to Prescription Drugs
Hearing Date: February 5, 2020
Time: 2:00 pm

PhRMA opposes the passage of **HB 1608 HD1** which seeks to establish a Wholesale Prescription Drug Importation Program. Attached is PhRMA's testimony in opposition.

Thank you for considering this testimony.

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to HB 1608 HD1

February 4, 2020

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes HB 1608 HD1 which establishes a Wholesale Prescription Drug Importation Program ("Program") because it mischaracterizes importation as a tool to lower drug costs and greatly understates the inherent threats to patient safety.

HB 1608 HD1 is unlikely to produce significant cost savings and fails to recognize the additional resources needed to implement and maintain an importation program.

Differences between prices of medicines in the US and other countries are often smaller than commonly believed, negating the need for the importation of medicines from other countries. The state of Vermont, has a population of just over 623,000. The Department of Vermont Health Access determined that, "drug importation from Canada would not provide net savings to the state or individuals because Medicaid's existing prescription drug rebate program already yields substantial savings."[i] Vermont estimated 0.3 to 1.3% savings in the private market, which comports with a Congressional Budget Office estimate that a national importation scheme would reduce prescription drug expenditures in the U.S. by just one percent.[ii]

Biopharmaceutical manufacturers provide deep discounts to state Medicaid programs who benefit directly from a statutorily set state-federal Medicaid partnership that allows participants to pay little or nothing for their prescription drugs. In the commercial market, payers would have to determine if the costs associated with participation in an importation program are worthwhile, considering there is limited financial incentive and a potential for significant increased administrative costs.

The challenge to the state to "estimate the extent to which some or all of the costs [of an importation program] may be offset by the anticipated reduction in prescription drug prices" is enormous, and falls well outside of the administrative and drug safety strictures promulgated by the federal government.

Additionally, a state must consider the numerous other costs associated with establishing and administering an importation program.

- *Start-up and Ongoing Costs:* HB 1608 HD1 assigns numerous new responsibilities on the Department including: the design of the Program, compliance with existing federal laws, including track and trace and development of a wholesale prescription drug importation list.

- *Repackaging and Relabeling:* The Congressional Budget Office has issued estimates of the cost to comply with FDA repackaging and relabeling

requirements for a national importation program and found such costs to be significant. The FDA has estimated that this requirement could raise the cost of prescription drugs by as much as $2 billion in the first year for a US-wide importation program.[iii]

- *Law Enforcement Costs:* In July 2017, the National Sheriffs Association approved a resolution opposing state importation legislation because such programs would "jeopardize law enforcement's ability to protect the public health, threaten the safety of our (US) drug supply, and endanger law enforcement officers, their canines, and other first responders."[iv] As former FBI director Louis J. Freeh recently wrote, "the sheer strain that legalized drug importation would have on law enforcement agencies cannot go unappreciated… [W]e've also been faced with resource and budget challenges that force us to do more with less. Rolling the dice on a drug importation law would undoubtedly take resources away from other important law enforcement efforts."[v]

- *Public and Stakeholder Education:* Any statewide prescription drug program requiring voluntary participation from supply chain entities and consumers will require training and education. Both the federal Notice of Proposed Rulemaking (NPRM) on Importation of Prescription Drugs and HB 1608 HD1 require establishment and upkeep of an educational website.

HB 1608 HD1 could increase the risk to consumer health and safety by weakening the closed supply chain and opening the State to increased criminal activity.

HB 1608 HD1 fails to address the complexities of the federal "track and trace" system established under the Drug Supply Chain Security Act (DSCSA) and the inherent risk to public safety if it is compromised. Both HB 1608 HD1 and the federal NPRM place significant responsibility on states to adhere to federal track and trace requirements and demonstrate that any importation program would pose no additional risk to public health.

In 2013, Congress unanimously enacted bipartisan legislation to address concerns of unsafe and counterfeit drugs entering the United States pharmaceutical supply chain. The DSCSA establishes an electronic system to uniquely identify each package of drugs and trace those packages as they are distributed. Through the DSCSA and prior actions, the United States has established one of the most secure supply chains in the world and ensures proper protection of patients. Drug importation programs severely undercut the protections of the DSCSA, compromising patient safety. If Hawaii pursues an importation program, it will assume significant risk and potential cost in an effort to ensure public safety.

An importation program could also expose Hawaii to greater risk of exposure to counterfeit medications that are transshipped through Canada and the potential for increased criminal activity. Canadian government health officials have stated that they cannot guarantee products sold to U.S. citizens are safe and effective. As Diane C. Gorman, Assistant Deputy Minister of Health Canada, stated in 2004, "Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future[vi]." This concern was more recently restated by Leona Aglukkaq, Canada's Health Minister from 2008 through 2013, in a letter to the Washington Post[vii]. Most recently, Canada's acting Ambassador to the United States, Kirsten Hillman, stated that "the Canadian market is too small to have a real impact on U.S. drug prices," and that "Canada's priority is to ensure a steady and solid supply of

medications at affordable prices for Canadians." In October, the Western Sheriffs Association approved a resolution opposing state importation legislation due to concerns that, "drug importation will likely become another loophole for criminals to exploit, importing drugs that are substandard, adulterated, misbranded and even counterfeit."[viii]

PhRMA shares a desire to address patient affordability within the health care system and reduce costs in the State of Hawaii. However, for the reasons stated above, PhRMA does not believe development of a drug importation program will produce the desired results and could significantly jeopardize patient safety.

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[i] Vermont Agency of Human Services, Report to the Vermont Legislature, "Wholesale Importation Program for Prescription Drug Legislative Report," December 31, 2018.
[ii] Congressional Budget Office, "Cost Estimate: S.1392 FTC Reauthorization Act of 2005," September 8, 2005.
[iii] CBO. "CBO Cost Estimate: The Pharmaceutical Market Access Act of 2003." 2003
[iv]Drug Enforcement Administration (undated; viewed on July 25, 2017), DEA Warning to Police and Public: Fentanyl Exposure Kills, https://ndews.umd.edu/sites/ndews.umd.edu/files/DEA%20Fentanyl.pdf. Also, Drug Enforcement Administration (July 2016), supra.
[v] Louis J. Freeh op-ed, "Cost of drug importation could unfairly shift to law enforcement," The Philadelphia Inquirer, May 5, 2017.
[vi] HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.
[vii] Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017.
[viii] RESOLUTION 2019 – 08. Western States Sheriffs' Association Opposes Drug Importation Legislation. October 2019.

House Committee on Consumer Protection and Commerce
Wednesday, February 5, 2020
2:00 p.m.
Conference Room 329

Testimony in Support of HB 1608 HDI
Relating to Prescription Drugs

Dear Chair Rep. Roy M. Takumi, Vice-Chair Rep. Linda Ichiyama,
and Members of the House Committee on Consumer Protection and Commerce.

My name is Anna Filler, and I am in strong support of HB 1608 HDI, Relating to Prescription Drugs. This bill authorizes the Department of Health to implement a program for wholesale importation of prescription drugs. Effective 7/1/2050. Many of our seniors over age 50 depend on prescription drugs to keep them healthy the price increases over the years is out of control

Thank you for providing the opportunity to testify in support of HB 1608 HDI, relating to Prescription Drugs.

Anna Filler
District 26, Downtown-Kakaako-McCully
Email: afiller@twc.com

To Chair Takumi, Vice Chair Ichiyama, and Members of the Committee on Consumer Protection & Commerce,

I am writing in opposition to HB 1608, which would establish a wholesale prescription drug importation program in Hawaii. My name is Don Bell. I am a thirty-three-year law enforcement officer, having served with the Ontario Provincial Police (OPP) and the Canada Border Services Agency (CBSA). I held the rank of Chief Superintendent within the OPP and was a Director of Enforcement and Intelligence for the CBSA.

Attempting to lower prescription drug prices is an important goal. However, there are significant unintended consequences of importation that will compromise the safety of Hawaii residents with no guarantee of cheaper medicine. Legalizing importation will create a dangerous loophole that criminals will exploit to smuggle counterfeit prescription drugs into Hawaii.

It's a simple supply/demand issue. Canada consumes only two percent of the global market of prescription drugs compared to 44% in America.[1] Canadian officials have stated that Canada's market is too small for the U.S. and it cannot increase its supply to meet the needs of Americans.[2] Our legitimate drug supply is designed for the needs of Canadians.

Canada is already struggling to provide its own citizens with life-saving medications and has 2,050 drug shortages.[3] Importation programs like HB1608 would exacerbate these shortages. Health Canada, our equivalent of the U.S. Food and Drug Administration, is not likely to send medicine in short supply to Hawaii before taking care of its own citizens. While Hawaii's population is small, our pharmaceutical market cannot meet your needs.

Besides the supply/demand concerns, Canadian authorities and law enforcement are neither resourced nor structured to guarantee the safety of such transnational drug shipments. While Canada's pharmaceutical supply chain is very safe, it was built to ensure the safety of drugs entering and being consumed in Canada. It was not built to, and is not the duty of, Health Canada to protect or ensure the safety of prescription drugs for other nations. While cognizant of pharmaceutical drugs being exported, our primary duties are commissioned for the protection of Canadians, not Americans. In other words, Canadian Law Enforcement, Border Protection and Health Canada do not routinely inspect outgoing shipments. Furthermore, drugs transshipped through Canada are not a resource or inspection priority for Canadian law enforcement.

The proliferation of online pharmacies have created further challenges for already stretched law enforcement resources in the area of substandard, adulterated, and/or counterfeit drugs. For example, Operation Pangea is an annual, global effort involving over 100 countries focusing on the online sale of counterfeit illicit medicines and devices. In 2018, eighty-seven percent or over 3,000, of those shipments inspected by Canadian law enforcement were seized or refused entry, since they contained counterfeit and/or unlicensed health products, such as illegal prescription drugs.[4] This initiative clearly emphasizes the message: do not compromise your health by importing fake drug products.

The opportunity for criminals to take advantage of Hawaii should not be taken lightly as illegitimate drug products are already an issue in America. The U.S. Customs and Border Protection (CBP) reported counterfeit pharmaceuticals are the seventh most seized product at the border, noting that the profit margins are high for the sale of counterfeit drugs and detection by law enforcement is low. These illegitimate products have been

[1] Connect2Canada (2019, November 1). *Readout of Acting Ambassador Kirsten Hillman's meeting with Joe Grogan Assistant to the President for Domestic Policy*. Retrieved from https://connect2canada.com/2019/11/readout-of-acting-ambassador-kirsten-hillmans-meeting-with-joe-grogan-assistant-to-the-president-for-domestic-policy/

[2] See Martel, A. (2019, November 1). *Canadian ambassador says drug imports would not lower U.S. prices*. Retrieved from https://www.reuters.com/article/us-canada-health-supplies-idUSKBN1XB55E

[3] Drug Shortages Canada. *Summary report*. Retrieved from https://www.drugshortagescanada.ca/rws-search?perform=1

[4] Canada Border Services. *The CBSA Participates in Operation Pangea*. Retrieved from https://cbsa-asfc.gc.ca/new-neuf/articles/pangea-eng.html

found across all types of therapeutic areas including lifestyle medications, over-the-counter medications, and even cancer and cardiovascular drugs.[5]

Criminals are already in the business of selling counterfeit drugs to Hawaiians. For example, an illegal operation ran for two years selling fake Botox to Hawaii residents hoping to receive anti-aging remedies. U.S. law enforcement believe hundreds of residents were injected at 'Botox parties' in hotels during this time. Two HI residents suffered permanent eye damage as a result of the substandard injections. The couple operating the criminal enterprise were arrested and served prison sentences for importing fake Botox and not having licenses to administer medicine.[6]

The ability for criminals to get away with the crime of importing substandard, adulterated, and counterfeit drugs is aided by the fact that they look like real medicine. Without robust inspections and testing, you cannot know if a medicine is legitimate. This will be an issue in Hawaii since no resources have been added in this bill for law enforcement and border protection to inspect and test prescription drugs. Criminals will be able to increase their operations to transship counterfeit drugs from a third-party country under the guise of importation through Canada into Hawaii.

From my experience, I know criminal networks are ready to seize at this importation loophole. This is even more concerning in that counterfeit drugs are becoming deadlier due to fentanyl-laced counterfeit opioids. The DEA reported that drug trafficking organizations have been sending fentanyl-laced counterfeit pills in bulk to the U.S. for distribution.[7]

Hawaii has been somewhat shielded from the devastation of the opioid epidemic with only 3.4 opioid-related deaths per 100,000 people[8] and has been able to be very proactive in prevention efforts.[9] Additionally, Hawaii is the only state without a confirmed counterfeit fentanyl-laced pill in the country.[10] This is surprising given the DEA's finding that 27% of all opioids seized nationwide were fentanyl-laced counterfeits.[11] It is not worth creating a counterfeit drug problem in Hawaii in the hopes of saving money on prescription drugs.

We need to be concerned about the unintended consequences of such policies for Hawaii as well as Canada. Drug importation creates a public safety and law enforcement issue. In the interest of the public safety of both of our nations, I urge you to not let the allure of importing cheaper drugs from Canada overshadow the real illicit trade concerns of drug importation. Importing drugs from Canada is not a long-term solution to the drug pricing concerns in Hawaii.

Sincerely,

Don Bell

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[5] U.S. Department of Homeland Security (2020, January 24). Combating Trafficking in Counterfeit and Pirated Goods. Retrieved from https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf

[6] Kawano, L. (2017, November 2). Couple behind lucrative fake Botox parties at Hawaii hotels sentenced. Retrieved from https://www.hawaiinewsnow.com/story/36753870/couple-who-smuggled-thousands-of-anti-wrinkle-medication-into-hawaii-sentenced-to-prison/

[7] DEA. (2019, November 4). *DEA issues warning over counterfeit prescription pills from Mexico*. Retrieved from https://www.dea.gov/press-releases/2019/11/04/dea-issues-warning-over-counterfeit-prescription-pills-mexico-0

[8] National Institute on Drug Abuse (2019, May). Opioid Summaries by State. Retrieved from https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state

[9] Fawcett, D. (2019, April 16). *Why Hawaii Has Many Opioid Users But Few Overdose Deaths*. Retrieved from https://www.civilbeat.org/2019/04/denby-fawcett-why-hawaii-has-many-opioid-users-but-few-overdose-deaths/

[10] Partnership for Safe Medicines (2019, July). *48 states have reported deadly counterfeit pills made with fentanyl*. Retrieved from https://www.safemedicines.org/wp-content/uploads/2019/08/2019-48state-33deadcounting-1pager-SECURE.pdf

[11] DEA. (2019, November 4). *DEA issues warning over counterfeit prescription pills from Mexico*. Retrieved from https://www.dea.gov/press-releases/2019/11/04/dea-issues-warning-over-counterfeit-prescription-pills-mexico-0