DAVID Y. IGE
GOVERNOR OF HAWAII

BRUCE S. ANDERSON, PHD
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
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Testimony COMMENTING on HB1608
RELATING TO PRESCRIPTION DRUGS.

REP. JOHN M. MIZUNO, CHAIR
HOUSE COMMITTEE ON HEALTH
Hearing Date: January 28, 2020 Room Number: 329

Fiscal Implications: Unknown appropriation amount 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 DEPARTMENT OF THE ATTORNEY GENERAL
THIRTIETH LEGISLATURE, 2020

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

BEFORE THE:
HOUSE COMMITTEE ON HEALTH

DATE: Tuesday, January 28, 2020 **TIME:** 8:35 a.m.

LOCATION: State Capitol, Room 329

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

Chair Mizuno 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 the Department of Commerce and Consumer Affairs currently fulfills the role of licensing wholesalers. 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 15-16.)

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 18, 2019. The rules are not yet final. They can be found at: https://www.hhs.gov/sites/default/files/nprm-importation-of-prescription-drugs_12-18-2019.pdf. 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.

HOUSE OF REPRESENTATIVES
Committee on Health
Tuesday, January 28, 2020
8:35 a.m.
Conference Room 329

RE: HB 1608 RELATING TO PRESCRIPTION DRUGS

To: Representative John Mizuno, Chair

AARP is a membership organization of people age fifty and over, with nearly 145,000 members in Hawaii. AARP advocates and provides information on issues that matter to our kūpuna and their families, including affordable, accessible, quality healthcare, financial resiliency, and livable communities.

HB 1608 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. 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.

Keali'i Lopez, State Director
AARP Hawaii

HDA
Healthcare Distribution Alliance

PATIENTS MOVE US.

January 27, 2020

Hawaii House of Representatives
House Committee on Health
415 South Beretania St.
Honolulu, HI 96813

Re: Healthcare Distribution Alliance (HDA) Opposition to HB 1608

Chairman Mizuno and Members of the House Committee on Health,

The Healthcare Distribution Alliance (HDA) offers this letter to indicate our opposition to House Bill 1608, relating to the importation of prescription drugs from Canada. HDA is the national trade association representing primary pharmaceutical wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies and other healthcare settings nationwide. Specific to Hawaii, our members operate four facilities in the state and deliver lifesaving medicines to approximately 1,033 customers in Hawaii. On behalf of the industry, HDA would like to express our concerns with HB 1608 due to the potential impact on pharmaceutical supply chain and risk to patient safety.

The U.S. pharmaceutical supply chain is the most sophisticated, efficient and highly secure drug supply chain system in the world. The security of the supply chain was further strengthened in 2013 by the passage of the federal Drug Supply Chain Security Act, commonly referred to as DSCSA. This law outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. This will enhance the Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Under the confines of DSCSA, any drug distributed in the U.S. must distributed to and from an authorized trading partner. Further, any drug distributed within the U.S. must also be a serialized product, incorporating the National Drug Code, Serial Number, Lot Number and expiration date. Drugs that are sold or designated for sale in Canada as well as other countries do not conform with these U.S. traceability regulations, it would be a violation of federal law for any wholesaler or other trading partner to accept or distribute product within the U.S. that do not meet these standards. Allowing for the importation of drugs from Canada or other countries would hinder the intent of the DSCSA Statute, and thereby increase the risk of illegitimate or counterfeit medications entering the U.S. market.

Drug approval by the FDA is contingent upon the strictest guidelines for product integrity, good manufacturing practices, scientific data analysis and public safety. Although there are a number of drugs available for sale in Europe, Canada or other countries that may be priced at a lower cost for a variety of

reasons, it is important to recognize that other countries' regulatory agencies have different approval guidelines, dosage recommendations and quality assurances. At this point in time, the FDA cannot guarantee to an American consumer that a drug marketed and available abroad will be the same product his or her physician had written the prescription for, nor can it fully attest to its safety. [1] Further, four recent FDA Commissioners wrote an open letter to Congress in March 2017 expressing their continued concerns with a drug importation program stating that "such importation represents a complex and risky approach – one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers." [2]

Both branded and generic drugs are susceptible to counterfeiting, containing insufficient or too much of an approved medicine's active ingredient or to being contaminated by unsanitary manufacturing conditions. The U.S. supply chain, regulated by the FDA, devotes significant resources to ensuring good manufacturing practices, product authenticity and the safe and secure distribution of drugs through authorized parties from the point of manufacture to the point of dispensing. HDA members are an essential part of this closed distribution system, working daily with supply chain partners, law enforcement and government regulators to help ensure prescription medicines are safely delivered to licensed pharmacies within the U.S.

Given the recent actions to enhance security within our pharmaceutical supply chain, allowing for importation of prescription drug products, even from a specific country, increases the likelihood of counterfeit or adulterated drugs entering the country. Due to these concerns, we ask that you oppose HB 1608. Please contact Leah Lindahl, Llindahl@hda.org or (303) 829-4121, if you have any questions or would like to discuss this issue further.

Thank you,

Leah D. Lindahl

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

[1] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi, Esq., The Kullman Firm https://www.crowell.com/pdf/FDALetter.pdf

[2] Open letter to Congress authored by four FDA commissioners opposing drug importation, (March 2017)https://www.documentcloud.org/documents/3519007-FDA-Commissioners-Drug-Reimportation.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals

January 27, 2020

TO: Chair John M. Mizuno
Vice Chair Bertrand Kobayashi
Members of the House Committee on Health

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

RE: **HB 1608** - Relating to Prescription Drugs
Hearing Date: January 28, 2020
Time: 8:35 am

PhRMA opposes the passage of **HB 1608** 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 Hawaii House Bill 1608

January 27, 2020

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes HB 1608 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 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, with a population 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 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 require establishment and upkeep of an educational website.

HB 1608 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 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 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, we do 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.

An Independent Licensee of the Blue Cross and Blue Shield Association

January 26, 2020

The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
House Committee on Health

Re: HB 1608 – Relating to Prescription Drugs

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 1608, which authorizes the Department of Health to implement a program for wholesale drug importation.

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,

Pono Chong
Vice President, Government Relations

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

Chairman Mizuno, Vice Chair Kobayashi, Representative Au Belatti, Representative Nakamura, Representative Buenaventura, Representative Say, Representative Tokioka, and Representative Ward:

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

LATE

HEALTH COMMITTEE
TESTIMONY IN SUPPORT OF HB 1608
RELATING TO PRESCRIPTION DRUGS
Tuesday, January 28, 2020, 8:35 a.m.

The Honorable John M. Mizuno, Chair,
Representative Bertrand Kobayashi, Vice Chair, and
Members of the House Committee on Health:

Aloha mai kakou:

I am Melodie Aduja, Chair of the Health Committee of the Democratic Party of Hawai`i. The Democratic Party is the major political not-for-profit organization in the State of Hawai`i; its membership is approximately 75,000 members strong. The Legislative body comprises of predominately democratic members with only one republican senator and five republican members of the House. As such, the will of this Legislative body should reflect the voice, Platform and Resolutions of the Democratic Party of Hawai`i. Mahalo for this opportunity to address you.

The Health Committee of the Democratic Party of Hawai`i strongly supports HB 1608. This Act would authorize the Department of Health to implement a program for wholesale drug importation.

As noted in The Commonwealth Fund article entitled, States are Using Drug Importation to Lower Costs and Provide Safe Access to Drugs, by Jane Horvath, June 27, 2019, (please see, link below), several states such as Colorado, Vermont and recently, Florida, have legislation which allow these states to import lower-cost prescription drugs. In this article, even the Trump Administration has directed the Secretary of Health and Human Services (HHS) Alex Azar to help Florida create its program. These states are important test cases of how to legally permit the safe importation of lower-cost prescription drugs by entities other than manufacturers or the FDA. Existing law in some states permits both wholesale and personal importation of prescription drugs from Canada with the approval of the HHS Secretary. State and federal policymakers increasingly see importance to improve market functioning through increased price competition.

Currently, at least 40 percent of the prescription drugs used in the U.S are manufactured abroad and considered safe. Former FDA Commissioner Scott Gottlieb has note that any drug manufactured overseas for the U.S market is made in the same FDA-registered plant that makes

the drug for markets in other countries. In addition, the U.S. has a long-standing reciprocity agreement with Canada for sharing information about manufacturing issues and compliance.

State-administered wholesale importation programs can provide price competition, relieve cost pressures on residents, and maintain safety and savings in a way that a national, commercial importation program cannot. Importation programs at the state level also solve the problem of overburdening the FDA with a large-scale national program.

HB 1608 would allow for a competitive marketplace to the benefit of the citizens of Hawaii who can then purchase their prescription drugs at an affordable price through State-administered importation under the Department of Health.

Thank you very much for this opportunity to provide testimony in support of HB 1608.

Sincerely yours,

/s/ Melodie Aduja
Chair, Health Committee

1. https://www.commonwealthfund.org/blog/2019/states-are-using-drug-importation-lower-costs-and-provide-safe-access-drugs