DAVID Y. IGE
GOVERNOR

JOSH GREEN
LT. GOVERNOR

STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
335 MERCHANT STREET, ROOM 310
P.O. BOX 541
HONOLULU, HAWAII 96809
Phone Number: 586-2850
Fax Number: 586-2856
cca.hawaii.gov

CATHERINE P. AWAKUNI COLÓN
DIRECTOR

JO ANN M. UCHIDA TAKEUCHI
DEPUTY DIRECTOR

Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committee on Health
Tuesday, March 19, 2019
10:00 a.m.
State Capitol, Conference Room 329

On the following measure:
S.B. 1328, RELATING TO PRESCRIPTION DRUGS

Chair Mizuno and Members of the Committee:

My name is Colin Hayashida, and I am the Insurance Commissioner of the Department of Commerce and Consumer Affairs' (Department) Insurance Division. The Department offers comments on this bill.

This bill requires that if a proposed increase in the wholesale price of certain drugs would result in a 16% or more increase in the wholesale acquisition cost over a two-year period, the drug manufacturer shall provide notice to various drug insurance providers. The Department is concerned the Insurance Division will be unable to enforce the measure's proposed amendments to Hawaii Revised Statutes chapter 431R, as the Insurance Division has no regulatory oversight over drug manufacturers and no expertise in regulating wholesale prescription drugs.

If, however, the Committee chooses to pass this measure, the Department respectfully requests a delayed implementation date of at least one year. In addition, the Department respectfully requests adjusting the Insurance Division's budget ceiling

to cover the fiscal impact of this bill, including the cost to retain an outside expert consultant on prescription drug wholesale pricing to assist with implementation and enforcement of this bill.

Finally, the Department notes that similar legislation passed in California is currently the subject of litigation before the United States District Court, Eastern District of California, Case No. 2:17-cv-02573, on grounds that the law is unconstitutional.

Thank you for the opportunity to testify on this measure.

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Government Relations

Testimony of
Jonathan Ching
Government Relations Specialist

Before:
House Committee on Health
The Honorable John H. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair

March 19, 2019
10:00 a.m.
Conference Room 329

Re: SB1328, Relating to Prescription Drugs

Chair Mizuno, Vice-Chair Kobayashi, and committee members, thank you for this opportunity to provide testimony on SB1328, which requires drug manufactures to notify prescription drug insurers and pharmacy benefit managers of a proposed increase in the wholesale price of certain drugs.

Kaiser Permanente Hawai‘i SUPPORTS SB1328.

Among the greatest threats to the affordability of health care coverage is the pharmaceutical industry's pricing of new and existing medications. New drugs are being approved and marketed with higher prices than their predecessor treatments, often with no difference in effectiveness or safety. Drugs that have been on the market for years are seeing double digit price increases each year without an explanation. In some cases, drugs that have long been available are going up in price even faster, with triple and quadruple digit price increases.

Kaiser Permanente's Specialty Pharmacy, which services Kaiser Permanente Hawai‘i members, focuses on high cost, high touch medication therapy for patients with complex disease states. As such, Kaiser Permanente Specialty Pharmacy's overall drug spending for Hawai‘i members increased 146% from 2015 to 2018. This problem is only going to get worse, with spending on specialty drugs expected to continue to rise at an alarming rate. Unchecked, this trend will bankrupt public and private payors alike. Even common drugs that have been around for many years are seeing unexplainable, staggering price increases. Manufacturers raise prices on existing drugs once, twice, or even three times per year − and yet, that new, higher price seldom brings any additional value or clinical benefit. This would never be acceptable in any other industry and is simply unsustainable.

Hospitals and health plans report pricing information. It's time for pharmaceutical manufacturers to do the same when they implement major price increases.

Because individuals are required to buy health care, and public and private purchasers are required to cover an FDA approved medication when one is available for a patient's condition, there is a compelling public interest for drug manufacturers to be required to provide a rationale as to how they arrived at a particular price. Price transparency is quickly becoming the norm in the health care industry in order to contain costs and encourage healthy competition.

Kaiser Permanente Hawai'i is appreciative of the innovation in pharmaceuticals that makes a profoundly better quality of life available to our patients. However, patients will not benefit if a medication is priced out of reach and does not provide additional value from a quality and/or safety perspective or if ultimately these price increases bankrupt the system.

SB1328 is a good first step toward shining a light on manufacturer pricing practices and will also help purchasers and policy makers better understand this large and growing expense.

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

Association for Accessible Medicines

Your Generics & Biosimilars Industry

Letter in Opposition of Senate Bill 1328
House Committee on Health - March 19, 2019

Chairman Mizuno, Vice-Chair Kobayashi, and members of the House Committee on Health,

The Association for Accessible Medicines (AAM) is the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Its core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. AAM members provide more than 36,000 jobs at nearly 150 facilities and manufacture more than 61 billion doses of prescription medicines in the U.S. every year. AAM supports policies that help reduce overall prescription drug costs while ensuring access to affordable medications.

AAM opposes SB 1328 because it would not accomplish this goal and could, instead, cause harm to patients in Hawaii by reducing access to needed medication. The House already acted on HB 267, the companion bill to SB 1328, and elected to defer implementation of this law until 2050. AAM requests your committee take the same course of action on SB 1328.

SB 1328 is partially modeled on a 2017 California law that required manufacturer reporting as well as reporting by other supply chain entities, including insurers and pharmacy benefit managers (PBMs). The California Department of Managed Health Care released its first report required by the law and found that generics accounted for nearly 90% of all prescribed drugs but represented only 23.6% of the state's total pharmaceutical spending. The report also found that the 25 most frequently prescribed generics accounted for 39.9% of all prescriptions but only 4.8% of the total annual spend on medicines and only 0.3% of the total health plan premium. It further found that the 25 most expensive generic drugs accounted for nearly 25% of all prescribed drugs which only had an 8% impact on the total pharmaceutical spend resulting in less than 1% of health care premiums. In fact, even when considering the 25 generics drugs with the highest year-over-year increase, these drugs only accounted for only 4.7% of the total annual spend on prescription drugs.

Generic and biosimilar medicines drive cost savings. In 2017, generics and biosimilars saved Hawaii $815 million while saving the U.S. health care system $265 billion, about $5 billion every week. Over the past decade, generic medicines have saved U.S. healthcare system $1.79 trillion. Patients thrive with access to generic medicines, both in terms of health outcomes and financial savings. Insured patients benefit from an average copay for generics of only $6.06, while paying more than $40 for brand drugs. In fact, 93% of generic prescriptions are filled for $20 or less out-of-pocket, as compared to just 39% for brand drugs. Thus, the solution to lowering prescription drug prices is not by increasing regulatory and administrative burdens on manufacturers of low-cost generic medicines but in focusing on high-priced brand drugs while ensuring robust access to more affordable generic medicines. Generic drugs play a critical role in achieving

healthcare savings and enacting legislation that infringes on the generic drug market could have serious consequences in Hawaii.

By focusing on low percentage increases, this measure ignores the actual cost impact on the health care system. Minimal price changes on low-cost generic products can result in large percentage increases. Including a higher wholesale acquisition cost (WAC) floor and a more significant percentage increase could avoid disturbing the market for low-cost products subject to pricing variability. For example, as drafted SB 1328 would require reporting on drugs with a WAC floor of $40. In other words, the bill would apply to drugs that cost only $1.33 per day. At a 16% increase over more than two years, the bill would capture price increases as low as $0.07 for those medications taken three times per day.

Percentage-based thresholds tied to a low WAC will jeopardize patient access to lower-cost products by placing undue burdens on generic manufactures. The burden will not only be felt in the generic market but will also place unwarranted stress on the system put in place by this legislation to review these costs and could lead to wasted government resources analyzing data related to drugs that are helping to reduce the state spending in the healthcare system.

Brands and generic drugs function differently in the market and create different incentives for entities throughout the supply chain. Brand drugs are protected from direct price competition by patents. Generics, on the other hand, compete within a multi-competitor model with drug prices decreasing as competitors enter the market. Generic drugs typically enter the market significantly lower than the brand product price. Brands maximize revenue through price rather than volume and negotiate discounts or rebates with other supply chain stakeholders while generic companies compete solely on price and ability to meet supply. As a result, generic companies retain only 36% of revenue while others in the supply chain capture 64%. Brand companies retain 76% of revenue within that marketplace.

The differences in the two markets also leads to different financial incentives for other stakeholders in the supply chain who each play a role in patient costs. Once a generic manufacturer sells its products to a wholesaler; 3 of which control more than 90% of the market for generic drug purchasing the company no longer plays a role in the price of the products. Brand manufacturers will negotiate sales price and formulary placement based on rebates with PBM's and insurers.

The price patients pay for a generic drug is affected not only by wholesaler and pharmacy price markups, but also by insurance copay and formulary design choices made by insurance plans and PBMs. For instance, between 2011-2015, Part D health plans moved generics to higher cost sharing tiers. In 2011, 71% of generics were on tier 1, the lowest tier in the formulary. By 2015, only 19% of generics were on tier 1 causing patient out of pocket spending on these products to increase by $6.2 billion (93%) even though the price of the products increased by only 1% and the volume of sales for the products increased by only 22%.

In 2017, the market share for generics increased to 90% of all prescriptions. At the same time the net value of those generic sales fell by more than $5 billion. Conversely, the overall price of brand name drugs has risen 208% since 2008. The competitive generic market can prevent generic manufacturers from raising prices to reflect changing demand or increases in manufacturing costs for products. This results in a dynamic landscape in which manufacturers regularly enter and exit markets as conditions change. Hawaii should focus on high brand and specialty drug prices that contribute to significant state spending and directly impact patient out-of-pocket costs.

I would be happy to discuss AAM's concerns as SB 1328 continues to move through the legislative process.

Sincerely,

Tara C. F. Ryan
Vice President, State Government Affairs

An Independent Licensee of the Blue Cross and Blue Shield Association

March 18, 2019

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

Re: SB 1328 – 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 SB 1328, which requires that if a proposed increase in the wholesale price of certain drugs would result in a 16% or more price increase over a 2-year period, the drug manufacturer shall notify various drug insurance providers.

HMSA supports requiring prescription drug manufacturers to notify prescription drug benefit plans and pharmacy benefit managers of any planned price increases. We believe this measure may assist in our attempt to keep costs down for our members and is an important step towards reigning in the skyrocketing costs of prescription drugs.

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

Sincerely,

Pono Chong
Vice President, Government Relations

March 18, 2019

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: **SB 1328** - Relating to Prescription Drugs
Hearing Date: March 19, 2019
Time: 10:00 am

PhRMA **opposes SB 1328**.

This bill requires the manufacturer of a prescription drug which has a wholesale acquisition cost (WAC) of more than $40 for a course of therapy to notify each drug plan and pharmacy benefit manager of any increase of 16% or more in the WAC over any 2-year period and the reason for the increase at least 60 days before it's effective date.

The mandatory advance notification of the WAC of a prescription drug is not information that will be very meaningful to patients who are primarily concerned about the affordability and accessibility of medications to them. Patients want to know about what a prescription drug will cost them regardless of what the WAC is. If anything, other factors such as rebates and discounts have a more direct impact on drug pricing.

Advance notification of an increase in pricing will result in the unnecessary disclosure of proprietary information at the expense of drug manufacturers that would potentially be advantageous to drug plans or pharmacy benefit managers who may make bulk purchases prior to any price increase taking place and sell them at a higher price later. The constitutionality of mandatory advance price notification is also questionable and the subject of litigation in the State of California. A California state court has recently ruled that the California Correctional Health Care Services (CCHCS) could not release such information provided by a drug manufacturer and that the CCHCS could be liable for attorneys' fees as well.

Further, there will be startup and maintenance costs associated with implementing the advance notification requirement which again would not be of meaningful benefit to patients and hence, unnecessary and unneeded. Although not identical in content, the California law (SB 17) upon which this legislation is based is estimated to cost $1.4 million

in the first two years and $850,000 annually thereafter. Included would be the costs to enforce the manufacturer reporting requirements as well as to collect, coordinate and publish information to the entity collecting the information. Moreover, since California law requires that notice be given to entities that purchase drugs through national contracts, the advance notification would mean that the WAC is likely to be accessible to parties outside California which would make the current bill an unnecessary duplication of efforts.

Instead, PhRMA proposes that the attached amendment to SB 1328 be inserted in place of the current language which creates more meaningful transparency in drug pricing.

The amendment provides for the insurance commissioner to identify annually up to 10 prescription drugs on which the State of Hawaii spends significant health care dollars and for which the WAC increased by a total of 50% or more during the prior two years or by 20 percent or more during the prior year. For each prescription drug identified, the drug manufacturer would report increases in the WAC for the previous five years, information of the factors contributing to the price increases and the amount of expenditures for research and development of the drug. This information would be available to the patient wanting to know of why and how the price of a drug was arrived and is currently at without the disclosure of proprietary information.

Thank you for considering this testimony.

THE SENATE
THIRTIETH LEGISLATURE, 2019
STATE OF HAWAII

S.B. NO. 1328

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Senate Bill No. 1328, is amended as follows:

1. By striking sections 1 through 3 in their entirety and replacing them with the following:

SECTION 1. Chapter 431R, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and read as follows:

"§431R-Mandatory notification of prescription drug price increases. (a) The insurance commissioner shall identify annually up to 10 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost increased by a total of 50 percent or more during the prior two calendar years or by 20 percent or more during the prior calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The drugs identified shall represent different drug classes and must include generics.

(b) For each prescription drug identified pursuant to subsection (a) of this section, the insurance commissioner shall

require the drug's manufacturer to report the following information:

(1) a schedule of drug's wholesale acquisition cost increases over the previous five calendar years;

(2) a written, narrative description, suitable for public release, of the factors that have contributed to the drug's recent cost increase;

(3) the date and price of acquisition of the identified drug if it was not developed by the manufacturer, and the drug's wholesale acquisition cost at the time of acquisition, if known; and

(4) the manufacturer's aggregate, company-level research and development and other relevant capital expenditures (*e.g.*, facility construction) for the most recent year for which final audited data are available.

(c) Information provided by a manufacturer under this section shall be generally consistent with the level and type of data made available in a manufacturer's 10-k filing or to other publicly available data sources. The insurance commissioner shall consult with representatives of manufacturers to establish a single, standard format for reporting information under this section that minimizes administrative burden for the State and manufacturers.

(d) Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.

(e) By June 1 of each calendar year, the insurance commissioner shall publish on the website of the department of commerce and consumer affairs a report on its website based on the information that it receives under subsection (b).

(f) Information provided to the insurance commissioner is limited to the information pursuant to subsection (b), is exempt from public inspection and copying under the Uniform Information Practices Act (Hawaii Rev. Stat. Chapter 92F), and shall not be released in a manner that would allow for the identification of an individual drug, therapeutic class of drugs, or manufacturer, or in a manner that is likely to compromise the financial, competitive, or proprietary nature of the information.

(g) The regulation of pharmaceutical manufacturers' disclosures of revenue-, expense-, and drug pricing-related information, pursuant to this article, is not subject to further regulation by a county, city, town, or other political subdivision of this State."

SECTION 2. Section 431R-1, Hawaii Revised Statutes, is amended by adding new definitions to be appropriately inserted and to read as follows:

"Rebates" means all rebates, discounts, or other price concessions that the State or another prescription drug benefit plan or payor receives or expects to receive, directly or indirectly, from a pharmaceutical manufacturer related to utilization of prescription drugs produced by the pharmaceutical manufacturer.

"Research and development expenditures" means all costs that a pharmaceutical manufacturer incurs during a calendar year that relate to the research and development of products, processes, or services, and including the costs of research and development of products, processes, or services that the pharmaceutical manufacturer has acquired or obtained via a license.

"Wholesale acquisition cost" or "WAC" has the meaning specified at 42 U.S.C. § 1395w-3a(c)(6)(B)."