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Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committee on Consumer Protection & Commerce
Thursday, February 13, 2020
2:00 p.m.
State Capitol, Conference Room 329

On the following measure:
H.B. 1804, H.D. 1, RELATING TO PHARMACEUTICAL REPRESENTATIVES

Chair Takumi, and Members of the Committee:

My name is Charlene Tamanaha, and I am the Licensing Administrator of the Department of Commerce and Consumer Affairs' (DCCA or Department) Professional and Vocational Licensing Division (PVL). The PVL offers comments on this bill.

The purposes of this bill are to: (1) require pharmaceutical representatives to register with the DCCA; and (2) create a program within the DCCA for the administration and enforcement of pharmaceutical representative registrations.

H.D. 1 creates a new chapter to regulate pharmaceutical representatives. Hawaii Revised Statutes section 26H-6 requires that new regulatory measures being considered for enactment be referred to the State Auditor for a sunrise analysis. Referral must be made by concurrent resolution that identifies a specific legislative bill to be analyzed. HRS section 26H-6 further requires that the analysis set forth the probable effects of the proposed regulatory measure and assess whether its enactment is consistent with the legislative policies of the Hawaii Regulatory Licensing Reform Act,

as well as alternative forms of regulation. Therefore, the Department respectfully requests that the Legislature defer this bill until the State Auditor conducts a sunrise analysis on this measure.

Thank you for the opportunity to testify on this bill.

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Government Relations

Testimony of
Jonathan Ching
Government Relations Manager

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

February 13, 2020
2:00 p.m.
Conference Room 329

Re: HB1804, HD1, Relating to Pharmaceutical Representatives

Chair Takumi, Vice Chair Ichiyama, and committee members, thank you for this opportunity to provide testimony on HB1804, HD1, which requires pharmaceutical sales representatives in Hawai‘i to register with the Department of Commerce and Consumer Affairs, comply with ethical standards and complete continuing education requirements in order to market drugs in the state.

Kaiser Permanente Hawai‘i SUPPORTS HB1804, HD1.

Over the years, the public has become more aware of the influence of pharmaceutical company marketing on drug spending and prescribing decisions. Most recently, landmark litigation in the wake of the opioid crisis revealed extensive information about how manufacturers marketed opioids to physicians through sales representatives. For example, in the case of OxyContin, sales representatives allegedly used a range of tactics with physicians to encourage prescribing of high doses for longer periods of time, despite knowing the risks for patients. OxyContin sales ultimately exceeded $35 billion, generating profits for manufacturers while patients and their families suffered the consequences.

Pharmaceutical marketing is not limited to opioids. But the public generally has very limited insight into how drugs are marketed outside of what is revealed in discovery from court cases and the advertisements they see on television. While direct-to-consumer television advertisements for drugs have gotten the most attention from policymakers in recent years, the industry spends more money on other forms of marketing. For example, pharmaceutical companies spent $20 billion on marketing in 2016, the vast majority of which was related to sales representatives and samples.[1] **The industry devotes substantial resources to marketing because it is an effective tool for selling more drugs. Marketing goals can therefore conflict with what's best for patients and keeping health care affordable.**

[1] Schwartz, L. & Woloshin, S. (January 2019). Medical Marketing in the United States, 1997-2016. *JAMA*. Available at: https://jamanetwork.com/journals/jama/fullarticle/2720029?alert=article&utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

At Kaiser Permanente Hawai‘i, we have long recognized the impact pharmaceutical marketing can have on prescribing decisions and affordability. As a result, we limit interaction between our clinicians and pharmaceutical sales representatives as part of our commitment to evidence-based medicine. In Hawaii, pharmaceutical sales representatives are generally prohibited from entering or accessing our facilities to promote drugs. This helps us ensure that our clinicians rely on unbiased evidence about different treatment options reviewed by experts in our system. We believe these best practices can help contribute to both affordability and high-quality care.

Kaiser Permanente Hawai‘i therefore applauds the committees for considering HB1804, HD1**. This is a commonsense policy that would help shine light on and foster ethical pharmaceutical marketing practices.** Similar policies are already law in major cities like Washington, D.C. and Chicago. Ensuring that sales representatives meet basic requirements, adhere to a code of ethics, and disclose high-level information about their interactions with providers would also reveal important information and build a valuable foundation for future work on this topic.

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

February 12, 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 1804 HD1** - Relating to Pharmaceutical Representatives
Hearing Date: February 13, 2020
Time: 2:00 pm

PhRMA **opposes HB 1804 HD1** requiring pharmaceutical representatives to register with the DCCA. Attached is PhRMA's testimony in opposition. PhRMA **supports** the Health and Intrastate Commerce Committees' desire to have the State Auditor conduct a sunrise report pursuant to Section 26H-6 of the Hawaii Revised Statutes as this bill proposes to enact a new regulatory measure.

Thank you for considering this testimony.

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to HB 1804 HD1
February 12, 2020

Position: PhRMA respectfully opposes HB 1804 HD1, which seeks to establish a registration mechanism for pharmaceutical sales representatives that is administratively burdensome and largely duplicative of federal reporting requirements. This type of activity is heavily regulated at the federal level and a patchwork of state and local laws will unnecessarily create a complex regulatory structure.

PhRMA believes that ethical relationships with health care professionals are critical to its mission of helping patients by developing and marketing new medicines. A cornerstone to achieving this mission is ensuring that health care professionals have the latest, most accurate information available regarding prescription medicines, which play an increasingly important role in patient health care.

This bill is unnecessary as pharmaceutical sales and marketing practices are broadly regulated by the federal government in a number of ways. Additionally, industry practice and extensive training serve to further regulate interactions. For example:

- **The U.S. Food and Drug Administration (FDA) regulates all information and promotional materials distributed about a prescription medicine.** Before a new drug is marketed, the FDA reviews all of the promotional materials for that medicine. Sales representatives are not permitted to discuss information that is not contained in the FDA-approved labeling or promotional materials. All sales representatives must adhere to this standard.

- **The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, requires prescription drug manufacturers to annually report payments and transfers of value provided to prescribers and teaching hospitals.** Reportable payments and transfers of value include meals, travel, and fee-for-service payments. The SUPPORT Act passed in October, 2018 extended the Sunshine Act to non-physician prescribers. Reported data are posted on a public website.

- **Pharmaceutical companies and their representatives are subject to criminal anti-kickback statutes and other federal criminal and civil laws, enforced by the U.S. Department of Justice, that govern relationships with health care providers.** The U.S Department of Health and Human Services (HHS) Office of Inspector General has published detailed guidance for pharmaceutical companies designed to deter violations of these federal laws. These marketing guidelines prohibit *quid pro quos* between drug makers and health care professionals.

- **The PhRMA Code on Interactions with Health care Professionals (the "Code") offers guidance about appropriate interactions between pharmaceutical manufacturers and health care providers.** Pharmaceutical manufacturers may offer items primarily for the benefit of patients (items that are $100 or less or items of minimal value that are primarily associated with a health care professional's practice).

- **Company representatives have extensive training about their company's medicines and the conditions that their medicines treat.** Pharmaceutical companies employ many physicians, pharmacists, and other scientists who work with others to create the information that is provided to healthcare professionals.

In addition to requiring duplicative reporting, this legislation places further administrative burden on manufacturers and the state by requiring a training program, assessing undefined fees, and maintening a list of pharmaceutical sales representatives. Making matters worse, these efforts are largely duplicative of reports already available under the Sunshine Act.

Thank you for considering this testimony.