STAND. COM. REP. NO. 3452

Honolulu, Hawaii

APR 0 8 2016

RE: H.B. No. 254
H.D. 2
S.D. 1

Honorable Ronald D. Kouchi
President of the Senate
Twenty-Eighth State Legislature
Regular Session of 2016
State of Hawaii

Sir:

Your Committee on Commerce, Consumer Protection, and Health, to which was referred H.B. No. 254, H.D. 2, entitled:

"A BILL FOR AN ACT RELATING TO MEDICINES,"

begs leave to report as follows:

The purpose and intent of this measure is to allow for the dispensing of biosimilar medicines under specified conditions and regulate interchangeable biological products to ensure patient safety and access to medicines at lower prices.

Your Committee received testimony in support of this measure from the University of Hawai'i System, Hawaii Medical Association, Hawaii Medical Service Association, Healthcare Association of Hawaii, National Patient Advocate Foundation, International Cancer Advocacy Network, National Hispanic Medical Association, American Cancer Society Cancer Action Network, American Liver Foundation, Global Colon Cancer Association, Biotechnology Innovation Organization, National Organization for Rare Disorders, Alliance of Specialty Medicine, HealthHIV, Pharmaceutical Research and Manufacturers of America, Coalition of State Rheumatology Organizations, Alliance for Patient Access, Women Against Prostate Cancer, U.S. Pain Foundation, Alliance for Safe Biologic Medicines, Lupus and Allied Diseases Association, National Psoriasis Foundation, American Autoimmune Related Diseases Association, Global Healthy Living Foundation, RetireSafe, and three individuals. Your Committee received comments on this measure from the Department of Health and CVS Health.

Your Committee finds that biologics are a class of medicines available to treat disease, which, unlike traditional drugs that are chemically manufactured, are manufactured in living cells. Common biologics in use today include human growth hormone, injectable treatments for arthritis and psoriasis, the Hepatitis B vaccine, and stem cell therapy.

Your Committee further finds that biosimilars are substitute versions of brand-name biologics, and while these substitutes are not identical to brand-name biologics, they are designed to provide commensurate benefits to patients at lower costs. As of September 15, 2015, sixteen states and Puerto Rico have passed legislation to regulate the substitution of biosimilars for brand-name biologics by pharmacists, and at least thirty-one states have considered similar legislation.

Your Committee further finds that the Drug Product Selection Board is no longer necessary and its purpose, namely creating the Hawaii additions and deletions list, is better served by reassigning that responsibility to the Director of Health, which, combined with the responsibility to amend the list of substitutable drug products and biological products, simplifies the process to updating and maintaining the list. Furthermore, by consolidating what was formerly referred to as the "compendia of therapeutically equivalent generic drug products" and "Hawaii additions and deletions list" into one list, the "Hawaii list of equivalent drug products and interchangeable biological products", the Director of Health may more efficiently update the list as necessary and according to periodic updates by the United States Food and Drug Administration.

Your Committee has amended this measure by:

(1) Amending the definition of "biological product" to include a reference to "biologic product";

(2) Defining "Hawaii list of equivalent generic drug products and interchangeable biological products";

(3) Amending the definitions of "interchangeable biological product" and "equivalent generic drug product";

(4) Deleting the definitions of "board", "compendia of therapeutically equivalent generic drug products",

"Hawaii additions and deletions list", and "multiple source drug";

(5) Requiring pharmacists and authorized agents to inform a consumer of savings and product differences when filling a prescription order for a drug prescribed by its brand name and offering a consumer an equivalent generic drug product or an interchangeable biological product;

(6) Specifying that a pharmacist shall not substitute an equivalent generic drug product or interchangeable biological product unless the practitioner and consumer provide consent;

(7) Requiring a dispensing pharmacist or designee to communicate to the prescriber the name and manufacturer of a biological product provided to a patient, within twenty-four hours following the dispensing of the biological product;

(8) Clarifying language related to notice of dispensing a biological product by a pharmacist to a prescriber using an electronic records system or other means;

(9) Amending section 328-96, Hawaii Revised Statutes, to:

(A) Delete language that allowed the Drug Product Selection Board to establish a Hawaii additions and deletions list and other various responsibilities related to the list;

(B) Provide the Director of Health with the sole authority to create and amend, not subject to chapter 91, Hawaii Revised Statutes, the Hawaii list of equivalent drug products and interchangeable biological products pursuant to findings of the United States Food and Drug Administration;

(C) Require the Director of Health to notify all pharmacies in the State if the Hawaii list of equivalent generic drug products and interchangeable biological products has been updated;

(D) Specify that the Hawaii list of equivalent generic drug products and interchangeable biological products include only substitutable generic drug products and interchangeable biological products that are determined by the Director of Health to be safe, effective, and therapeutically equivalent or interchangeable;

(E) Require the Department of Health to distribute the Hawaii list of equivalent generic drug products and interchangeable biological products, including any revisions, to all pharmacies in the State and any other interested individuals and may publish the Hawaii list of equivalent generic drug products and interchangeable biological products and notice of any amendments thereto on the Department of Health's website; and

(F) Require each pharmacy in the State to update and maintain its physical copies and electronic records of the Hawaii list of equivalent generic drug products and interchangeable biological products;

(10) Repealing the Drug Product Selection Board; and

(11) Making technical, nonsubstantive amendments for the purposes of clarity and consistency.

As affirmed by the record of votes of the members of your Committee on Commerce, Consumer Protection, and Health that is attached to this report, your Committee is in accord with the intent and purpose of H.B. No. 254, H.D. 2, as amended herein, and recommends that it pass Second Reading in the form attached hereto as H.B. No. 254, H.D. 2, S.D. 1, and be placed on the calendar for Third Reading.

Respectfully submitted on behalf of the members of the Committee on Commerce, Consumer Protection, and Health,

Rosalyn H. Baker

ROSALYN H. BAKER, Chair

The Senate
Twenty-Eighth Legislature
State of Hawai'i

Record of Votes
Committee on Commerce, Consumer Protection, and Health
CPH

Bill / Resolution No.:*	Committee Referral:	Date:
HB 254, HD 2	CPH	3-29-16

☐ The Committee is reconsidering its previous decision on this measure.

If so, then the previous decision was to: _____

The Recommendation is:

☐ Pass, unamended 2312 ☑ Pass, with amendments 2311 ☐ Hold 2310 ☐ Recommit 2313

Members	Aye	Aye (WR)	Nay	Excused
BAKER, Rosalyn H. (C)	✓			
KIDANI, Michelle N. (VC)	✓			
ESPERO, Will	✓			
IHARA, Jr., Les	✓			
NISHIHARA, Clarence K.				✓
RUDERMAN, Russell E.	✓			
SLOM, Sam				✓
TOTAL	5			2

Recommendation: ☑ Adopted ☐ Not Adopted

Chair's or Designee's Signature: Michelle N. Kidani

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*Only one measure per Record of Votes

Revised: 6/4/15