HB254 HD2

Measure Title:	RELATING TO MEDICINES.
Report Title:	Biosimilar Medicines; Interchangeable Biological Products
Description:	Allows for the dispensing of biosimilar medicines under specified conditions. Regulates interchangeable biological products. (HB254 HD2)
Companion:	
Package:	None
Current Referral:	CPH
Introducer(s):	EVANS, MCKELVEY, Belatti, Creagan

DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

Testimony COMMENTING on HB 254 HD2
RELATING TO MEDICINES

SENATOR ROSALYN BAKER, CHAIR
SENATE COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH
Hearing Date: March 29, 2016 Room Number: 229
Time: 9:00 am

Fiscal Implications: None

Department Testimony: The department supports the intent of this bill but would like to provide the following important comments.

The bill proposes to amend the approval of generic equivalents for substitution and new interchangeable biological drugs by resurrecting the currently defunct Drug Product Selection Board (DPSB) "…board" to approve all generic drugs and these interchangeable biologics and to then notify the pharmacies of the approved change.

As currently written, HRS 328-91 allows the "director" (Director of Health) to adopt listings of first time generics with therapeutic equivalency evaluations, as well as adopting, maintaining and updating the compendia of therapeutically equivalent drugs which also includes interchangeable biological products.

By allowing the changes from "director" to "board" in pg. 6 line 20, pg. 13 line 7, and pg. 15, line 16 as well as changing "department" to board on pg. 13 line 8, to go forward, it will appear

to require the defunct DPSB to "approve" new substitutions for generic and biological drugs as well as adopting, maintaining, and updating changes to the compendia.

In the past, the DPSB met and "approved" the new substitutions, but that process was slow and inefficient, so the law was changed to remove the approval process from the DPSB and given directly to the "director". We believe that reverting the authority back to DPSB is not in best interest of public and will require the re-establishment of the board to "approve" substitutions that have been already approved by FDA. Pharmacists can determine current substitutions by reviewing the "orange" and/or "purple" books referenced in the bill.

Offered Amendments: Please delete the changes in the bill that remove "director" and "department" and are replaced by "board". The changes are on pg. 6 line 20, pg. 13 line 7, and pg. 15, line 16 and pg. 13 line 8. Remove the requirement on page 13, line 8-10 that indicates the department will notify all pharmacies in the State and other interested individuals, within thirty days after the formulary has been updated. Remove the word "board" on page 13, line 12 and replace with "director".

Thank you for the opportunity to testify.

UNIVERSITY OF HAWAI'I SYSTEM
Legislative Testimony

Testimony Presented Before the
Senate Committee on Commerce, Consumer Protection and Health
Tuesday, March 29, 2016 at 9:00 a.m.
By
Carolyn Ma, Pharm D and Interim Dean
UH Hilo – Daniel K. Inouye College of Pharmacy

HB 254 HD2 – RELATING TO MEDICINES

Chair Baker, Vice Chair Kidani, and members of the committee:

My name is Carolyn Ma, and I am the interim Dean for the Daniel K. Inouye College of Pharmacy testifying on HB 254 HD2, which allows for the dispensing of biosimilar medicines under specified conditions and regulates interchangeable biological products. The college finds this an interesting proposal and supports the intent of the bill to allow for more affordable medicines, especially in this area of biologics.

Thank you for the opportunity to testify.

TO:
COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH
Senator Rosalyn H. Baker, Chair
Senator Michelle N. Kidani, Vice Chair

DATE: Tuesday, March 29, 2016
TIME: 9:00am
PLACE: Conference Room 229

From: Hawaii Medical Association
Dr. Scott McCaffrey, MD, President
Dr. Linda Rasmussen, MD, Legislative Co-Chair
Dr. Ronald Keinitz, MD, Legislative Co-Chair
Dr. Christopher Flanders, DO, Executive Director
Lauren Zirbel, Community and Government Relations

On behalf of the Hawaii Medical Association we are writing to express our support of HB 254 HD1, to allow for the regulation of biosimilar medicines to ensure patient safety and access to medicines at lower prices.

HMS supports legislative initiatives that meet the Associations objectives to help physicians put patient care first, and to assure high quality health care for all the people of Hawaii. This legislation will improve access to newly approved biosimilars, which are an important treatment option for patients and physicians.

Biologics differ from small molecule chemically manufactured drugs as they are more complex and comprised of large molecules, and typically used to treat chronic diseases. A biosimilar is not the exact generic copy of a brand name biologic, but if this bill passes, when a biosimilar has been deemed “interchangeable” by the FDA, pharmacists in Hawaii will be able to substitute these safe substitutes to patients at lower costs.

HB 254 HD1 maintains the physicians authority to use the term Brand Medically Necessary as is outlined in current law for generic substitution. Also mimicking the generic substitution law, patients will be notified of the interchangeable biosimilar substitution. An important addition to this legislation is the assurance that the physician will receive the information regarding the substitution from the pharmacist in an after the fact communication into the patient record.

HB 254 HD1 is a necessary update to allow a clear substitution process for Hawaii patients to have access to lower costs medicines and HMA supports the passage of this legislation.

An Independent Licensee of the Blue Cross and Blue Shield Association

March 29, 2016

The Honorable Rosalyn H. Baker, Chair
The Honorable Michelle N. Kidani, Vice-Chair
Senate Committee on Commerce, Consumer Protection and Health

Re: HB 254, HD2 – Relating to Medicines

Dear Chair Baker, Vice-Chair Kidani and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 254, HD2 which specifies the conditions under which biosimilar medications may be dispensed. HMSA supports the intent of this Bill, and we offer an amendment.

HMSA certainly appreciates the importance of generic drugs in helping to control the ever-rising cost of healthcare. In that same vein, we recognize the potential role biosimlars could play in helping temper healthcare costs in our State. However, cost-control must be balanced against the safety of our members, which is paramount. We would want to ensure that any legislation authorizing the use of biosimilars is in our members' overall best interest.

While we believe HB 254, HD2, may reasonably balance the concerns of many of us in the healthcare system, we suggest that there may be confusion with the alternative use of "interchangeable drug product" and "interchangeable biological product. To address this, the Committee may want to consider the following amendment:

> *"Interchangeable biological product" or "interchangeable drug product" means a biological product that the United States Food and Drug Administration:*
>
> *(1) Has licensed and has determined meets the standards for interchangeability pursuant to Title 42 United States Code section 262(k)(4); or*
>
> *(2) Has determined is therapeutically equivalent as set forth in the latest edition of, or supplement to, the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations"."*

Thank you for allowing us to testify on HB 254, HD2.

Sincerely,

Jennifer Diesman
Vice President, Government Relations

March 29, 2016 at 9:00 AM
Conference Room 229

Senate Committee on Commerce, Consumer Protection, and Health

To: Chair Rosalyn H. Baker
Vice Chair Michelle N. Kidani

From: George Greene
President and CEO
Healthcare Association of Hawaii

Re: Testimony in Support
HB 254 HD 2, Relating to Medicines

The Healthcare Association of Hawaii (HAH), established in 1939, serves as the leading voice of healthcare on behalf of 180 member organizations who represent almost every aspect of the health care continuum in Hawaii. Members include acute care hospitals, skilled nursing facilities, home health agencies, hospices, assisted living facilities and durable medical equipment suppliers. In addition to providing access to appropriate, affordable, high quality care to all of Hawaii's residents, our members contribute significantly to Hawaii's economy by employing over 20,000 people statewide.

The Healthcare Association of Hawaii would like to thank the committee for the opportunity to **support** HB 254 HD 2. This legislation would create a pathway for consumers to access biosimilar drugs that are approved as interchangeable biological drugs by the U.S. Food and Drug Administration. Biological drugs, which are often classified as specialty drugs, tend to be complex and high in cost. Increasingly, these specialty drugs are driving the rising costs of prescription drugs – while only one percent of all drugs prescribed are classified as specialty drugs, they account for almost one third of all spending.

Biosimilars offer an opportunity for patients and providers to access specialty or high-cost drugs at lower costs. We support the provisions of this legislation that seek to help consumers access interchangeable biosimilar drugs and appreciate provisions that preserve choice for consumers and practitioners alike.

Rising drug costs are increasingly placing financial burdens on patients and providers alike. We are appreciative of this effort, and look forward to working with the legislature on other initiatives that will help to reduce the rising costs of drugs for Hawaii residents. Efforts to stem these cost increases will be critical to maintaining patient access to quality, affordable care and ensuring the sustainability of the health care system in our state.

Thank you for your consideration of this important matter.

Phone: (808) 521-8961 | Fax: (808) 599-2879 | HAH.org | 707 Richards Street, PH2 - Honolulu, HI 96813

NPAF National Patient Advocate Foundation

The Patient's Voice | since 1996

March 18, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: Support for HB 254 HD2 - Biologics

Dear Senator Baker:

The National Patient Advocate Foundation (NPAF) serves as a voice for patients across America in regard to legislation and regulations that will benefit patient rights and needs. This letter is in regard to HB 254 HD2, legislation that would permit a pharmacist to fill a prescription for a biological product to select an alternative, interchangeable biological product if the prescriber does not personally indicate to not substitute. Our position on this issue is as follows:

- NPAF recommends that state and federal laws should facilitate patient access to new and innovative medications and therapies that have been approved by the US Food and Drug and Administration.
- NPAF recommends that all decisions for the use of new and innovative medication and therapies be made transparently and with the consent of the patient and provider.
- NPAF recommends that in any transition to a new or alternative medication or therapy, the patient and health provider must be directly informed of the transition and agree to the change.

We believe that biosimilars can improve access and expand treatment options for Hawaii patients with chronic, debilitating, and life-threatening diseases, but we also feel that they must be prescribed and administered with transparency and concurrence. Please consider our position on biosimilars as you deliberate on HB 254 HD2.

Sincerely,

Melissa J. Williams

Melissa Lorenzo Williams
Coordinator, State Government Relations

cc: Members, Senate Committee on Commerce, Consumer Protection and Health

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ican international cancer advocacy network
the virtual lifeline for proactive cancer patients

March 22, 2016

Senator Rosalyn H. Baker
Chair
Committee on Commerce, Consumer Protection, and Health
State Senate
Hawaii State Capitol
415 South Beretania St., Room 230
Honolulu, HI 96813

Re: HB254 HD2—Urging Support for the Measure—Biosimilars and Interchangeable Biological Products, to be considered by the Senate Committee on Commerce, Consumer Protection, and Health on March 29, 2016.

Dear Chair Baker,

All over the country, state legislatures are considering legislation, and many have already passed bills, to ensure that their residents have access to biosimilars and interchangeable biological products. We are at the beginning of a new age of biological therapies, and laws and regulations must reflect this new reality.

HB254 HD2, to be considered by the Senate Committee on Commerce, Consumer Protection, and Health on March 29, 2016, is an excellent example of legislation that does just that.

ICAN, the International Cancer Advocacy Network, is in strong support of HB254 HD2 because of its patient safety protections when dispensing biosimilars and interchangeable biological products. ICAN, a five-star rated 501(c)(3) charitable cancer patient advocacy organization, helps late-stage cancer patients in Hawaii and throughout the country (our *Marilyn Fagan Ovarian Cancer Patient Advocacy Program* is named in memory of one of our Hawaii patients). We deal daily with biologic therapies for our U.S. patients, and for our patients in 53 countries. Biologic therapies, and thus interchangeable biological products, will become a growing area for metastatic cancer patients.

This is a particularly timely issue given the first approval of a biosimilar in the United States just last year, and the expected approval of many more in the future. HB254 HD2 ensures that when an FDA-approved, lower-cost, interchangeable biological product is substituted by a pharmacist for a brand-name biologic, records will be kept, and the pharmacist will communicate to the patient and prescribing physician the precise drug that was dispensed—thus ensuring patient safety.

Communication to the patient and physician is essential because, unlike generic drugs that are an exact copy, the interchangeable biological product can be slightly different due to manufacture, transportation, or handling. If a patient experiences any adverse reactions, a physician needs to know all possible causes, including and especially, that the patient received an interchangeable biological product. Failing to communicate to the patient and physician when a substitution is made is an unnecessary risk to patient safety.

While we acknowledge (and welcome) the economic impact on healthcare of interchangeable biological products, patient safety can easily be protected by requiring communication to the patient and physician. Because of their complexity, size, and sensitivity, all biologics—whether reference, biosimilar, or interchangeable biological products—have potential for unintended induction of potent, immunologic reactions. Each and every patient may respond differently to any biologic, depending on their individual genetics and immunologic status.

Your support for HB254 HD2 in the hearing on March 29, and throughout the legislative process, is a powerful voice for the safety of ICAN's Hawaii patients, and for all Hawaii patients. It is also supporting well-crafted legislation that can serve as a model for other states.

Please do not hesitate to contact me at marcia@askican.org if you need additional information.

Thank you for your consideration, and for your support.

Respectfully submitted,

Marcia K. Horn

Marcia K. Horn, J.D.
President and CEO
International Cancer Advocacy Network (ICAN)
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Phoenix, AZ 85021-7246
602-618-0183 (phone)
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marcia@askican.org

NHMA
National Hispanic Medical Association

March 22, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: **Support for HB 254 HD2**

Dear Senator Baker:

On behalf of the Board of Directors of the National Hispanic Medical Association we urge support for HB 254 HD2 regarding substitution of biological drug products.

HB 254 would provide physicians with enhanced access to information regarding specific biological products dispensed to their patients.

We recognize the rising use of biologics and biosimilars in our population now aging with increased chronic disease. Biosimilars go through an extensive review process and manufacturers are required to submit immense studies and data demonstrating a products' efficacy and ensuring it is safe for use by consumers. A pathway for biosimilar regulation in the U.S. was established as a provision of the 2008 Patient Protection and Affordable Care Act (ACA) and in 2012 the FDA issued draft guidelines for biosimilars and a list of biosimilars and interchangeable biological products.

In summary, the National Hispanic Medical Association urges your support for HB 254 to clarify the procedures for biosimilar substitution for biologic treatments in a way that increases safety for the patient. We are especially supportive since this bill will help provide increased access to quality treatment for Hispanics and all persons in Hawaii with chronic diseases.

Sincerely,

Elena Rios, MD, MSPH
President & CEO

CC: Members of the Senate Committee on Commerce, Consumer Protection and Health

American Cancer Society
Cancer Action Network
2370 Nu`uanu Avenue
Honolulu, Hawai`i 96817
808.432.9149
www.acscan.org

Senate Committee on Consumer Protection and Health
Senator Rosalyn Baker, Chair
Senator Michelle Kidani, Vice Chair
Members of the Committee

HB 254, HD2 - RELATING TO MEDICINES

Cory Chun, Government Relations Director – Hawaii Pacific
American Cancer Society Cancer Action Network

Thank you for the opportunity to provide testimony in support of HB 254, HD2, which defines and regulates the dispensing of interchangeable biologic drugs.

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization. ACS CAN works with federal, state, and local government bodies to support evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

We support the current version because it addresses three main concerns that we have with biosimilar legislation.

Consent

Physicians should have the ability to withhold or provide consent for biosimilar substitution. Physicians can typically mark “Do not substitute” or “Medically necessary” to prevent substitution or conversely “Substitution allowed” to grant consent for substitution. In this measure the physician consent is consistent between small molecule drugs and biologics. Patient consent is also addressed in a similar manner.

Notification and Recordkeeping

When there is an interchangeable biosimilar, the prescribing physician should be notified of the actual biologic dispensed, whether an innovator or a biosimilar, to ensure an accurate and enduring patient medical record with longitudinal prescribing history. This notification should be via automated and electronic means that enable effective integration of this information into the patient’s electronic medical record in as close to real time after dispensing as feasible. Phone calls, fax or email would only be acceptable means of notification if the appropriate automated means to directly import into the patient’s medical record do not exist. Patients should also be informed of the actual drug dispensed at the time of dispensing. These issues are also addressed in the current draft.

Safety and Interchangeability

Robust evidence is needed to prove sufficient equivalence in terms of safety and efficacy between innovator biologics and those deemed as “interchangeable biosimilars.” The U.S. Food and Drug Administration (FDA) is the sole entity responsible for ensuring the integrity of this designation. Such a designation should be withheld or removed if evidence shows a clinically meaningful difference in safety or efficacy between products either in isolation, or when products are used sequentially. FDA guidance and analysis of interchangeability should be transparent and utilize the best science and tools available. FDA-deemed interchangeability will be cataloged in the “Purple Book” and this book should be the sole reference for products suitable for interchange.

We feel that any biosimilar measure should address these issues to ensure the safety and transparency for the benefit of the consumer. Thank you for the opportunity to provide testimony on this matter.

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Tel: 212-668-1000 | fax: 212-483-8179
www.liverfoundation.org

National HelpLine 800-GO-LIVER (800-465-4837)

March 23, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: **Support for HB 254 HD2**

Dear Senator Baker:

On behalf of the American Liver Foundation and the millions of Americans who face the daily struggles of debilitating liver disease, we respectfully urge you to support HB 254 HD2 which includes provisions for prescriber communication. While the development of biosimilars is a positive step for our patients, substituting a biosimilar absent the medical judgment of the patient's prescribing physician could affect patient safety.

Treatment of all forms of liver disease requires a great deal of clinical judgment. What works for one patient doesn't always work for another. The physician is in a unique position to consider the needs of individual patients, factoring in disease duration and severity, prognosis, treatment history and response, risk for adverse events, co-morbidities and potential impact on quality of life. It is to this end, that inappropriate therapy substitutions can result in disease progression and long-term consequences.

Similarly, biosimilars differ from generics in that they are not identical to their biologic counterpart. While generics can be interchanged for a brand-name drug because their basic compounds are matching, biologics and biosimilars are not identical and should be treated as such. It is feasible that a patient could have a different reaction to a biosimilar than he would with its original biologic.

Biosimilars represent a new generation of drugs in liver and gastrointestinal diseases. Interchangeability, automatic substitution and switching are key issues to consider for safety and efficacy when treating patients with biosimilars in clinical practice. Given the importance of the specific needs of each individual patient and the distinct differences between biologics and biosimilars, we believe that communication between pharmacists and physicians is crucial to patient care to ensure that patients are receiving the best treatment as prescribed by their physicians.

In order to protect Hawaii patients, the American Liver Foundation strongly supports HB 254 HD2 which includes a framework for clear communication between prescribers and pharmacists regarding biosimilars. We appreciate the opportunity to comment on this legislation. Please contact Jonathan Martin, National Director of Programs at (212) 668-1000, should you require any additional information or clarification.

Sincerely,

Thomas F. Nealon, III
CEO and Board Chairman
American Liver Foundation

CC: Members, Senate Committee on Commerce, Consumer Protection and Health

Global Colon Cancer Association
a 501(c)3 not-for-profit organization
www.GlobalCCA.org
tel: +1 610.668.8600
info@globalcca.org

March 21, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Dear Senator Baker:

On behalf of the Global Colon Cancer Association, an international not for profit organization, we are writing to request that you **support HB 254 HD2** regarding the pharmacy substitution of biosimilar medical products. As patient advocates, we are often the first contact with newly diagnosed patients and we have decades of seeing the impact colon cancer patients have had from biologic medicines and recognize the promise of biosimilars expanding access to more treatments.

"Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at reduced cost. Yet unlike generic versions of chemical drugs biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient. Therefore, the issue of interchangeability has been a new challenge for policymakers.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support **HB 254 HD2** and are concerned that patient safety will be compromised if this legislation is not enacted.

It is our view that **HB 254 HD2** appropriately reflects the importance of pharmacist-physician communication and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) or which are "therapeutically equivalent" to their reference products may ever be substituted.
- It allows a physician to prevent a substitution they consider inappropriate for their patient by writing "do not substitute" on the prescription.
- Finally **HB 254 HD2** requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

HB 254 HD2 will extend these valuable protections to Hawaii's patients while increasing their access to biologic therapies.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Hawaii by supporting HB 254 HD2.

Sincerely,

Andrew Spiegel
Executive Director

CC: Members of the Senate Committee on Commerce, Consumer Protection and Health:

March 29, 2016

The Honorable Rosalyn Baker
Chair, Senate Committee on Consumer Protection and Health
Hawaii State Senate
Hawaii State Capitol
Honolulu, HI 96813

Aloha Chair Baker and members of the committee,

On behalf of the Biotechnology Innovation Organization (BIO), we would like to convey our full support for House Bill 254 HD2, which permits substitution of biologic medicines by Hawaii pharmacists. BIO represents over 1,000 biotechnology manufacturers, biotechnology centers and research centers across the United States and around the word.

Our organization supports HB 254 because it contains important provisions that take into account the special and complex characteristics of biologic medicines. Unlike traditional chemically derived medicines, biologics are made from living organisms making them effective in treating life threatening diseases and conditions such as cancer, rheumatoid arthritis and diabetes. Pharmacy substitution with these special medicines should therefore ensure patient safety by limiting substitution to biologics designated as interchangeable by the U.S. Food and Drug Administration and by establishing open communications between the pharmacy and prescriber as a way to ensure all those involved in a patient's care know exactly the course of treatment for that patient. HB 254 contains those important provisions, which is why we encourage you and your colleagues on the Health Committee to support this legislation.

We are encouraged that your committee is giving full consideration to HB 254. Please do not hesitate contacting me if you have questions or require any additional information.

Regards,

Patrick Plues
Senior Director, State Government Affairs
BIO

March 23, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: Support for HB 254 HD2

Dear Senator Baker:

The National Organization for Rare Disorders (NORD) respectfully requests you to consider and support House Bill 254 HD2, an act relating to interchangeable biologic products (biosimilars). The bill has the potential to benefit many of our organization's members, and it will protect patients by including language calling for prescriber communication. With your support, you will be benefiting numerous patients suffering from rare disorders in Hawaii.

According to the legislation, pharmacists will be required to communicate – to a patient's prescribing physician – any and all dispensations of a substitute biological product for another biologic drug. NORD applauds the development of these innovative and valuable therapeutic treatments and supports the expanded access that biological products will offer for rare disease patients. Given the distinctions between biologics, the substitution of a biological product must include communication between the prescriber and pharmacist to keep patient safety a top priority.

NORD is the leading voice of the rare disease community dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. Any disease affecting fewer than 200,000 Americans is considered rare. With nearly 7,000 rare diseases identified and 30 million Americans affected, the population represented by NORD is extraordinarily heterogeneous. We believe strongly that every patient deserves the medical care that is best suited for their medical situation and that is most likely to give them the best results. Based on the reports we receive from member organizations, as well as individuals, it is increasingly difficult for rare disease patients to receive optimum care if any degree of customization to individual patients is required.

In light of this challenge of access to optimum care, prescriber communication between a pharmacist and a doctor about which biological product has been dispensed can help address this important concern to the rare disease community.

Since biological products differ from generics, they are not identical to their biologic counterpart. Due to the sensitive manufacturing process of biological products, even the slightest change can have a significant negative impact on a patient's therapeutic regimen. This is a

serious issue for a large segment of the rare disease community because not all drugs work the same for every patient, especially when dealing with unpredictable disease progression.

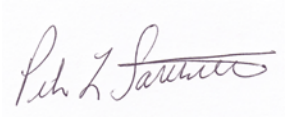
To ensure patient safety, health care providers need to know which medicine was dispensed to the patient, whether a substitution was made and to what alternative product. These factors are all critical information that needs to be taken into consideration when supplying a patient with medication.

NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service. Patients in the rare disease community experience many unforeseeable variables and outcomes. By securing effective biological product substitution laws, Hawaii can guarantee these patients prudence in prescriber communication that has the potential to alter dramatically the course of their treatment.

On behalf of NORD and the millions of Americans who face the struggles of a rare disease, we appreciate the opportunity to comment on this legislation. We strongly urge you to support HB 254 HD2, which includes prescriber communication and will ensure increased access to this new age of medicines is done in a safe, reliable and consistent way for patients and physicians.

If we can supply additional information, please do not hesitate to let us know.

Sincerely,



Peter L. Saltonstall, President and CEO

CC: Members, Senate Committee on Commerce, Consumer Protection and Health

Alliance of Specialty Medicine

Sound Policy. Quality Care.

March 18, 2016

The Honorable Rosalyn H. Baker
Chair, Senate Committee on Commerce, Consumer Protection and Health
Hawaii State Senate
Hawaii State Capitol, Room 230
415 South Beretania St.
Honolulu, HI 96813

sent electronically to: CPHtestimony@capitol.hawaii.gov and submitted online

RE: HB 254 HD2 – dispensing of interchangeable biosimilars

Dear Chairwoman Baker:

The Alliance of Specialty Medicine (Alliance) is a coalition of national medical specialty societies representing more than 100,000 physicians and surgeons. We are dedicated to the development of sound health care policy that fosters patient access to the highest quality specialty care. The undersigned member organizations of the Alliance of Specialty Medicine write in regards to House Bill 254 HD2 regarding the dispensing of interchangeable biosimilar products and urge that the committee consider and advance the bill.

The Alliance has closely followed the development of federal policy related to biosimilars and the safety considerations that should be taken into account as more biosimilar versions of existing biologic medicines become a new treatment option for our patients. **Importantly, HB 254 HD2 addresses key policy issues to ensure patient safety is preserved, including physician authority to prevent substitutions and ensuring that the treating physician is notified if another version of the biologic medicine is substituted for the version prescribed by the doctor.**

Specifically, we appreciate that HB 254 HD2 requires that the consumer be informed of his/her *"right to refuse substitution"* and that substitution is not allowed if *"the practitioner indicates "brand medically necessary" or words of similar meaning on the prescription."* Also, we support that the bill requires notifying the prescribing practitioner of substitution *"within five business days following the dispensing of a biological product…"*.

The practice of automatic substitution that is seen with generic drugs is not entirely appropriate for biosimilar products given that they are not simply "generic" versions of biologics. Physicians need to know what medicine their patient receives and therefore, the prescribing physician should be notified whenever a patient's biologic medicine is substituted. This will help to ensure the accuracy of patient medical records and identify any issues should there be an adverse event.

Advances in medical treatment have transformed the way we fight certain diseases. Biologics, and biosimilars, will continue to be an important treatment option for patients. The Alliance of Specialty Medicine appreciates that HB 254 HD2 ensures appropriate safeguards and urges your support of the bill.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions

Cc: members, Senate Committee on Commerce, Consumer Protection and Health

HealthHIV
Putting Health First

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www.healthhiv.org

March 23, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: **Support for HB 254 HD2**

Dear Senator Baker:

I am writing out of concern for the health and safety of Hawaii residents living with HIV/AIDS. Individuals who are living with HIV/AIDS face a broad range of health issues and require careful care and management of their medical conditions. Because of this, we support House Bill 254 HD2 because it creates a framework to dispense biosimilar medications while still maintaining vital communication between patients and prescribers.

We have specific and serious concerns regarding legislation around the substitution of biosimilars for biologic drugs. Given the reliance individuals with HIV/AIDS have on their physicians' judgment regarding the most effective combinations of medications to effectively treat their conditions, there are potentially severe ramifications if pharmacists are permitted to substitute a biosimilar drug without communicating to the patient's prescribing physician.

Let me make it clear that HealthHIV welcomes the emergence of biosimilars. Biologic therapies have brought tremendous, life-strengthening benefits to the HIV/AIDS community, and biosimilars offer the promise of greater affordability. Substituting a biosimilar for a biologic, though, is substantially different than substituting a generic drug for the original chemical compound. Chemicals can be reproduced with exactness. Biologic material cannot, and those differences can have a significant impact on a patient's health.

In short, we support HB 254 HD2 as it that includes communication requirements that are essential to patient safety, and we welcome the opportunity to work with Hawaii Senate Committee on Commerce, Consumer Protection and Health to ensure that biosimilars can be utilized in a way that doesn't endanger any patient's health and overall well-being.

Sincerely,

Brian Hujdich
Executive Director

CC: Members, Senate Committee on Commerce, Consumer Protection and Health

March 28, 2016

TO: Chair Rosalyn H. Baker and Members of Senate Committee on Commerce, Consumer Protection, and Health

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

RE: **HB 254 HD2** - Relating to Medicines
Hearing Date: March 29, 2016
Time: 9:00 am

My name is William Goo. I represent the Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA supports passage of **HB 254 HD2**. Attached is PhRMA's testimony in support.

Thank you for considering this testimony.

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

Statement in Support of Hawaii House Bill 254 HD2

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) supports Hawaii House Bill 254 HD2 which would amend the law in Hawaii to reflect changes to federal law that created an abbreviated pathway for FDA approval of biosimilar products. HB 254 HD2 will put into place several patient protections that recognize the unique attributes of biosimilar products. Because patient safety is paramount, PhRMA is pleased that HB 254 HD2 will ensure that patient safety is protected when interchangeable biosimilars become available.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone

This legislation will allow for the substitution of biologics deemed interchangeable by the Food and Drug Administration (FDA) and will apply several important patient health and safety protections to this substitution process.

Understanding the distinction between a chemically synthesized prescription drug and a biologic is important when crafting state law to address pharmacy substitution practices. Unlike traditional medicines, which are chemically synthesized, biologic medicines are more complex and are manufactured from living organisms. A biosimilar product is highly similar to, but not the same as, its FDA-licensed reference biological medicine. Federal legislative and regulatory activity has created an abbreviated regulatory pathway for approving biosimilar products. Ensuring patient safety is essential in the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and the amendment of state substitution laws to permit the substitution of interchangeable biosimilars. HB 254 HD2 amends Hawaii law to put into place several patient protections that recognize the unique attributes of biosimilar products.

The legislation requires a substitution can only occur when the FDA has designated a biologic product as interchangeable.

HB 254 HD2 would permit substitution of a biosimilar only when the FDA has designated a biologic product as interchangeable. Biosimilars will not be exactly the same as the reference product, so it is essential that only those the FDA has determined are interchangeable be dispensed.

The legislation allows prescribers the ability to prevent substitution.

Any decision to substitute a biosimilar medicine should be made with the oversight and guidance of the treating physician, and the well-being of patients must remain the paramount concern. HB 254 HD2 permits a prescriber to expressly prohibit substitution by indicating on the prescription "brand medically necessary." This provision

ensures that the physician, who is knowledgeable about a patient's specific health history and therapeutic regimen, have ultimate decision-making authority for patient care.

The legislation requires the pharmacist to communicate to the prescribing practitioner that an interchangeable biologic has been dispensed.

HB 254 HD2 requires a pharmacist to communicate to the prescriber when they dispense an interchangeable biologic or interchangeable's reference product. Record keeping will aid in facilitating efficient patient care in the event that an adverse reaction to the substituted drug occurs and will ensure proper product attribution if an adverse event were to occur.

The legislation requires pharmacists to communicate to patients when a substitution occurs.

Additionally, this legislation requires that a patient must be informed of a substitution. Patients who are managing chronic conditions often have tried many therapies before finding the one that best manages their condition or multiple conditions. It is important that a patient realizes that a substitution has taken place so they can continue to be informed and in control of their disease management.

The legislation requires pharmacies to keep records of the substitution.

This safeguard would be beneficial in the event of an adverse reaction or change in a patient's chronic condition. It is important that prescribers and pharmacists have access to historical data to best interpret any health changes and respond appropriately.

For these reasons, PhRMA respectfully urges Hawaii legislators to support HB 254 HD2.

CSRO
Coalition of State Rheumatology Organizations

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March 21, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate
Hawaii State Capitol, Room 230
415 S Beretania St, Honolulu, HI 96813

Re: HB 254 HD2 – Relating to the regulation of biosimilar medications

Dear Senator Baker:

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of approximately 35 state and regional professional rheumatology societies. CSRO formed by physicians to ensure excellence and access to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease.

Rheumatologists are on the forefront of treatments for patients with autoimmune diseases. With the advent of biologic medications, we have been able to stop the progression of some of these diseases and avoid the development of life-long deformities. Biological products available for the treatment of rheumatoid arthritis and other autoimmune diseases have had a significant impact on improving our patients' quality of life, preventing deformities and disability, and lowering mortality.

As your committee considers HB 254 HD2, CSRO wishes to convey its support for this important legislation.

This bill provides important pathways for access to these unique medications. It also creates much needed patient safety rules for dispensing pharmacists to communicate to physicians about biosimilar substitutions within 5 business days. Requiring this communication as soon as possible provides physicians an opportunity to counter and correctly report any adverse effects of medications.

With FDA approval of the first biosimilar drug last year, biological products continue to be of growing importance for rheumatology patients. CSRO supports the safe introduction of interchangeable biologic drugs into the practice of medicine in Hawaii and urges passage of HB 254 HD2.

Sincerely,

Michael P. Stevens, MD

Michael Stevens, MD
President
Coalition of State Rheumatology Organizations

March 21, 2016

The Honorable Rosalyn H. Baker
Chair, Committee on Commerce, Consumer Protection and Health
Hawaii State Senate
415 South Beretania Street, Room 230
Honolulu, HI 96813

RE: Support for HB 254 HD 2 – FDA-designated interchangeable biological drug products; allow pharmacists to dispense.

Dear Chairwoman Baker:

The Alliance for Patient Access (AfPA) would like to express support for HB 254 HD 2, allowing for the substitution of biological medicines when certain conditions are met. The legislation as drafted contains the patient safety principles that AfPA member physicians have identified as critical for safe access to biosimilar medications, notably physician communication of substitution, and is worthy of your support.

AfPA is a national network of more than 700 physicians with the shared mission of ensuring and protecting patient access to approved medical treatments and therapies, including prescription pharmaceuticals, biologics, and medical devices. Since 2011, AfPA has convened the National Physicians Biologics Working Group (NPBWG) as a home for physicians interested in policy issues relating to access to biologic therapies.

The NPBWG identified key principles that biosimilar substitution must meet to ensure patient safety and promote prescriber confidence. These include FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic, that pharmacists communicate to the prescribing physician and patient any substitution with in a reasonable timeframe, that physicians be allowed to specify no substitution, and that patients be notified of any substitution. HB 254 HD 2 contains these safety provisions, most importantly the physician communication provision that helps ensure a complete medical record and helps assure the best medical response to a patient adverse event. AfPA is pleased that HB 254 HD 2 allows for substitution while containing provisions to implement these safeguards.

The Food and Drug Administration (FDA) has already approved one biosimilar medicine and may soon approve interchangeable biosimilar medicines. AfPA supports making potentially less costly medicines available to patients and physicians but all efforts must be made to create policies that balance access, safety and cost. HB 254 HD 2 provides this pathway for biosimilar medicines by maintaining communication safeguards and is worthy of your support in its current form.

Sincerely,

Brian Kennedy
Executive Director

Cc: Members, Senate Committee on Commerce, Consumer Protection and Health

Alliance for Patient Access
2000 M Street, NW, Suite 850
Washington, D.C. 20036
www.AllianceforPatientAccess.org

March 24, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: **Support for HB 254 HD2**

Dear Senator Baker:

On behalf of all women and men who have been adversely affected by prostate cancer, Women Against Prostate Cancer (WAPC) respectfully urges the Hawaii Senate Committee on Commerce, Consumer Protection and Health to support HB 254 HD2, which includes language that requires communication between prescribers and pharmacists regarding biosimilars.

WAPC represents advocates, widows, healthcare professionals, and caregivers working together to bring an end to prostate cancer. As the organization that represents the caregivers for patients with prostate cancer, we have an equally vested interest in the advent of biosimilars and the legislation surrounding its safe uptake.

While this disease might only affect men physically, it also has a devastating impact on women – mothers, daughters, wives – in their daily lives. Biologics, and soon biosimilars, have revolutionized treatment options for those living with prostate cancer. As biosimilars are poised to enter the U.S. market it will expand access to the millions of men affect by prostate cancer.

However, Hawaii must prioritize patient safety as its chief concern, and recognize that a clear line of communication is the best way to achieve trust in biosimilars and safeguard patient safety. This applies to caretakers as much as patients. We are concerned about the possibility of biologic substitution without prescriber-pharmacist communication and how that will affect caretakers as well.

With biologics, we know that individual patients can respond differently to even seemingly insignificant changes in the manufacturing process, packaging, storage, or handling, which could cause unintended adverse effects. Treatment requires a great deal of clinical judgment from the prescribing physician, who carefully weigh the expected benefits and risks. The women of WAPC know first-hand the importance of having trust in their loved one's medical team. They oversee medical appointments, manage treatment options and navigate the health care system. They trust that the medications prescribed by physicians are being dispensed at the pharmacy setting and that any deviation would be communicated back to the prescribing physician. If a substitution was made by a pharmacist without the physician or the caretaker's knowledge, it could undermine the established relationship that is crucial to a patient's care.

We hope that you and your members of the Senate Committee on Commerce, Consumer Protection and Health will support HB 254 HD2 as it has prescriber-pharmacist communication included in order to ensure patient safety for not only the patients living with prostate cancer but the women who are adversely affected as well.

Sincerely,

Theresa Morrow

Theresa Morrow
Vice President, Board of Directors
Women Against Prostate Cancer

CC: Members, Senate Committee on Commerce, Consumer Protection and Health

March 23, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: **Support for HB 254 HD2**

Dear Senator Baker:

U.S. Pain Foundation is an organization created by people with pain for people with pain. Our mission is to educate, connect, inform and empower pain patients while advocating on behalf of the entire pain community. Currently, there are more than 100 million Americans who suffer from chronic pain, including residents of Hawaii. On behalf of all Hawaii residents who suffer from chronic pain, U.S. Pain Foundation respectfully urges you to support HB 254 HD2, which includes prescriber communication. We applaud the cost benefits that might occur from biosimilars; however, substituting a biosimilar or an interchangeable biological product without informing the prescriber could be detrimental to patient safety.

Biosimilars are biological medicines that are produced by living cells for the prevention, treatment, or cure of a disease. U.S. Pain Foundation supports strong patient protections and transparency relative to state legislation for substitution of biosimilars, such as HB 254 HD2. By securing effective biosimilar substitution laws, Hawaii can increase access to this new age of medicines and do it in a safe, reliable and consistent way for patients and physicians.

Treatment of chronic pain requires a great deal of clinical judgment. Sometimes treatments that work for one patient with a chronic disease do not work for another. The physician must take into consideration the needs of each individual patient, factoring in many different variables that can affect a patient's treatment options. Therefore, inappropriate therapy substitutions can result in disease progression and long-term consequences. Since biosimilars differ from generics, they are not identical to their biologic counterpart. While generics can be interchanged for a brand-name drug because their basic compounds are matching, biologics and biosimilars are not identical and should be treated as such. It is feasible that a patient could have a different reaction to a biosimilar than he/she would with its original biologic.

Given the importance of the specific needs of each individual patient and the distinct differences between biologics and biosimilars, we believe that communication between pharmacists and physicians is crucial to patient care to ensure that patients are receiving the best treatment as prescribed by their physicians.

On behalf of U.S. Pain Foundation and the millions of Hawaii residents and Americans who face the daily struggles of this debilitating disease, we appreciate the opportunity to comment on this proposed legislation. We strongly urge you to support HB 254 HD2, which includes prescriber communication and helps to protect patient safety.

Please contact Shaina Smith, should you require any additional information or clarification.
Thank you for your consideration.

Sincerely,
Shaina Smith
Shaina Smith
Director of State Advocacy & Alliance Development
U.S. Pain Foundation, Inc.

Cc: Members, Senate Committee on Commerce, Consumer Protection and Health

info@uspainfoundation.org **Main: (800) 910.2462** **670 Newfield Street, Suite B**
www.uspainfoundation.org **Fax: (800) 929 -4062** **Middletown, CT 06457**

March 22, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Subject: Support for HB 254 HD2

Dear Senator Baker,

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to request that you **support House Bill 254 HD2 (HB 254 HD2)** regarding the pharmacy substitution of biosimilar medical products. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovator biologic medicines and biosimilars, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

As a retired pediatric rheumatologist and a former president of the American Society of Health-system Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like cancer, rheumatoid arthritis, diabetes, and MS. "Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at reduced cost. Yet unlike generic versions of chemical drugs biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient. Therefore, the issue of interchangeability has been a new challenge for policymakers.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support HB 254 HD2 and are concerned that patient safety will be compromised if this legislation is not enacted.

Since 2012, ASBM has conducted surveys of physicians in eleven countries, to gather their perspectives on biosimilars. The results of these surveys have since been shared with policymakers in the U.S., Canada, Europe, and the World Health Organization in Geneva, Switzerland.

- **Our survey of 376 U.S. physicians found that 80% of those surveyed called notification in the event of a biosimilar substitution "very important" or "critical".**

- **Further, 82% of U.S. physicians called the authority to block a substitution by indicating "do not substitute" or "dispense as written" on a prescription "very important" or "critical".**

These results are consistent with those of physicians around the world, including those surveyed in Canada and Europe, where biosimilars are currently in clinical use. All ASBM surveys are available on our website at www.safebiologics.org.

It is our view that **HB 254 HD2 appropriately reflects the importance of pharmacist-physician communication** and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) or which are "therapeutically equivalent" to their reference products may ever be substituted.

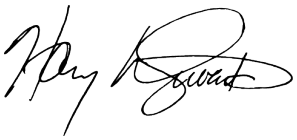
- It allows a physician to prevent a substitution they consider inappropriate for their patient by writing "brand medically necessary" on the prescription.

- Finally HB 254 HD2 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

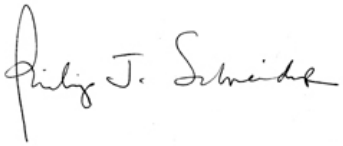
HB 254 HD2 will extend these valuable protections to Hawaii's patients while increasing their access to biologic therapies.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Hawaii by supporting House Bill 254 HD2.

Sincerely,



Harry Gewanter, MD
Chairman, The Alliance for Safe Biologic Medicines



Philip J. Schneider, MS, FASHP
Advisory Board Chair, Alliance for Safe Biologic Medicines
Professor, University of Arizona College of Pharmacy

ASBM Steering Committee Members:
Alliance for Patient Access
American Academy of Dermatology
American Autoimmune Related Diseases Association (AARDA)
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
Health HIV
Hepatitis Foundation International
International Cancer Advocacy Network
Kidney Cancer Association
National Psoriasis Foundation
ZeroCancer

Cc: Members, Senate Committee on Commerce, Consumer Protection and Health

March 20, 2016

The Honorable Rosalyn H. Baker
Chair, Committee on Commerce, Consumer Protection and Health
Hawaii State Senate
415 South Beretania Street, Room 230
Honolulu, HI 96813

Re: Hawaii HB 254 HD2 An Act relating to biological products

Dear Madame Chairwoman:

On behalf of the Lupus and Allied Diseases Association and the millions of Hawaii residents struggling to manage autoimmune conditions like lupus and other diseases of unmet need who eagerly await access to affordable, appropriate and safe therapies, I passionately urge you to support HB 254 HD2. This landmark legislation creates a new pathway for biologic substitution where none currently exists in Hawaii, while at the same time enhancing patient access to new and potentially less costly medications.

The Lupus and Allied Diseases Association, Inc., is a passion driven, all-volunteer patient advocacy organization dedicated to improving quality of life for those impacted by lupus and allied diseases and conditions of unmet need by fostering collaboration among all stakeholders and promoting innovative advocacy, awareness and biomedical research program initiatives.

As patient stakeholders who represent patients and loved ones dealing with serious chronic medical conditions on a daily basis, we support HB 254 HD2 as it promotes patient safety and collaboration among all members of the patient's health care team by facilitating consumer knowledge and communication between pharmacists and prescribing physicians when biosimilars designated as "interchangeable" are substituted for a prescribed biologic. It also gives the pharmacist authorization to select an alternative biological product if it is interchangeable and the prescriber does not indicate an intent to prevent substitution.

Furthermore, the proposed legislation ensures that the treating physician is aware of the exact biologic, indicated by manufacturer, given to a patient in order to facilitate patient care and accurate attribution of any adverse events that may occur. Pharmacist-Prescriber communication is paramount in identifying exactly which medicine was received if an adverse event occurs since biologics and biosimilars in reality will be administered to patients suffering from serious, life-threatening diseases who usually take several concomitant medications and are not participating in a controlled clinical study.

Unlike small molecules, biologics are extremely complex large molecules patterned after human tissue and cells that have the ability to target the underlying cause of some diseases. They have advanced with each generation; evolving from proteins that are naturally-occurring to monoclonal, and eventually to polyclonal and fusion proteins. Biosimilar drugs hold tremendous promise and therapeutic advantages for

lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-threatening and life-diminishing diseases. As more biosimilars become available in the United States we want to ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant in protecting patient safety while promoting unfettered access to vital and effective treatments.

HB 254 HD2 outlines the parameters for substitution of interchangeable biologics, guaranteeing patients have access to high quality, safe, and efficacious biologic medicines. Substitution should only occur when the FDA has designated a biologic product as interchangeable and proper patient protections are upheld including Pharmacist-Patient communication to ensure complete transparency. Pharmacist-Prescriber communication regarding the dispensed product must occur within five business days and be conveyed by making an entry that can be electronically accessed by the prescriber. Communicating through an electronic-record keeping system guarantees that the patient has a longitudinal health record and given that many patients have comorbidities requiring treatment by multiple health care providers, an accurate medical record is essential.

For the above reasons we ask you to please facilitate communication between patients, pharmacists, and healthcare providers by supporting HB 254 HD2. This legislation is especially important given the FDA's approval of the first biosimilar last March, the second one recently reviewed in February and additional products in the pipeline. It is imperative that these safeguards are put in place to ensure that healthcare professionals continue to be empowered to provide the best medical care possible and that patients have access to lifesaving and life-enhancing therapies.

Please feel free to contact me at 315-264-9101 if you have any questions. Thank you.

Sincerely-

Kathleen A. Arntsen
President/CEO

NATIONAL PSORIASIS FOUNDATION®

Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

March 22, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate, Room 230

RE: Support HB 254 HD 2 – Interchangeable Biological Products

Dear Senator Baker:

The National Psoriasis Foundation (NPF) is a non-profit, voluntary health agency dedicated to curing psoriatic disease and improving the lives of those affected. The Psoriasis Foundation is the leading patient advocacy group for the 7.5 million Americans living with psoriasis and psoriatic arthritis.

The introduction of biologic products for the treatment of psoriasis and psoriatic arthritis has been the most significant advancement in care for the psoriasis and psoriatic arthritis community in recent decades. Biologics have provided some patients with an effective therapy—many for the first time in their lives. While the community welcomes new and affordable treatments, patients with psoriasis and psoriatic arthritis are keenly aware of the risks associated with biologics, including suppression of the immune system and the lack of long-term safety data for new treatments.

In contrast to the case with generic drugs, which are chemically identical to their branded counterparts, biosimilars are not chemically identical to their branded biologics counterparts because, as large, complex molecules derived from living cells using recombinant DNA technology, biologics can never be exactly replicated due to their inherent variability. The NPF believes that legislation concerning biologics is both an access and safety issue and neither should be sacrificed for the other, a balance can and has been found. We urge you to support HB 254 HD2 with the communication provision intact.

Sincerely,

Randy Beranek
President & CEO

cc: Members, House Committee on Health

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1800 Diagonal Rd., Suite 360 | Alexandria, VA 22314 | Fax 703-739-9800
www.psoriasis.org

American Autoimmune
Related Diseases Association, Inc.
www.aarda.org
A nonprofit association bringing a national focus to autoimmunity, the major cause of chronic disease

March 21, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: **Support HB 254 HD2 – Biologics**

Dear Senator Baker and Senate CPH Committee Members:

On behalf of the American Autoimmune Related Diseases Association (AARDA), a national not for profit health organization, we are writing to request that you **support HB 254 HD2** regarding the pharmacy substitution of biosimilar medical products. As patient advocates, we are often the first place newly diagnosed patients come for help and information. Until one decade ago, the treatment choice for most autoimmune diseases was cortical steroids which had significant side effects for the patient. The use of biologics have made a significant impact on improving the lives of patients with serious and life threatening autoimmune diseases such as Crohn's disease, lupus, multiple sclerosis and rheumatoid arthritis. Biosimilars hold much promise in expanding access to better treatments.

"Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at a reduced cost. Yet unlike generic versions of chemical drugs, biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient. Therefore, the issue of interchangeability has been a new challenge for policymakers.

AARDA believes that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support HB 254 HD2 and are concerned that patient safety will be compromised if this legislation is not enacted. It is our view that this bill appropriately reflects the importance of pharmacist-physician communication and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist.

HB 254 HD2 will extend these valuable protections to Hawaii's patients while increasing their access to biologic therapies.

Thank you in advance for taking support the necessary steps to keep patient safety a priority in Hawaii by supporting HB 254 HD2.

Sincerely,

Virginia T. Ladd

Virginia Ladd
President

22100 Gratiot Avenue - Eastpointe, MI 48021-2227 - Phone (586) 776-3900 - Fax (586) 776-3903 - E-mail: aarda@aarda.org

Global Healthy Living Foundation
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www.ghlf.org

March 22, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

RE: **House Bill 254 HD 2 – *Support***

Chairwoman Baker,

The Global Healthy Living Foundation (GHLF) is a 501 (c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. As a patient advocacy organization, GHLF represents more than 90,000 chronically ill patients, including your fellow Hawaii residents. Many of these individuals have rheumatoid arthritis, take biologics, and stand to benefit greatly from the addition of biosimilars.

I am writing you today to express our support for HB 254 HD 2 which addresses patient and physician notification during the substitution of a biosimilar and biologic product.

At the GHLF, our focus is on improving the lives of patients with chronic illnesses through health care education and mobilization programs that stress the importance of diagnosis, early and innovative medical intervention, long-term lifestyle improvement and therapeutic compliance. Using various channels of influence, we work to communicate and leverage new and improved medical treatments, such as biologics and biosimilars, to patients. As promising as these innovative drugs are, GHLF believes that assuring their safety and transparency in the substitution process should be of paramount concern.

HB 254 HD 2 takes positive steps toward updating Hawaii law to cover biologics and biosimilars in a way that protects patients. As you know, unlike traditional chemical drugs, biologics are unique, complex structures made from living cells that are not easily replicated. A small change or difference in the biosimilar or biologic manufacturing process has the potential to adversely impact the patient.

There are four provisions in HB 254 HD 2 that GHLF believes are key to ensuring patients' safety and needs are met in the best way possible.

- First, the bill requires a pharmacist dispensing an interchangeable biosimilar to notify the prescribing physician within five business days.

- Second, the bill clearly states that the patient for whom the biological product is prescribed must be informed of the substitution and has the right to refuse it.

- Third, it requires pharmacies to retain record of the substitution.

- Fourth, it requires that physicians have the opportunity to prevent a substitution by instructing “do not substitute” or “dispense as written” on the prescription.

Notification is crucial to preserving the doctor/patient relationship as well as the integrity of medical records, which are invaluable if there is an adverse event from using the drug.

If it is determined by the doctor and patient that an interchangeable biosimilar can be substituted for a biologic, or is the preferred treatment, it is obvious to healthcare providers, patients and, we think, the majority of legislators, that proper record keeping be in place in order to track any adverse events that may occur.

As patient advocates, it is our duty to ensure that physicians are in charge of the drugs prescribed and that both patients and their doctors are aware of what drugs they are taking. Patients and physicians are the primary individuals who report any adverse events that occur while on therapy. Adverse events can only be reported accurately if patients and physicians have received proper communication from a pharmacist about what medication has been dispensed. Patient safety is the top priority in the health care process and medical decisions must remain between a doctor and patient. We urge the passage of HB 254 HD 2 because it introduces biosimilars in a way that ensures the safety of patients and preserves the physician-patient relationship.

We appreciate your thoughtful consideration of this legislation and would be pleased to provide any further information that you may require.

Sincerely,

Seth Ginsberg
President, Global Healthy Living Foundation

CC:
Members, Senate Committee on Commerce, Consumer Protection and Health

March 23, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

Re: Support for HB 254 HD2

Dear Senator Baker:

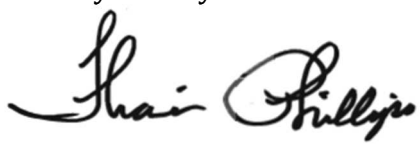
As the President of RetireSafe, a nationwide non-partisan non-profit organization with more than 300,000 supporters, I urge you to support HB 254 HD2, which includes a provision for prescriber communication. We find it essential that there is open communication between a prescribing physician and dispensing pharmacist in the event of a substitution of an interchangeable biologic, and this amendment supports this communication.

We have seen the significant impact biologic medicines have had in improving the quality of the health of Americans. To increase access to these important therapies, we have a vested interest in seeing biosimilar medicines introduced to the U.S. market. Lower cost medications mean more access and more lives saved. Yet we recognize the inherent safety challenges associated with this class of medicines and therefore, the issue of substitution has been a new challenge for policymakers, such as you. We fear that if safety issues are ignored as we begin this transition to biosimilars that health concerns will arise that will inhibit the trust in all biosimilars and delay the overall acceptance of biosimilars by healthcare professionals. We believe that when interchangeable biosimilar products are substituted, communication among patients, pharmacists and health care providers is essential to patient care and to establishing a trust in biosimilars.

Others have weighed in on the science behind this groundbreaking medicine and why biosimilars are unique. Because the medicine and its structure are complicated, from the perspective of the older Americans in Hawaii, it seems such a common sense requirement that the patient's physician be notified if a biosimilar is substituted by the pharmacist. A recent survey that we sent out nationwide on this issue received over 1,400 replies. Over 90% of those respondents thought that the communication between the doctor, the patient and the pharmacist should be open and required when a substitution is made concerning biologics, biosimilars and interchangeable biologics. Procedural inconvenience should not stand in the way of patient safety especially with the communication flexibility offered in this bill.

We know that you are concerned with patient safety and want to protect the citizens of Hawaii. It is because of that commitment to safety that we ask you to support HB 254 HD2, which includes prescriber communication.

Thank you for your consideration.



Thair Phillips,
President/CEO, RetireSafe

CC: Members, Senate Committee on Commerce, Consumer Protection and Health

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March 23, 2016

The Honorable Rosalyn H. Baker
Committee on Commerce, Consumer Protection and Health
Hawaii State Senate

RE: **Support for HB 254 HD2**

Chairwoman Baker,

My name is Carole Wiedmeyer, and I have been a resident of Waikoloa, Hawaii for one and a half years. My senator is Lorraine Inouye.

I have lived with rheumatoid arthritis for nearly three years, and have tried numerous medicines to treat my condition, including a biologic, which I am currently taking. I am a patient advocate with the Global Healthy Living Foundation (GHLF), a 501 (c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. As a patient advocacy organization, GHLF represents more than 90,000 chronically ill patients, including Hawaii residents like me. Many of these individuals have rheumatoid arthritis, take biologics, and stand to benefit greatly from the addition of biosimilars.

I am writing you today to express our support for HB 254 HD 2, which addresses patient and physician notification during the substitution of a biosimilar and biologic product.

HB 254 HD 2 takes positive steps toward updating Hawaii law to cover biologics and biosimilars in a way that protects patients. As you know, unlike traditional chemical drugs, biologics are unique, complex structures made from living cells that are not easily replicated. A small change or difference in the biosimilar or biologic manufacturing process has the potential to adversely impact the patient.

I am one of the lucky patients who was diagnosed quickly after onset of my symptoms. As a result, I have been able to forestall much permanent joint damage and disability. A lot of the credit is the result of access to a biologic medication. Even though my story is a positive one, my symptoms have not completely abated. It took nearly two years to find the combination of five different medicines I now take, and the best doses of each for me.

If a substitution were to occur in my case, I could potentially set this process back, experiencing more symptoms and/or more side effects. In the best case, such a setback would be temporary, but could take six months to a year to recover from. At worst, it could result in permanent damage to my joints, or severe, life-threatening side effects such as pneumonia or cancer.

There are four provisions in HB 254 HD 2 that GHLF and I believe are key to ensuring patients' safety and needs are met in the best way possible.

- First, the bill requires a pharmacist dispensing an interchangeable biosimilar to notify the prescribing physician within five business days.
- Second, the bill clearly states that the patient for whom the biological product is prescribed must be informed of the substitution and has the right to refuse it.
- Third, it requires pharmacies to retain record of the substitution.
- Fourth, it requires that physicians have the opportunity to prevent a substitution by instructing "do not substitute" or "dispense as written" on the prescription. For patients like me who receive copay assistance from the manufacturer, a switch to the biosimilar version could potentially cost me thousands of extra dollars per year if the biosimilar manufacturer does not offer a copay assistance program. For many patients, this could result in deciding to no longer take this necessary medication.

Notification is crucial to preserving the doctor/patient relationship as well as the integrity of medical records, which are invaluable if I experience increased symptoms of my disease or an adverse event from using the drug.

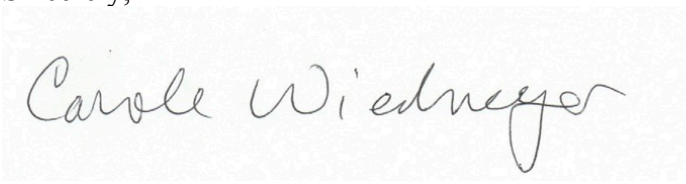
If it is determined by my doctor and me that an interchangeable biosimilar can be substituted for a biologic, or is the preferred treatment, it is obvious to healthcare providers, patients and I think, the majority of legislators, that proper record keeping be in place in order to track any adverse events that may occur.

As patient advocates, it is our duty to ensure that physicians are in charge of the drugs prescribed and that both patients and their doctors are aware of what drugs they are taking. Patients like me and physicians are the primary individuals who report any adverse events that occur while on therapy. Adverse events can only be reported accurately if my physician and I have received proper communication from a pharmacist about what medication has been dispensed.

Patient safety should always be the top priority in the health care process, and medical decisions must remain between my doctor and me. We urge the passage of HB 254 HD 2 because it introduces biosimilars in a way that ensures the safety of patients and preserves the physician-patient relationship.

We appreciate your thoughtful consideration of this legislation and would be pleased to provide any further information that you may require.

Sincerely,



Carole Wiedmeyer
Patient Advocate, Global Healthy Living Foundation

CC: Members, Senate Committee on Commerce, Consumer Protection and Health
Stephen Marmaras, Global Healthy Living Foundation

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ican international cancer advocacy network
the virtual lifeline for proactive cancer patients

Testimony of Heather M. Spencer for the Committee on Commerce, Consumer Protection, and Health, Hawaii State Senate, March 29, 2016, in support of HB254 HD2—Biosimilars and Interchangeable Biological Products

Chair Baker, and Members of the Committee on Commerce, Consumer Protection, and Health:

I am Heather M. Spencer of Kaneohe. I am the wife of a six-year colorectal cancer survivor, the daughter of a mother who battled lymphoma and lung cancer and unfortunately did not survive, and I am a documentary filmmaker who recently completed a film chronicling the journeys of 12 cancer patients from diagnosis to survivorship.

I am also testifying on behalf of ICAN—the International Cancer Advocacy Network. ICAN is a Phoenix-based non-profit that helps late-stage cancer patients in Hawaii, throughout the United States, and in 53 foreign countries. ICAN's *Marilyn Fagan Ovarian Cancer Patient Advocacy Program* is named in memory of one of ICAN's Hawaii patients.

On behalf of the thousands of patients ICAN has served, and will be serving in the future, we strongly support HB254 HD2 to require that pharmacists communicate to physicians and patients when dispensing a biological product.

This is a fundamental matter of patient safety. Imagine if a patient, such as my husband, or any of the cancer patients whose journeys I have chronicled, were prescribed a biologic, but a pharmacist substituted an interchangeable biological product or biosimilar without communicating that to the physician. If adverse reactions ensued, the physician would be in the dark as to the true cause. That is unacceptable—and it is also unnecessary.

Chair Baker and Members of the Committee on Commerce, Consumer Protection, and Health, we urge you to favorably consider HB254 HD2 and ensure its ultimate passage into law to protect Hawaii patients.

Thank you for your consideration.

Respectfully submitted,

Heather M. Spencer

Heather M. Spencer

From: mailinglist@capitol.hawaii.gov
To: CPH Testimony
Cc: rontthi@gmail.com
Subject: *Submitted testimony for HB254 on Mar 29, 2016 09:00AM*
Date: Tuesday, March 22, 2016 5:44:09 PM

HB254
Submitted on: 3/22/2016
Testimony for CPH on Mar 29, 2016 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Ronald Taniguchi, Pharm.D.	Individual	Support	No

Comments:

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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