TESTIMONY OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
TWENTY-EIGHTH LEGISLATURE, 2016

ON THE FOLLOWING MEASURE:
H.B. NO. 254, H.D. 1, RELATING TO MEDICINES.

BEFORE THE:
HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE

DATE: Monday, February 22, 2016 **TIME:** 2:30 p.m.

LOCATION: State Capitol, Room 325

TESTIFIER(S): Douglas S. Chin, Attorney General, or
Wade H. Hargrove III, Deputy Attorney General

Chair McKelvey and Members of the Committee:

The Department of the Attorney General provides the following comments.

This bill amends chapter 328, Hawaii Revised Statutes (HRS), in order to regulate the substitution of biosimilars for brand-name biologics to ensure public safety and access to medicines at lower prices. We respectfully recommend that the following technical edits be made to the current draft in the interest of legal clarity:

(1) Section 2 of this bill adds labeling requirements for an "interchangeable drug product" in the new paragraph (10) being added to existing section 328-16(a) (page 4, lines 3-7). We suggest either that the term "interchangeable drug product" be defined in section 328-1, HRS, or, since that term does not appear to be used elsewhere in the chapter, the wording of the product to which this new requirement is meant to apply be conformed to the wording in the rest of chapter 328 as amended. It would seem that the term "equivalent generic drug product" (page 3, lines 20-21), which is already utilized in existing section 328-16 but currently has no definition in part I, has the same meaning as intended by the use of the wording "interchangeable drug product." In other words, existing section 328-16(a)(9), concerning an "equivalent generic drug product," seems to already serve the same purpose that the new section 328-16(a)(10) would, thus creating unnecessary confusion. This confusion might best be remedied by adding a definition of "equivalent generic drug product" to existing section 328-1 for added clarity and deleting the new paragraph (10) of section 328-16 from this bill since it is redundant.

(2) Section 3 of this bill changes the existing definition of "compendia of therapeutically equivalent generic drug products" (page 6, lines 3-4) in order to make the wording of that term consistent with the changes being made to chapter 328 (which introduces the concept of

"interchangeable biological products"). For consistency throughout part VI, to which this new definition will apply, we suggest that instead of "compendia of therapeutically equivalent generic drugs and interchangeable biological products" that this term read: "compendia of therapeutically equivalent generic drug products and interchangeable biological products." This would make this newly rephrased term mirror the wording "therapeutically equivalent generic drug products and interchangeable biological products" that appears throughout part VI as amended.

(3) Section 4 of this bill adds a requirement that the dispensing pharmacist communicate the specific product dispensed to the patient, but is somewhat less clear about to whom this communication should be made (page 10, lines 18-21). Presuming from what follows in section 4 that the intent of the legislature is to have the pharmacist communicate this information to the prescribing physician (the "prescriber"), we suggest that this be made more clear by adding specific language to that effect in the first sentence of this newly created subsection 328-92(d).

Thank you for the opportunity to provide these comments.

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320
415 South Beretania Street
Honolulu, HI 96813

RE: Support for HB 254 HD 1 – FDA-designated interchangeable biological drug products; allow pharmacists to dispense.

Dear Chairman McKelvey:

On behalf of our Hawaii members and their patients, the Alliance for Patient Access (AfPA) would like to express support for HB 254 HD 1, 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 1 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 1 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 1 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, House Committee on Consumer Protection & Commerce

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

February 19, 2016

To: Representative Angus L.K. McKelvey, Chair
Representative Justin H. Woodson, Vice Chair
Committee on Consumer Protection and Commerce

Fr: Cynthia Laubacher, Senior Director, State Affairs
Express Scripts Holding Company

Re: House Bill 254 HD1 – Biosimilars
Hearing Date: Monday, February 22, 2016 2:30 p.m.

Express Scripts appreciates the opportunity to submit testimony regarding House Bill 254 HD1 ("HB 254"), relating to biosimilars. Express Scripts manages the pharmacy benefit for 85 million Americans.

HB 254 represents a compromise that allows pharmacists to dispense interchangeable biologics and ensures prescribers have easy access to information regarding the drug dispensed. HB 254 takes a very important step forward, ensuring that less expensive FDA-approved interchangeable biologics can be automatically substituted by a pharmacist when they become available.

HB 254 simply requires pharmacies to "communicate" to prescribers which drug was dispensed. This communication is achieved by either entering the information into an interoperable electronic medical records system, e-prescribing technology or into a pharmacy record that is electronically accessible to a prescriber.

Surescripts –a joint venture of Express Scripts, CVS Health, the National Association of Chain Drug Stores, and the National Community Pharmacists Association - is the nation's largest health information network that connects doctor's offices, hospitals, pharmacists and health plans through an integrated and technology neutral platform. They partner with more than 700 electronic health record applications used by over 800,000 healthcare professionals and more than 1,000 hospitals, impacting more than 270 million insured lives. Ninety-eight percent of electronic prescriptions run through Surescripts. Cash transactions are available through Surescripts and Surescripts' connected electronic medical records if the retail pharmacy provides the information. When a prescriber submits an electronic request for a patient's electronic medical record they receive twelve to twenty-four months worth of data – in seconds!

In short, HB 254 relies on existing systems already in use by prescribers and pharmacies. In that most rare occasion that a pharmacy or prescriber's technology does not currently link to electronic medical record data through Surescripts, the software to enable them to do so is simple to download and available for free.

Finally, there is no known opposition. For these reasons, Express Scripts respectfully requests your support for HB 254. Thank you for your consideration.

Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 348 0210 fax
www.ghlf.org

February 19, 2016

The Honorable Angus L.K. McKelvey
Chair, House Consumer Protection & Commerce Committee
Hawaii House of Representatives
Hawaii State Capitol, Room 320

Representative Justin Woodson
Vice Chair, House Consumer Protection & Commerce Committee
Hawaii House of Representatives
Hawaii State Capitol, Room 331

RE: **House Bill 254 HD 1 – *Support***

Chairman McKelvey and Vice-Chairman Woodson,

My name is Carole Wiedmeyer, and I have been a resident of Waikoloa, Hawaii for one and a half years. My legislators are Representative Cindy Evans and Senator 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 1, which addresses patient and physician notification during the substitution of a biosimilar and biologic product.

HB 254 HD 1 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 1 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.

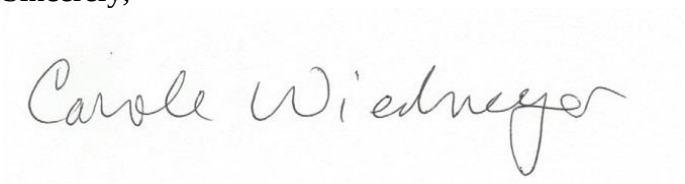
If it is determined by my doctor and me that an interchangeable biosimilar can be substituted for a biologic, or is the preferred treatment, it is obvious to healthcare providers, patients and I think, the majority of legislators, that proper record keeping be in place in order to track any adverse events 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 1 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

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

Dear Representative McKelvey,

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 HD1 (HB 254 HD1)** 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 HD1 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 HD1 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.

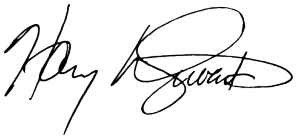
- Finally HB 254 HD1 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that

prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

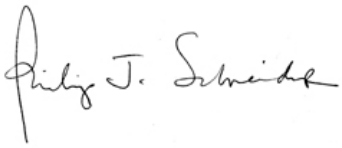
HB 254 HD1 will extend these valuable protections to Hawaii's patients while increasing their access to biologic therapies.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Hawaii by supporting House Bill 254 HD1.

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, House Committee on Consumer Protection & Commerce

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

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

2/19/2016

Dear Chairman Mckelvey:

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** 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 HD1 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:

a. 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.

b. It allows a physician to prevent a substitution they consider inappropriate for their patient by writing "do not substitute" on the prescription.

c. Finally HB 254 requires that the pharmacist communicate to the physician within a reasonable time frame 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 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.

Sincerely,

Virginia T. Lasko

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

February 19, 2016

Representative Angus L. K. McKelvey
Chair, Committee on Consumer Protection and Commerce
House of Representatives
Hawaii State Capitol
415 South Beretania St., Room 320
Honolulu, HI 96813

Re: HB 254 HD1—Biological Products and Patient Safety, to be considered by the House Committee on Consumer Protection and Commerce on February 22, 2016.

Dear Chair McKelvey,

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.

HB 254 HD1, to be considered by the House Committee on Consumer Protection and Commerce on February 22, is an excellent example of legislation that does just that.

ICAN, the International Cancer Advocacy Network, is in strong support of HB 254 HD1 because of its patient safety protections when dispensing 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. HB 254 HD1 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 HB 254 HD1 in the hearing on February 22, 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)
27 West Morten Avenue
Phoenix, AZ 85021-7246
602-618-0183 (phone)
602-926-8109 (fax)
www.askican.org
marcia@askican.org

27 West Morten Avenue
Phoenix, AZ 85021-7246
phone (602) 618-0183 · fax (602) 926-8109
programs@askican.org · www.askican.org

3944 Pine Avenue
Long Beach, CA 90807
phone (562) 427-5561

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

Testimony of Heather M. Spencer before the Committee on Consumer Protection and Commerce, Hawaii House of Representatives, February 22, 2016

Chair McKelvey and Members of the Committee on Consumer Protection and Commerce:

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 HB 254 HD1 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 McKelvey and Members of the Committee on Consumer Protection and Commerce, we urge you to favorably consider HB 254 HD1 and ensure its ultimate passage into law to protect Hawaii patients.

Thank you for your consideration.

Respectfully submitted,

Heather M. Spencer

Heather M. Spencer

National Hispanic Medical Association

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

Re: Support for HB 254 HD1

Dear Chairman McKelvey:

On behalf of the Board of Directors of the National Hispanic Medical Association we urge support for HB 254 HD1 regarding substitution of biological drug products.

HB 254 HD1 would (1) authorize a pharmacist to substitute an alternative biological product when filling a prescription for a prescribed biological product if the alternative biological products is designated as interchangeable with the reference product and (2) provide physicians with 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 product's 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 recommends your support for HB 254 HD1 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 provide increased access to quality treatment for Hispanics and all persons in Hawaii with chronic diseases.

Sincerely,

Elena Rios, MD, MSPH
President & CEO

cc: Committee Members, House Committee on Consumer Protection & Commerce

woodson2-Shingai

From: mailinglist@capitol.hawaii.gov
Sent: Friday, February 19, 2016 12:18 PM
To: CPCtestimony
Cc: arlen.valdivia@edelman.com
Subject: *Submitted testimony for HB254 on Feb 22, 2016 14:30PM*

HB254
Submitted on: 2/19/2016
Testimony for CPC on Feb 22, 2016 14:30PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
arlen valdivia	National Patient Advocate Foundation	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.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 348 0210 fax
www.ghlf.org

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives

RE: **House Bill 254 HD 1 – *Support***

Chairman McKelvey,

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 1 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 1takes 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 1 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 1 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, House Committee on Consumer Protection & Commerce

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

Re: The Biosimilars Council Support for HB 254 HD1

Dear Representative McKelvey,

The Biosimilars Council, a division of the Generic Pharmaceutical Association (GPhA), represents manufacturers and distributors of biosimilars and works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products. The Biosimilars Council fully supports HB 254 HD 1. House bill 254 HD 1 amends current pharmacy practice to allow for the automatic substitution of biological products deemed interchangeable by FDA. With the first biosimilar approved in 2015 and seven more currently before FDA, it is critical that states take action. States will need new legislation in place to amend pharmacy practice to allow for substitution of interchangeable biological products.

Numerous other states have passed similar substitution legislation for interchangeable biological products. House bill 254 HD 1 relies on electronic records to fulfill the communication requirement and presumes that entry into a record satisfies communication. This means that in an increasing number of pharmacies, nothing else must be done once the product is dispensed. This communication would occur whether an originator biologic ***or*** an interchangeable biologic is dispensed, providing a level, pro-competitive playing field for all biologics.

Leaders in the generic industry have successfully produced safe and effective biosimilars for sale outside the U.S. since the early 2000s. Although biosimilars and interchangeable biological products are not generics, with proper state legislation in place, the biosimilar and interchangeable biological product market is primed to take off like the generic drug market—creating competition which drives down costs and saves Hawaii patients and payors millions.

House bill 254 HD 1 reflects compromise language supported by a broad coalition of brand and generic manufacturers, trade associations, and pharmacies. The Biosimilars Council has always supported legislation that treats interchangeable and brand biologics the same, and we fully support HB 254 HD 1. The Biosimilars Council applauds this committee and Representative Evan's commitment to Hawaii's access to affordable interchangeable biologics with HB 254 HD 1. Thank you so much for your time and consideration on this matter. Please let me know if you have any questions.

Sincerely,

Brynna M. Clark, Esq.
Senior Director of State Affairs
The Biosimilars Council, A Division of GPhA

February 19, 2016

TO: Chair Angus L. K. McKelvey and Members of House Committee on Consumer Protection & Commerce

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

RE: **HB 254 HD1** - Relating to Medicines
Hearing Date: February 22, 2016
Time: 2:30 pm

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

PhRMA supports passage of **HB 254 HD1**. 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 – HD1

February 2, 2016

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) supports Hawaii House Bill 254 – HD1 which would amend the law in Hawaii law to reflect changes to federal law that created an abbreviated pathway for FDA approval of biosimilar products. HB 254 – HD1 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 – HD1 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 – HD1 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 – HD1 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 – HD1 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 – HD1 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 – HD1.

TO:
COMMITTEE ON CONSUMER PROTECTION & COMMERCE
Rep. Angus L.K. McKelvey, Chair
Rep. Justin H. Woodson, Vice Chair

DATE: Monday, February 22, 2016
TIME: 2:30 pm
PLACE: Conference Room 325
State Capitol
415 South Beretania Street

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.

ARTHRITIS FOUNDATION, PACIFIC REGION
800 W. 6th Street, Suite 1250
Los Angeles, CA 90017
www.arthritis.org

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320
Honolulu, HI 96813

RE: House Bill 254 HD1
Position: Support

Dear Representative McKelvey,

The Arthritis Foundation urges the members of the House Committee on Consumer Protection & Commerce to support this bill. House Bill 254 HD1 will update current law and allow the substitution of biologic medicines with interchangeable biological products. This bill would also require a pharmacist, when dispensing an interchangeable biological product, to notify both the patient and the prescriber of the switch thus ensuring a complete medical record.

Arthritis is an umbrella term for more than 100 different conditions such as rheumatoid arthritis, lupus, ankylosing spondylitis that affects the spine, and uveitis that affects the eye and can lead to permanent vision loss. For more than 218,000 adults and 3,500 children in Hawaii suffering from this debilitating disease, ensuring they have access to life-changing medications is vital. In many cases that means the difference between a lifetime of disability and full participation in work and civic life. In addition to the ongoing management of a patient's arthritis, of which there is no cure, the vast majority of patients with arthritis also have multiple other chronic conditions. Because of the complexity to not only treat rheumatic conditions, but also the patient's comorbidities, it is imperative the patient and their physician are able to discuss their treatment options, switches in medications, as well as options available to them.

When therapeutic innovations come to market, patient safety must remain the number one priority in any discussion; even if a drug is less expensive, these advantages mean nothing if the drug does not successfully treat the patient. It is important to remember that these are complex medications, and that interchangeable biological products are not the same as generics. Because of this, the Arthritis Foundation is committed to ensuring that the concerns of people who take these medications, and the specialist physicians who treat them, are kept at the forefront. By doing so, the patient and physician can continue a dialogue ensuring they receive optimal care with these game-changing medicines. House Bill 254 HD1 takes a step in the right direction to encourage a high level of communication between all players on the healthcare team.

On behalf of the Arthritis Foundation, I thank you for your consideration and urge your support of HB 254 HD1, which will keep patients and providers informed when medications are substituted.

Sincerely,

Krystin Mieko Herr
Vice President, Government Affairs & Advocacy
Cell (916) 502-2979
kherr@arthritis.org

cc: Representative Cindy Evans
Representative Della Au Belatti
Representative Richard P. Creagan, Vice Chair
Members, House Committee Consumer Protection & Commerce

arthritis.org

Biologics Change Lives for People With Arthritis

ARTHRITIS FOUNDATION®

The faces of juvenile arthritis a generation ago.

The faces of juvenile arthritis today WITH biologics.

THEN

NOW

arthritis.org

Biologics Change Lives for People With Arthritis

ARTHRITIS FOUNDATION®

The faces of juvenile arthritis a generation ago.

The faces of juvenile arthritis today WITH biologics.

THEN

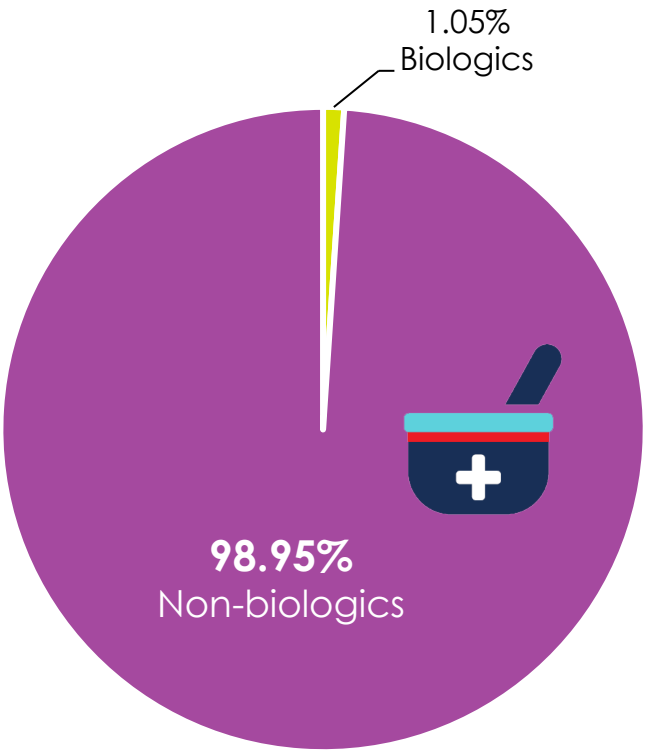
NOW

Arthritis Foundation℠

Yes

How many biologic prescriptions do retail pharmacies actually dispense?

Total Prescriptions



The average pharmacy in Hawaii dispenses 1,604 prescriptions per week, compared with 17 per week for biologics.

That is 1.05% of all scripts.

Only 0.007% of all scripts handled by retail pharmacists were biologics.

Source: IMS data of 2012 National Sales Projections

Contact:
Krystin Herr
VP, Government Relations
Pacific Region
KHerr@arthritis.org • 916-340-0733

Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320
415 South Beretania St.
Honolulu, HI 96813

sent electronically to: repmckelvey@Capitol.hawaii.gov

RE: HB 254 HD1 – dispensing of interchangeable biosimilars

Dear Chairman McKelvey:

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 HD1 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 HD1 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 HD1 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 HD1 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

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

February 20, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

Dear Chairperson McKelvey:

On behalf of the Global Colon Cancer Association, an international not for profit organization, we are writing to request that you **support HB 254 HD1** 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 HD1 and** are concerned that patient safety will be compromised if this legislation is not enacted.

It is our view that **HB 254 HD1** 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 HD1** 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 HD1 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 HD1 .

Sincerely,

Andrew Spiegel
Executive Director

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer
Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

Re: Hawaii HB 254 HD 1 An Act relating to biological products

Dear Chairman:

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 HD 1. 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 HD 1 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

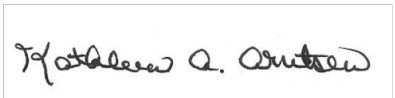
lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-threatening and life-diminishing diseases. As more biosimilars become available in the United States we want to ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant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

HB 254 HD 1 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 HD 1. This legislation is especially important given the FDA's approval of the first biosimilar last March, with a second one recently reviewed 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

Cc: Members, House Committee on Consumer Protection & Commerce

CSRO
COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

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Two Woodfield Lake
1100 E Woodfield Road, Suite 350
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Phone: (847) 517-7225 | (847) 517-7229
Email: csro@wjweiser.com | Website: www.csro.info

February 19, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320
415 S Beretania St, Honolulu, HI 96813

Re: HB 254 HD1 – Relating to the regulation of biosimilar medications

Dear Representative McKelvey:

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 you consider HB 254 HD1, 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 including for dispensing pharmacists to communicate with physicians about biosimilar substitutions within 5 days. Requiring this communication as quickly 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 HD1.

Sincerely,

Michael P. Stevens, MD

Michael Stevens, MD
President
Coalition of State Rheumatology Organizations

An Independent Licensee of the Blue Cross and Blue Shield Association

February 22, 2016

The Honorable Angus L.K. McKelvey, Chair
The Honorable Justin H. Woodson, Vice-Chair
House Committee on Consumer Protection and Commerce

Re: HB 254, HD1 – Relating to Medicines

Dear Chair McKelvey, Vice-Chair Woodson and Members of the Committees:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 254, HD1 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, HD1, 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, HD1.

Sincerely,

Jennifer Diesman
Vice President, Government Relations

NATIONAL PSORIASIS FOUNDATION®

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

February 21, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

RE: Support HB 254 HD 1 – Interchangeable Biological Products

Dear Representative McKelvey:

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 HD1 with the communication provision intact.

Sincerely,

Randy Beranek
President & CEO

cc: Members, House Committee on Health

6600 SW 92nd Ave., Suite 300 | Portland, OR 97223-7195 | 800-723-9166 | Fax 503-245-0626
1800 Diagonal Rd., Suite 360 | Alexandria, VA 22314 | Fax 703-739-9800
www.psoriasis.org

February 22, 2016

The Honorable Angus McElvey
Chair, House Committee on Consumer Protection
House of Representatives
Hawaii State Capitol
Honolulu, HI 96813

Dear Chairman McElvey 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 HD1, 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 HD1 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 HD1 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 HD1. Please do not hesitate contacting me if you have questions or require any additional information.

Regards,

Patrick Plues
Senior Director, State Government Affairs
BIO

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

House Committee on Consumer Protection and Commerce
Representative Angus McKelvey, Chair
Representative Justin Woodson, Vice Chair
Members of the Committee

HB 254, HD1 - 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, HD1, 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 HD1 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.

February 20, 2016

The Honorable Angus L. K. McKelvey
Chair, House Committee on Consumer Protection & Commerce
Hawaii House of Representatives
Hawaii State Capitol, Room 320

RE: Support House Bill 254 HD1

Dear Representative McKelvey,

The National Organization for Rare Disorders (NORD) respectfully requests you to support House Bill 254 HD1, 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 HD1, 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: Representative Justin H. Woodson, Vice Chairman
Representative Della Au Belatti
Representative Mark M. Nakashima
Representative Tom Brower
Representative Marcus R. Oshiro
Representative Richard P. Creagan
Representative Joy A. San Buenaventura
Representative Sharon E. Har

Representative Gregg Takayama
Representative Mark J. Hashem
Representative Ryan I. Yamane
Representative Derek S.K. Kawakami
Representative Beth Fukumoto Chang
Representative Chris Lee
Representative Bob McDermott

CVSHealth

Longs Drugs

LATE

Eric P. Douglas
Senior Director, Government Affairs

2211 Sanders Road
Northbrook, IL 60062

p 847.559.3422
c 847.651.9807
f 401.652.9342

Eric.Douglas@CVSHealth.com

LATE TESTIMONY

The Honorable Angus McKelvey
Chair, House Committee on Consumer Protection & Commerce

Monday, February 22, 2016
Conference Room 325; 2:30 PM

RE: HB 254 HD1 – Relating to Medicines

Aloha Chair McKelvey, Vice Chair Woodson and members of the Committee:

CVS Health appreciates the opportunity to comment on HB 254 HD1 and propose a technical amendment. Biologic medications represent the fastest growing segment of the prescription drug pipeline, in both numbers as well as cost. The bill would allow Hawaii statutes to recognize biosimilars in addition to brand-name biologics as exists today. As these follow-on drugs become more and more available, both biosimilars and interchangeable biosimilars alike promise to save consumers in Hawaii significantly over the cost of the brand-name biologics today.

The language contained in this version accurately reflects common biosimilars language we have seen elsewhere. In particular, we would like to note that the notification section of the measure, applicable upon the dispensing of an interchangeable biosimilar, fairly reflects agreed-to language reached in other states . CVS Health has no objections to the intent of the HB 254 HD1, however we would like to offer the following amendment for clarification to match the term with the definition.

> *Section 2, Page 4, Line 4 strike the word "~~drug~~" and insert the word "biological".*
> *Rationale: "interchangeable drug product" is not defined, "interchangeable biological product" is and would then have the term match the needed definition as in 328-91, HRS, in Section 3, Page 5, Line 11 of the bill.*

CVS Health proudly operates as the largest pharmacy chain in Hawaii, under our Longs Drugs banner; offering our patients and clients a wide range of comprehensive, integrated pharmacy and healthcare related operations statewide including: Pharmacy Benefit Management (PBM) services (CVS/caremark), Specialty Pharmacy (CVS/specialty), Mail-Order and Retail Pharmacy (CVS/pharmacy/Longs Drugs), Retail Health Clinics (CVS/minute clinic) and a distribution center.

We thank you for your consideration of our comments.

Respectfully,

Eric P. Douglas