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

Representative Della Au Belatti, Chair
Representative Richard P. Creagan, Vice Chair
Members of the House Committee on Health

HB 254, Proposed 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, proposed 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 proposed 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.

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

February 3, 2016

Representative Della Au Belatti
Chair, House Committee on Health
Hawaii State Capitol
Room 426

Dear Representative Belatti,

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 251 HD1 (HB 251 HD1)** regarding the pharmacy substitution of biosimilar medical products. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovative and biosimilar medicines, 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 251 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 251 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.

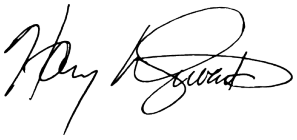
- Finally HB 251 HD1 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that

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

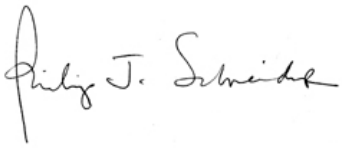
HB 251 HD1 will extend these valuable protections to Hawaii's patients while increasing their access to biologic therapies.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Hawaii by supporting House Bill 251 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 Health

Global Healthy Living Foundation
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+1 845 348 0210 fax
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January 28, 2016

Representative Della Au Belatti
Chair, House Committee on Health
Hawaii State Capitol, Room 426

Representative Richard P. Creagan
Vice Chair, House Committee on Health
Hawaii State Capitol, Room 331

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

Madam Chair Belatti and Vice-Chairman Creagan,

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 Health Living Foundation

CC:
Members, House Committee on Health

NHMA
National Hispanic Medical Association

February 2, 2016

The Honorable Della Au Belatti
Chair, House Committee on Health.
Hawaii House of Representatives

Re: Support for HB 254 HD1

Dear Representative Belatti:

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 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 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 Health

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February 2, 2016

Representative Della Au Belatti
Chair, Committee on Health
House of Representatives
Hawaii State Capitol
415 South Beretania St., Room 426
Honolulu, HI 96813

Re: HB 254 HD1—Biological Products and Patient Safety, to be considered by the House Committee on Health on February 5, 2016.

Dear Chair Belatti,

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 Health on February 5, 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 5, 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
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marcia@askican.org

EXPRESS SCRIPTS®

February 2, 2016

To: Representative Della Au Belatti, Chair
Representative Richard P. Creagan, Vice Chair
Committee on Health

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

Re: House Bill 254 – Biosimilars – As proposed to be amended
Hearing Date: Friday, February 5, 2016 10:00 a.m.

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

As proposed to be amended, 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.

Opponents claim this legislation creates an undue and added burden on pharmacists. As one of the nation's largest mail service and specialty pharmacies, we respectfully disagree. HB 254 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.

For these reasons, Express Scripts respectfully requests your support for HB 254. Thank you for your consideration.

NATIONAL PSORIASIS FOUNDATION®

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

February 2, 2016

Representative Della Au Belatti
Chair, House Committee on Health
Hawaii House of Representatives

RE: Support HB 254 HD 1 – Interchangeable Biological Products

Dear Representative Belatti:

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

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February 1, 2016

The Honorable Della Au Belatti
Chairwoman
House Committee on Health
Hawaii State Capitol, Room 426
415 South Beretania Street
Honolulu, HI 96813

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

Dear Chairwoman Au Belatti:

On behalf of our Hawaii members and their patients, the Alliance for Patient Access (AfPA) would like to express support for HB 254, 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 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 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 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 Health Policy Committee

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

February 1, 2016

Chairwoman Della Au Belatti
House Health Committee
Hawaii State Capitol, Room 426
415 South Beretania St.
Honolulu, HI 96813

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

Dear Madam Chairwoman:

On behalf of the Lupus and Allied Diseases Association and the millions of Arizona 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. 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 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 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. This legislation is especially important given the FDA's approval of the first biosimilar last March, the second one to be 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

Cc: Representative Richard P. Creagan, Vice Chairman
Representative Mark J. Hashem
Representative Jo Jordan
Representative Bertrand Kobayashi
Representative Dee Morikawa
Representative Marcus R. Oshiro
Representative Beth Fukumoto Chang
Representative Andria P.L. Tupola

February 3, 2016

TO: Chair Della Au Belatti and Members of House Committee on Health

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

RE: **HB 254 HD1** - Relating to Medicines
Hearing Date: February 5, 2016
Time: 10:00 am

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.

An Independent Licensee of the Blue Cross and Blue Shield Association

February 5, 2016

The Honorable Della Au Belatti, Chair
The Honorable Richard Creagan, Vice-Chair
House Committee on Health

Re: HB 254, HD1 (Proposed) – Relating to Medicines

Dear Chair Au Belatti, Vice-Chair Creagan and Members of the Committees:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on the proposed HB 254, HD1 which specifies the conditions under which biosimilar medications may be dispensed. HMSA supports the intent of this Bill.

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.

HMSA appreciates the effort that has gone into crafting the proposed draft of HB 254, and we believe it may reasonably balance the concerns of many of us in the healthcare system.

Thank you for allowing us to testify on the proposed HB 254, HD1.

Sincerely,

Jennifer Diesman
Vice President, Government Relations

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

Testimony of Heather M. Spencer before the Committee on Health, Hawaii House of Representatives, February 5, 2016

Chair Belatti and Members of the Committee on 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 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 Belatti and Members of the Committee on Health, 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

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The Honorable Della Au Belatti
Chair, House Committee on Health

Friday, February 5, 2016
Conference Room 329; 10:00 AM

RE: HB 254 Proposed HD1 – Relating to Medicines

Aloha Chair Belatti, Vice Chair Creagan and members of the Committee:

CVS Health appreciates the opportunity to comment on the proposed HD1 to HB 254. Biologic medications represent the fastest growing segment of the prescription drug pipeline, in both numbers as well as cost. The proposed HD1 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 the proposed HD1 accurately reflects common biosimilars language we have seen elsewhere. In particular, we would like to note that the notification section of the proposed HD1, applicable upon the dispensing of an interchangeable biosimilar, fairly reflects agreed-to language reached in other states and therefore, CVS Health has no objections with the proposed HD1.

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

From: mailinglist@capitol.hawaii.gov
Sent: Tuesday, February 02, 2016 11:18 AM
To: HLTtestimony
Cc: mendezj@hawaii.edu
Subject: *Submitted testimony for HB254 on Feb 5, 2016 10:00AM*

HB254
Submitted on: 2/2/2016
Testimony for HLT on Feb 5, 2016 10:00AM in Conference Room 329

Submitted By	Organization	Testifier Position	Present at Hearing
Javier Mendez-Alvarez	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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