Support House Bill 2705 and Senate Bill 460
Creating a Pathway to Access for Safe, Affordable Biosimilars

February 28, 2013

Alliance for Patient Access
Brian Kennedy, Executive Director

Alliance for the Adoption of Innovations in Medicine (AAIMed)
Brett Hunt, Director of Public Affairs

American Academy of Neurology
Bruce Sigsbee, MD, FAAN, President

American Autoimmune Related Diseases Association (AARDA)
Virginia T. Ladd, President

Basic Rights Oregon
Jeana Frazzini, Executive Director

Center for Lawful Access and Abuse Deterrence
Michael Barnes, Founder & Executive Director

Kidney Cancer Association
William P. Bro, President

HealthHIV
Michael D. Shankle, MPH, Director of Prevention & Policy

The National Grange
Grace Boatright, Legislative Director

Veterans Health Council
Tom Berger, President

Representative Mitch Greenlick
900 Court Street, NE, H-493
Salem, OR 97301

Representative Jim Thompson
900 Court Street, NE, H-388
Salem, OR 97301

Representative Alissa Keny-Guyer
900 Court Street, NE, H-281
Salem, OR 97301

Senator Laurie Monnes Anderson
900 Court Street, NE, S-413
Salem, OR 97301

Senator Jeff Kruse
900 Court Street, NE, S-315
Salem, OR 97301

Dear Representatives Greenlick, Thompson & Keny-Guyer and Senators Monnes Anderson & Kruse:

Oregonians with serious chronic illnesses need access to affordable, effective medications. The Oregon state legislature is considering legislation to make biosimilars available to patients, creating the opportunity for better health and significant cost savings. To this end, we strongly urge passage of House Bill 2705 and Senate Bill 460.

This is an issue of profound importance to Oregon patients. Biologic medicines, made from living cells as opposed to chemical compounds, have shown tremendous potential to successfully address diseases and their symptoms and achieve improved health outcomes. FDA-approved biosimilars can place this medical progress within the reach of more of our state's citizens. The federal Affordable Care Act gives states the authority to set standards by which biosimilars can be safely substituted for prescribed biologic medicines. HB 2705 and SB 460 will establish those standards and, in so doing,

improve the health status of our state's citizens—including our seniors, veterans and children—who suffer from debilitating and life threatening illnesses such as rheumatoid arthritis, multiple sclerosis, psoriasis, diabetes and cancer, among others.

These bills take two essential steps to create a safe pathway to bring biosimilars to Oregon patients.

First, the legislation makes clear that biosimilars may only be substituted for original biologics if the FDA has certified that the drugs are interchangeable. This is a fundamental requirement in order to protect patient safety. Biologics are different than conventional medications. Because they are made from living cells, it is impossible to create an exact duplicate of any individual biologic drug. In order to ensure that a biosimilar is both safe and effective, FDA certification is essential.

Second, the legislation ensures that complete transparency takes place whenever biosimilars are involved. Patients and physicians are required to be notified whenever a biosimilar substitution has been made at the pharmacy. This is simply sound healthcare practice. When physicians have made a carefully-considered judgment regarding the use of a biologic drug to treat a patient's condition, it is both necessary and right that both physician and patient be apprised of a medication substitution.

This legislation is founded in common sense and a desire for accessible, high-quality healthcare. HB 2705 and SB 460 give patients access to affordable biosimilar medications, and is intended to increase, not restrict, the use of these breakthrough medicines. The bill does not impose significant costs—on patients, health providers or taxpayers—or administrative burdens. In fact, it should encourage greater health system cost savings because insurance companies and pharmacy benefit management companies will have full latitude to use their formularies and other coverage tools to incentivize the use of less expensive biosimilars.

Biologic medications are heralding-in an era of more effective treatments, improved health outcomes and longer, healthier lives. It is essential that all Oregonians have access to these therapies. HB 2705 and SB 460 make that accessibility possible, while also protecting patient safety and the sanctity of the physician-patient relationship. These are sensible, necessary measures and we strongly urge their adoption.

Organizations Supporting House Bill 2705 and Senate Bill 460 Creating a Pathway to Access for Safe, Affordable Biosimilars

Allergan
Alliance for Patient Access (AfPA)
Alliance for the Adoption of Innovations in Medicine (AAIMed)
Alliance of Specialty Medicine
American Academy of Dermatology
American Academy of Facial Plastic & Reconstructive Surgery
American Academy of Neurology (AAN)
American Association of Neurological Surgeons
American Autoimmune Related Diseases Association (AARDA)
American College of Mohs Surgery
American Council on Science and Health
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Amgen
Association of Black Cardiologists
Association of Clinical Research Organizations
Association of People with Disabilities
Association of Gastrointestinal Motility Disorders, Inc.
Basic Rights Oregon
Biotechnology Industry Organization (BIO)
Center for Lawful Access and Abuse Deterrence (CLAAD)
Coalition of State Rheumatology Organizations
Colon Cancer Alliance
Colorectal Cancer Coalition
Congress of Neurological Surgens
Genentech
Global Healthy Living Foundation
HealthHIV
Interamerican College of Physicians and Surgeons
International Cancer Advocacy Network (ICAN)
International Myeloma Foundation
Johnson & Johnson
Kidney Cancer Association
MANA
MedImmune
National Alliance on Mental Illness (NAMI)

North America Spine Society
Oregon Bioscience Association
Oregon Dermatology Society
Oregon Medical Association
Pharmaceutical Research & Manufacturers of America (PhRMA)
RetireSafe
Society for Cardiovascular Angiography and Interventions
Society for Excellence Eyecare
TechNet
The Alliance for Safe Biologic Medicines
The National Grange
UCB

Improving Lives • Finding the Cure®

Patient Safety Must Come First:
The International Myeloma Foundation (IMF) Supports State Guidelines for Substitution of Switchable Medicines for Cancer Patients

As state lawmakers in Oregon State consider policy changes surrounding the use of FDA approved biosimilar and interchangeable biologic products, in the treatment of cancer patients, The International Myeloma Foundation (IMF) strongly believes that patient safety and transparency must be the top consideration.

Follow-on biologics, or "biosimilars," are therapies produced using different cell lines and manufacturing processes, with the goal of closely mirroring the makeup of a drug originally produced by another company. Due to the chemical complexity of biologics in general, however, the "biosimilar" version of a drug has great potential for negative side effects for patients and their reaction to the treatment. Moreover, unlike generic copies of traditional small molecule drugs, biosimilar biologic products will be therapies that are similar to, but not exactly the same as the original, and the differences could be dangerous.

As the FDA works to develop appropriate standards for the approval of safe biosimilar and interchangeable biologic products, states are taking action to protect patient safety and to ensure transparency and communication between patients and their medical team. To address these and other concerns, states must consider the following:

- Allow substitution only when a biosimilar biologic product has been designated by the FDA as interchangeable. This standard will give patients and their physicians the assurance that all potential negative side effects and outcomes have been considered.
- Empower prescribing health care providers to prevent substitution. Knowing the patient's treatment history, personal values and preferences, puts the provider in the best position to make this determination.
- Allow permitting prescription pads to contain the phrase "dispense as written," or "brand medically necessary". This puts the provider in the driver's seat when determining whether or not to use biologic products in a patient's treatment plan, from the start, and enables them to better manage potential patient side effects.
- Require prescribing health care providers be notified of the substitution. Even though interchangeable biologics may produce the same clinical result, there is still a risk that the

patient could have a negative reaction to the change and having the primary provider in the loop from the start, will help to ensure quick and appropriate treatment to unintended consequences. This will also help facilitate the reporting of an adverse event.

- Require that the patient or the patient's authorized representative, be notified of the substitution. Often patients managing life threatening conditions, such as cancer, use multiple treatment regimens to strike a balance between managing their symptoms and minimizing side effects. Generally, patients are aware of which treatments work best in their unique circumstances and providing notice to the patient, or depending on current state law, requiring patient consent to substitute, gives that patient the opportunity to discuss with their pharmacist and/or health care provider, past treatment experiences so that potential, future problems can be avoided.

- Direct pharmacist and primary health care providers to keep records of the substitution. Because many biologic medicines are used to treat cancers and other life threatening conditions that can change over time, it is important for a patient's treatment team to have records that document how and when a patient was treated with biologic therapies. These records will also provide insight down the road in the event of an adverse reaction.

The IMF looks forward to working with policymakers in Oregon as you move forward on this issue. **For more information, please contact Zina Cary, National State Affairs Consultant for the IMF at zcary@myeloma.org.**

The IMF is the oldest and largest myeloma foundation dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure.

February 26, 2013

Senator Laurie Monnes Anderson
900 Court St, NE S-413
Salem, OR, 97301

Senator Jackie Winters
900 Court St. NE, S-301
Salem, OR 97301

Dear Senator Monnes Anderson and Senator Winters,

As the chairman of the Alliance for Safe Biologic Medicines (ASBM) and a practicing physician who prescribes biologics, I would like to express to you our support for Senate Bill 460 on the substitution of interchangeable biosimilar biological products. Our organization was formed in December 2010 after the FDA was given the authority to bring biosimilars to the U.S. and since then we have been working with patients, physicians, pharmacists, innovative medical biotechnology companies and others to ensure that patient safety is at the forefront of the biosimilars policy discussion. We have supported the FDA for over two years in its mission to safely bring biosimilars to patients in the U.S. and we support your efforts to safely bring biosimilars to patients in the Beaver State.

Biologics are highly complex, advanced prescription medicines used to treat diabetes, cancer, rheumatoid arthritis, MS, infertility and many other debilitating diseases. Unlike drugs derived from chemicals, biologics are manufactured using a unique process with living cells and for this reason no two biologics made from different cell lines are ever identical. When attempting to replicate biologics, their "copies," known as biosimilars, are similar to, but not exact versions of the biologic they aim to replicate and are often mistakenly referred to as "generics." Even the smallest difference in the structure of a biologic medicine and its attempted copy can have a significant impact on a patient and therefore, the issue of interchangeability has been a new challenge for policy-makers.

We believe it is absolutely critical that when substituting biosimilars for biologics there needs to be clear communication between physicians, pharmacists and patients and we have been very focused on bringing these stakeholders together to determine the best solutions on biosimilar interchangeability. In May 2012, we convened a working group of our Advisory Board members to discuss the elements of a physician notification policy for interchangeable biosimilars that prioritizes patient safety and protects the relationship between physicians and their patients but also respects the sovereignty of pharmacists as healthcare providers. In September, I presented findings from a physician survey we conducted at the FDA/DIA Biosimilars Conference that found that 86% of the 350 physicians who participated, responded they want to be notified BEFORE a patient is switched to a biologic other than the one prescribed EVEN IF there are no known concerns associated with the product.

In October 2012, ASBM released key principles that should be included in a formal policy recommendation. We believe that building policy around these common sense recommendations will help ensure safety without delaying the introduction of biosimilars to patients. ASBM agrees

with SB 460 that a pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

1. The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the biological product for the use for which the prescribing practitioner prescribed the biological product;
2. The prescribing practitioner has not designated on the prescription that substitution is prohibited;
3. The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;
4. The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and
5. The prescribing practitioner, and the pharmacy or pharmacist, retain a record of the substitution for a period of not less than three years.

Thank you for taking the necessary steps to ensure patient safety in Oregon. I've included a fact sheet that demonstrates broad support for physician notification when interchangeable biosimilars are automatically substituted. I hope ASBM can be a resource for you moving forward.

Sincerely,

Richard Dolinar, M.D.
Chairman, The Alliance for Safe Biologic Medicines

Members:
Alliance for Patient Access
American Academy of *Dermatology*
American Association of People with Disabilities
American Council on Science and Health
Amgen
Association of Black Cardiologists
Association of Clinical Research Organizations
Association of Gastrointestinal Motility Disorders, Inc.
Biotechnology Industry Organization
Colon Cancer Alliance
Colorectal Cancer Coalition
Genentech
Global Healthy Living Foundation
Interamerican College of Physicians and Surgeons
International Cancer Advocacy Network
Kidney Cancer Association
MANA
National Alliance on Mental Illness
RetireSafe

TO: Health Care & Human Services Committee

FR: Jeana Frazzini, Executive Director, Basic Rights Oregon

DA: February 28, 2013

RE: Support for HB 2705 and SB 460

Basic Rights Oregon, the state's largest organization representing the gay and transgender community, **urges passage of HB 2705 and SB 460**. The Oregon state legislature is considering legislation to make biosimilars available to patients, creating the opportunity for better health and significant cost savings. These two bills would increase access to affordable, effective medications for a variety of patients—including those with HIV/AIDS.

According to the Centers for Disease Control and prevention, young gay and bisexual men accounted for 69% of new HIV infections among people age 13-29. And according to the National Survey on Transgender Discrimination, transgender people are more than four times as likely to test positive for HIV than the national average, with rates even higher among transgender people of color. The sustained impact of HIV/AIDS on gay and transgender communities makes increasing access to effective treatments a top priority. HB 2705 and SB 460 take two essential steps to create a safe pathway to bring biosimilars to Oregon patients.

First, the legislation makes clear that biosimilars may only be substituted for original biologics if the FDA has certified that the drugs are interchangeable. This is a fundamental requirement in order to protect patient safety. Biologics are different than conventional medications. Because they are made from living cells, it is impossible to create an exact duplicate of any individual biologic drug. In order to ensure that a biosimilar is both safe and effective, FDA certification is essential.

Second, the legislation ensures that complete transparency takes place whenever biosimilars are involved. Patients and physicians are required to be notified whenever a biosimilar substitution has been made at the pharmacy. This is simply sound healthcare practice.

The bill does not impose significant costs—on patients, health providers or taxpayers—or administrative burdens. In fact, it should encourage greater health system cost savings because insurance companies and pharmacy benefit management companies will have full latitude to use their formularies and other coverage tools to incentivize the use of less expensive biosimilars.

Biologic medications are heralding-in an era of more effective treatments, improved health outcomes and longer, healthier lives. It is essential that all Oregonians have access to these therapies. HB 2705 and SB 460 make that accessibility possible, while also protecting patient safety and the sanctity of the physician-patient relationship. **Basic Rights Oregon supports HB 2705 and SB 460 and we urge you to vote YES.**

February 27, 2013

The Honorable Mitch Greenlick
Chair, House Health Care Committee
Oregon State Capitol
900 Court St. NE
Salem, Oregon 97301

RE: House Bill 2705 – dispensing of interchangeable biosimilars

Dear Representative Greenlick,

On behalf of the American Academy of Dermatology Association (Academy) and the Oregon Dermatology Society (ODS), we commend the members of the Oregon House Health Care Committee for considering biosimilar legislation during this legislative session. Dermatologists who treat severe psoriasis call the advent of biologic therapies a revolution. U.S. patents for these therapies expire in the next ten years, which will open the pathway for biosimilars. The availability of biosimilars is such a concern that the Academy's Board of Directors recently released a position statement regarding generic therapeutic and biosimilar substitution. To this end, we are pleased that HB 2705 largely reflects the Academy's position on dispensing of biosimilar products and recommends as a friendly amendment that the Committee amend the legislation to shorten the notification from three days to 24 hours prior to dispensing in order to ensure patient safety.

As you know, biosimilars are not exact replications of their reference biologic products; therefore, due to their variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. For this reason, patient substitution decisions for biosimilars should be carefully considered. The ODS and the Academy caution that authorizing a three-day notification period after the drug has been dispensed could jeopardize patient safety. Reducing the notification period to 24-hours prior to the substitution as outlined in the Academy's position statement could prevent adverse outcomes by requiring the approval of the physician before the medication is dispensed to the patient. Concerns raised that pre-notification would impede access to medication are not justified as most biologics are delivered via shipping to patients through specialty pharmacies and are not picked up at the pharmacy in the same way as more traditional medications.

We look forward to working with the Committee to ensure biosimilars are dispensed in a safe manner and without impeding access to patients of such medications. Please contact Lisa Albany, JD, Assistant Director of State Policy, at lalbany@aad.org or (202) 842-3555 should you require any additional information or clarification.

Sincerely,

Jonathan Alexander, MD, FAAD
President, Oregon Dermatology Society

Daniel M. Siegel, MD, FAAD
President, American Academy of Dermatology Association

American Academy of Dermatology Association

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Kidney Cancer Association
www.KidneyCancer.org

Statement of the Kidney Cancer Association in Support of Oregon House Bill 2705 and Senate Bill 460

February 28, 2013

The Kidney Cancer Association serves the needs of the more than 50,000 Americans each year who are diagnosed with kidney cancer. The number of individuals who are surviving kidney cancer -- approximately 200,000 in the United States today -- is on the increase because of advances in drug development that are giving new hope to individuals and families who once had little or none.

Because we believe this hope and promise for a healthier life should be available to all kidney cancer sufferers, including those with limited financial means, we urge you to support House Bill 2705 and Senate Bill 460. This legislation will create a safe and transparent pathway by which affordable biosimilar drugs can be accessible to all patients.

Biologic medications -- drugs made from living cells -- have been a godsend for many, aggressively attacking life-threatening diseases in ways that conventional chemical-based pharmaceuticals cannot. These drugs are very complex and comparatively expensive. Reproductions of these drugs, or biosimilars, are in development and will be approved for use in the United States soon.

House Bill 2705 and Senate Bill 460 create a process by which these biosimilar drugs can be substituted for brand-name biologics at the pharmacy in a way that protects the safety of patients and consumers. We strongly support the ability of a pharmacist to substitute biosimilars for treatments the Federal Food and Drug Administration (FDA) has deemed interchangeable with the original biologic. FDA's scientific review of these complex medicines is essential for patient safety. Additionally, we believe both patients and their prescribers have the right to be notified when a substitution has taken place. These are common sense provisions that allow prescribers, patients and pharmacists to work together to closely treat and manage chronic diseases. Finally, records of theses substitutions should be kept for a reasonable period of time in order to monitor any adverse health reactions.

We strongly encourage you to support this legislation because it strikes the appropriate balance between increasing access to new, innovative treatments, while protecting patient safety in an open and transparent manner. The day is coming when state-of-the-art medications will be available to patients of all socioeconomic backgrounds. This measure ensures that the state of Oregon will be ready for that day.

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February 15, 2013

Representative Mitch Greenlick
Chair
Health Care Committee
900 Court St. NE, H-493
Salem, OR 97301

RE: **HB 2705 – *Support***

Dear Representative Hudson:

I am writing you today on behalf of the Global Healthy Living Foundation (GHLF) and the more than 56,000 members we represent, including approximately 2100 in Oregon, to express our support for HB 365. We represent patients living with chronic illnesses nationwide, from those with osteoporosis to those with chronic mental illness. Many of the patients we represent, including the nearly 30,000 with Rheumatoid Arthritis, take biologics.

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, to patients. As promising as these innovative drugs are, GHLF believes that assuring their safety should be of paramount concern.

We believe that HB 2705 takes positive steps toward updating Florida law to cover biologics and biosimilars in a way that protects patients. Unlike traditional chemical drugs, biologics have very unique, complex structures made from living cells that are not easily understood or replicated. A small change or difference in the biosimilar or biologic has the potential to either help or adversely affect the patient.

There are two provisions in HB 2705 that the 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 and the patient. Second, the pharmacist and prescribing health care provider must also keep a written record of the substitution for at least three years.

For patients, these two provisions are crucial. A determination of product interchangeability could take the decision-making process out of the hands of patients and doctors and put it into

the hands of the pharmacists or insurers through states' automatic substitution policies. We believe that the choice of product should be decided only by patients and physicians, who are ultimately responsible for patient care and have the full spectrum of a patient's medical history. In addition, if it is determined by the doctor and patient that an interchangeable biosimilar can be substituted for a biologic, or is the preferred treatment in a particular case, it is important 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 patients and physicians are in charge of the drugs prescribed, that patient safety is the top priority in the health care process and that medical decisions remain between a doctor and his or her patient. We urge the passage of HB 2705 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

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

February 12, 2013

Rep. Mitch Greenlick
900 Court St NE, H-493
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Rep.MitchGreenlick@state.or.us

Rep. Jim Thompson
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Rep.JimThompson@state.or.us

Rep. Alissa Keny-Guyer
900 Court St NE, H-281
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Rep.AlissaKenyGuyer@state.or.us

Sen. Laurie Monnes Anderson
900 Court St NE, S-413
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Sen.LaurieMonnesAnderson@state.or.us

Sen. Jeff Kruse
900 Court St NE, S-315
Salem, OR 97301
Sen.jeffkruse@state.or.us

RE: Support of House Bill 2705 and Senate Bill 460 – dispensing of interchangeable biosimilars

Dear Representatives Geenlick, Thompson and Keny-Guyer and Senators Monnes Anderson and Kruse:

The Coalition of State Rheumatology Organizations is a national organization composed of 26 state and regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic care and to ensure access to the highest quality care for patients with rheumatologic and musculoskeletal disease. Rheumatologists are entrusted with the safe care of patients with rheumatoid arthritis and other autoimmune diseases that require the careful choice of safe and effective pharmaceutical and biological therapies.

Rheumatologists are keenly aware of the dramatic long term, life changing clinical improvements that biological agents have on some of the most crippling and disabling conditions that affect Americans. These biologic response modifying agents are available for the treatment of rheumatoid arthritis and other autoimmune diseases and have a

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significant impact on improving our patients' quality of life, preventing disability, decreasing morbidity and lowering mortality.

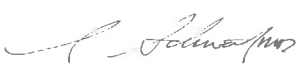
As the Oregon legislature considers H.B. 2705 and S.B. 460, CSRO wishes to convey its support. Importantly, the bill requires that *"[t]he pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product."*

In testimony before the U.S. Food and Drug Administration (FDA) regarding the approval pathway for biosimilars, Dr. Greg Schimizzi, past president of CSRO, recommended that after a biosimiar is approved, physicians should always be involved in decisions regarding their patient's use of a biosimilar. Allowing health systems to impose an automatic substitution for biologics is isn't safe for patients, without having a full understanding of their health history. Specifically, his testimony explained that, *"The physician should always be involved in decisions regarding selection of the biological product a patient receives. Automatic retail substitution of biotech medicines is not appropriate. Currently, all State laws allow the pharmacist to substitute a less expensive generic product for the brand name product, and the determination of the ability to substitute such products is based on the nonproprietary name. In some states, like Pennsylvania, unless the prescriber signs or initials "brand necessary" or "brand medically necessary," the pharmacist is required by law to provide the generic form, unless the patient demands a brand name drug."*

CSRO recognizes that follow-on biologic products are a natural evolution of biotechnology and we welcome the introduction of these medications. However, we must insist that physicians know what medicine their patient receives and that the prescribing physician is notified in a timely manner whenever a patient's biologic medicine is substituted.

Biologics, and soon biosimilars, will continue to be an important treatment option for rheumatology patients. CSRO appreciates that H.B. 2705/S.B. 460 supports safe introduction of biosimilars into the practice of medicine and urges its passage.

Sincerely,



Michael Schweitz, M.D.
President,
Coalition of State Rheumatology Organizations

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Biotechnology Industry Organization

John A. Murphy III, Esq.
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BIOTECHNOLOGY INDUSTRY ORGANIZATION
STATEMENT IN SUPPORT OF OREGON S.B. 460

FEBRUARY 2013

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology trade association. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. One of BIO's core missions is the promotion of a safe, innovative, and competitive market for biologics in the United States. To that end, BIO's member companies have approved five principles related to substitution of biologic medicines. The policies outlined in Senate Bill 460 align with all five of BIO's principles on biologic substitution and we therefore support its passage.

Biologics are very complex medicines. Unlike traditional "small molecule" drugs, biologics are not chemically synthesized but, rather, are manufactured from living cells and tissues using a highly controlled and optimized process. Each resulting biologic therapy is complex and unique, and in many cases cannot be fully characterized by current analytical tools. As a result, even minor differences in manufacturing processes can cause variations in the end product. Consequently, two biologics made using different cell lines and differing manufacturing processes will rarely, if ever, be exactly the same.

Biosimilars are biologic products manufactured with the goal of closely mirroring the composition and treatment profile of an innovator product but are produced without access to the innovator's proprietary manufacturing processes. The production of biosimilar products, therefore, will invariably lead to differences in composition compared to the original innovator product.

Currently, the Federal Food and Drug Administration (the "FDA") is developing guidance regarding the regulatory pathway for the approval of biosimilar and interchangeable biologic products. This approval pathway was established by federal law, and distinguishes clearly between biologic products that are "biosimilar" to an innovator biologic – meaning they are "highly similar" to an innovator product – and biologic products that meet a heightened standard to be deemed "interchangeable."

While FDA's role in the approval of biologic and biosimilar medicines includes the designation of an interchangeable status, the policy on whether one biologic product may be substituted by dispensers when a different biologic product was prescribed is governed by state law. In recognition of this state-level authority over biosimilar and interchangeable biologic medicines, BIO has developed a set of core Principles[1] that we believe should be considered by all states evaluating biologic substitution legislation. We believe that our Principles, if followed, strike the appropriate balance of preserving the physician-patient relationship, protecting patients, maintaining incentives for innovation, and promoting a competitive market for biologic therapies. As drafted, Senate Bill 460 is in-line with BIO's own Principles and we therefore support its passage.

* * * *

[1] *See:* BIO Principles on Patient Safety in the Substitution of Biologic Products

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Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 12, 2013

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Sen. Jeff Kruse
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Sen.jeffkruse@state.or.us

RE: Support of House Bill 2705 and Senate Bill 460 – dispensing of interchangeable biosimilars

Dear Representatives Geenlick, Thompson and Keny-Guyer and Senators Monnes Anderson and Kruse:

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 support of House Bill 2705 and Senate Bill 460 regarding the dispensing of interchangeable biosimilars.

The Alliance has closely followed the development of federal policy related to biosimilars and the safety considerations that should be taken into account as biosimilar versions of existing biologic medicines become a new treatment option for our patients. Importantly, HB 2705/SB 460 addresses key policy issues to ensure patient safety is preserved, including ensuring that

once biosimilars come to market the treating physician is notified if another version of the biologic medicine is automatically substituted for the version prescribed by the doctor. The bill requires that: *"[t]he pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar 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 notification will be very important once biosimilars are available because it will help ensure proper patient care and allow for accurate attribution of any adverse events that may occur. HB 2705/SB 460 requires notification soon after a substitution has been made in order to ensure accurate patient records are maintained.

Advances in medical treatment have transformed the way we fight certain diseases. Biologics, and soon biosimilars, will continue to be an important treatment option for patients. HB 2705/SB 460 recognizes this and puts in place safeguards to allow for the safe introduction of biosimilars into the practice of medicine. The Alliance of Specialty Medicine supports this legislation and hopes it will be passed into law without delay.

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
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions
Society for Excellence in Eyecare

AfPA
Alliance for Patient Access

February 26, 2013

Senator Laurie Monnes Anderson
Chair
Senate Health Care and Human Services Committee
Oregon Senate
900 Court Street, NE, S-413
Salem, OR 97301

Senator Jeff Kruse
Vice Chair
Senate Health Care and Human Services Committee
Oregon Senate
900 Court Street, NE, S-315
Salem, OR 97301

Representative Mitch Greenlick
Chair
House Committee on Health Care
Oregon House of Representatives
900 Court Street, NE, H-493
Salem, OR 97301

Representative Alissa Keny-Guyer
Vice Chair
House Committee on Health Care
Oregon House of Representatives
900 Court Street, NE, H-281
Salem, OR 97301

Representative Jim Thompson
Vice Chair
House Committee on Health Care
Oregon House of Representatives
900 Court Street, NE, H-388
Salem, OR 97301

Re: SB 460/HB 2705 – Creating a Pathway for Access to Safe, Affordable Biosimilars

Dear Senators and Representatives,

On behalf of AfPA's Oregon members and their patients, the Alliance for Patient Access would like to express support for SB 5469 and HB 1528, Creating a Pathway for Access to Safe, Affordable Biosimilars. The legislation as introduced contains several of the principles AfPA member physicians have identified as critical for safe patient access to biosimilar medications.

AfPA is a national network of 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 Biologics Working Group identified key principles that biosimilar substitution must meet to ensure patient safety. These include FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic, that physicians be notified of substitutions and be allowed to specify no substitution and that patients be notified of any substitution. We are pleased that these bills contain provisions to implement these safeguards.

NPBWG is holding a series of working group meetings with physicians representing several specialties that utilize biologic therapies in the treatment of their patients to developing educational resources relating to access, safety and costs. As such, AfPA wants to provide you some additional resources as you consider this legislation. Background materials on biologics can be found at http://www.biologicsdoc.org.

AfPA supports making less costly medicines available to patients and physicians but all efforts must be made to create policies that balance access, safety and cost. SB 460 and HB 2705 attempt to provide this pathway and are worthy of your support.

Sincerely,

Brian Kennedy
Executive Director

Alliance for Patient Access
700 12th Street, NW
Washington, D.C. 20005
www.AllianceforPatientAccess.org

Statement PhRMA

Oregon Senate SB 460:
Providing Important Patient Health & Safety Protections to Biosimilar Substitution

Unlike traditional medicines which are chemically synthesized, biologic medicines are complex and manufactured from living organisms. A biosimilar product is highly similar to, but not the same as, its FDA-licensed reference biological medicines. Recent federal legislative and regulatory activity has created an abbreviated regulatory pathway for the approval of biosimilar products and states are beginning to consider legislation to ensure that patient health and safety is protected when biosimilar interchange occurs.

PhRMA supports applying several important patient health and safety protections to the biosimilar substitution process, which place patient safety first, affirm the decision-making authority of physicians, and require that proper safeguards are in place in case of future need for information on prior substitution of medicines. Specifically, we support the following patient safety protections:

Substitution should only occur when the FDA has designated a biologic product as interchangeable.

PhRMA supports permitting the 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.

Prescribers should be able to prevent substitution.

Any decision to substitute a biosimilar medicine should be made with the oversight and guidance of the treating physician, as the well-being of patients must remain the paramount concern. PhRMA supports permitting a prescriber to prevent substitution by indicating in writing that the pharmacist should not substitute. 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.

A physician should be notified when a substitution occurs.

PhRMA supports requiring that a pharmacist provide notification to the prescriber of the substitution. 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.

Patients should be notified when a substitution occurs.

PhRMA supports requiring that a patient must be informed of a substitution prior to the dispensing of the biosimilar. 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.

Records should be kept of the substitution.

PhRMA supports requiring that records of substitutions be maintained by both the pharmacist and prescriber. This safeguard would be beneficial in the event of an adverse reaction or change in a patient's chronic condition. It is important that physicians and pharmacists have access to historical data in order to best interpret any health changes and respond appropriately.

In all, PhRMA respectfully urges Oregon legislators to put into place several patient protections that recognize the unique attributes of biosimilar products and ensure that patient safety is protected when interchangeable biosimilars become available.

Pharmaceutical Research and Manufacturers of America
950 F Street, NW Suite 300 Washington, DC 20004