Attachment A

Order for Support Testimony
SB 71

April Giles – Colorado Bioscience Association

Laura Rosseisen - Arthritis Foundation

Mark Godfrey – Lilly

Mariah Zebrowski Leach – Global Healthy Living Foundation

Patrick Boyle - ExpressScripts

Bill Ray - Parent

Evan Corazzari – Crohn's & Colitis Foundation of America

Frank Ramirez & Paul Thompson – International Cancer Advocacy Network

Eileen Doherty – CO Gerentological Society

Dr. Mitch Achee - ICAN

Anita Fricklas & Pam Snow – Arthritis patient

Testimony for CO SB 71
House Health, Insurance & Environment Committee
March 5th, 2015
Committee Hearing Room 0107 - basement
1:30 pm

Hearing will start at 1:30 sharp. This is the only billon the calendar.

Rep Ginal will be chairing the hearing.

Rep McCann opening comments
Rep Landgraf comments

Opposition will start testimony.
Expected testimony from:
Charlie – Retail Council, Brad – Independent pharmacists, Travis/Rachel – CVS/Kaiser, Bruce Lott – Mylan. Possibly: Ginny – AHIP, Ben - CHP, Jessica – Anthem, AARP.

Support Testimony:
Please keep all comments under 3 minutes! Less and succinct is better!
Do not repeat what someone else has said.

CBSA – April Giles
- Biologics and the importance of interchangeability
- BIO 5 principles

Arthritis Foundation – Laura Rosseisen
- Why the legislation is important to patients and patient advocates
- Communication is an essential part of the bill

Lilly – Mark Godfrey, Policy
- Therapeutically equivalent is more than insulin
- Insulin numbers in CO
- Part of Coalition and some differences

Global Healthy Living – Mariah Zebrowski Leach
- Why the legislation is important to advocates

Express Scripts – Patrick Boyle
- Who they are and why they support

Bill Ray – Parent of diabetic child
- Parent perspective
- How closely parents follow child's medical record

Crohn's & Colitis Foundation of America - Evan Corazzari, patient advocate

- Importance of complete patient medical record
-

ICAN Panel – Frank Ramirez & Paul Thompson

- Patient story

CO Gerontological Society – Eileen Doherty

- Access to less expensive biologics is important to seniors
- Refut anything that AARP says

Dr. Mitch Achee – ICAN

- physician perspective
- patient

Arthritis Foundation Patient – Anita Fricklas & Pam Snow

- Patient testimony
- Summary
  - Legislation offers patients access to lower cost medications
  - Pharmacists can not substitute without legislation
  - For my safety and the safety of all other patients on biologics, the information must be sent from the pharmacist to my doctor.
  - I want my doctor to know what drug I am on.

People in audience available to testify:

Gino Grampp – Amgen scientist
Kiki Traylor - Amgen

Questions for Biosimilars Committee Hearing

How is the group that is opposing the bill directly affected by it?
Things addressed in bill:

1. Definitions of biologics and of interchangeable biological products.
2. Pharmacists can substitute FDA-designated interchangeable biosimilars
3. Physicians can designate Dispense as Written (DAW) – same as generics
4. Patient is notified both orally and in writing of substitution on label – same as generics
5. Pharmacist is required to communicate substitution information to prescribing physician within a reasonable time and with any prevailing means.
6. Pharmacist must retain substitution record for 2 years – same as generics

Physician/Pharmacist Communication

If the patient, who is fighting for their life and the one taking these medications want their doctor to know what drug they are on, who are any of us to say that is not a valid argument.

Clarify with each person opposing:

a. Do you support the bill?
b. Do you oppose patient and physician/pharmacist communication?
c. How does physician/pharmacist communication directly impact you?

For Pharmacist

- Why are you opposed to including the information in the physician patient record?
- We understand that pharmacists as a whole would like to be more integrated into the health care team. Is that true?
    - Why are you opposing this opportunity work directly with physicians in managing some of the sickest patients?
- Do you communicate with physicians now? How often? In what circumstance?
- Do the pharmacies that you represent dispense biologic drugs? How often?
- If you profit more from dispensing generic drugs, we can assume you will make more dispensing biosimilars. Why would a simple fax, email, call or automatically generated electronic message prevent you from switching products?
- Most biologics are dispensed by physicians in their clinics and very few will come through the retail pharmacy setting – estimated less than **4 a week** for the average pharmacy. Why are you opposing?
- Even with insulin prescriptions, at one per pharmacy per day, so a total of around 10 communications a week, does this burden out weigh patient safety?

For CVS:

- The largest PBM, Express Scripts is supporting. Why are you opposing?
- If a physician is treating a patient with an adverse reaction, how does he/she contact the mail order pharmacy to determine which product the patient received?
- Why are you opposed to physician/pharmacist communication?
- Do you currently contact the prescribing physician's office for any reason? How often?
- I heard CVS went neutral on the same language in PA. Why not CO?

For Mylan:

- We heard the association you belong and the vast majority of generic companies support this legislation including communication, why are you opposed?
- Why do you think that pharmacist / physician communication after dispensing of a drug is a barrier?
- We agree that for a biosimilar to reach an interchangeable designation it will go through extensive clinical studies and will be safe. If brand name drugs can cause adverse events, why would we think that a biosimilar would cause less side effects than a brand name drug? Why shouldn't a doctor have the substitution information?
- What is the harm in having the pharmacist communicate the substitution information to the prescribing physician?
- Why would you as a MANUFACTURER opposed to physician/pharmacist communication? From my understanding, any perceived burden would be between the pharmacist and the physician, not the manufacturer.

For Insurance Companies/Health Plans

- This legislation does not affect your company's ability to manage drug benefits through reimbursement, formulary or cost-sharing design. Why are you opposed to this legislation?
- Why do you care about physician/pharmacist communication? How does it affect your business?
- How does this affect you if the communication is between the physician and the pharmacist?
- Prior Authorization (PA) is a common practice for insurance companies now for some drugs. Do you require physicians to fill out paperwork to seek a Prior Authorization before prescribing some drugs?
    - If so, why are you comfortable requiring the physician to fill out paperwork to get approval prior to a drug being dispensed, but opposed to physician/pharmacist communication AFTER the drug has been dispensed?
- Is there financial incentive for you to eliminate physician/pharmacist communication?

AARP

- Why would your group ever be opposed to any legislation that will allow substitution of a safe and less expensive biosimilar for your patients?

For any opposing doctor

- What is your specialty and do you prescribe these medicines? If so, what is standard practice now for having dispensed product information in the patient record? So, why are you opposed to having the substitution information in the patient record?
- In the current health care environment, why do you not believe having this information

in the patient record is a good thing?

- Why are you neutral or opposed to physician/pharmacist communication when there are so many specialty (doctors that use biologic drugs) national physician groups that support such communication?

Therapeutically equivalent language:

- What is your issue with insulin?
- Does your company make insulin products or are they scheduled to make a biosimilar insulin?
- Why should we not include all biologics, when they are used for chronic illnesses for our sickest patients

Organizations in Support of SB 71

Pharmacist Substitute Interchangeable Biological Drug

AbbVie
Actavis
Alliance for Patient Access
Alzheimer's Association - Colorado
Amgen
Arthritis Foundation - Colorado
AstraZeneca
Biogen Idec
Biotechnology Industry Organization
Boehringer Ingelheim
Brian Injury Alliance of Colorado
Bristol-Myers Squibb
Coalition of Hematology and Oncology Practices
Colorado BioScience Association
Colorado Dermatological Society
Colorado Gerontological Society
Colorado Medical Society
Colorado Rheumatology Alliance
Colorado State Grange
Crohn's and Colitis Foundation of America – Rocky Mountain
Eli Lilly
EMD Serono
Express Scripts
Federations of Families
Genentech
Generic Pharmaceutical Association
GlaxoSmithKline
Global Healthy Living Foundation
Hospira
International Cancer Advocacy Network
Johnson & Johnson
Merck & Co., Inc.
Metro Denver Oncology Society
National Kidney Foundation
Novartis
Novo Nordisk
Pharmaceutical Research and Manufactures of America
Rocky Mountain Human Services
Rocky Mountain Stroke Center
Sandoz
Sanofi
Takeda
TEVA
UCB
Women Against Prostate Cancer

Update 2/19/2015

We are UNITED In our Position on Prescriber Communication:

"In any instance of an interchangeable biologic product substitution for a biologic medicine, prescriber communication is essential."

We support a prescriber communication requirement because:

- Interchangeable biologic products, like biologics, will be used to treat complex, rare, or chronic medical conditions.
- The prescriber must know of an interchangeable biologic product substitution in order to appropriately assess the patient's experience and further treatment options.
- Interchangeable biologic products will require a difficult or unusual process of delivery to the patient in preparation for infusion or injection. Handling, storage, inventory or distribution of the drug is not typically available at retail pharmacies.
- Interchangeable biologic products will require significantly enhanced patient education, management or support, beyond those required for traditional dispensing at a community or retail pharmacy, before and/or after administration of the drug.
- Interchangeable biologic products are complex medications derived from living sources – not simple generics produced through chemical processes.
- Prescribers and pharmacists must work collaboratively to ensure the protection of the patient!

ARTHRITIS FOUNDATION®

www.arthritis.org

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AfPA
Alliance for Patient Access

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GLOBAL HEALTHY LIVING FOUNDATION

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LUPUS and ALLIED DISEASES Association, Inc.

COLON CANCER ALLIANCE

National Kidney Foundation®

NHMA
National Hispanic Medical Association

American Association of Neurological Surgeons

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

Kidney Cancer Association

March 3, 2015

Support SB 71

Pharmacist Substitute Interchangeable Biological Drug

Help remove barriers to lower cost drugs and ensure patient safety.

What the bill does:

- SB 71 will update the Colorado Pharmacy Practice Act.
- Allows Colorado pharmacists the ability to dispense safe and less expensive biologic medications to patients, by allowing substitution of an interchangeable biologic for a prescribed brand name biologic.
- Current Colorado law has no clear pathway for substitution of biologic drug products. Therefore, pharmacists will be required to obtain advanced approval from the prescriber before they are allowed to substitute an interchangeable biologic for a brand name biologic. **SB 71 will remove this requirement.**
- The current pharmacy practice act has specific rules that must be followed to ensure safe generic substitution. Passing SB 71 would update these laws to include a similar process to ensure safe biologic substitution. Biosimilars are expected on the market in 2015.
- Assures only FDA approved "interchangeable" biologic products may be substituted without prior prescriber consent. This is similar to substitution requirements of generic substitution.
- Physicians will retain the authority to use Dispense as Written or DAW. This is identical to the authority they have with generic substitution.
- Ensures patients will be notified of the substitution, in the same way they are notified about a generic substitution.
- Because biologic products differ from generics in complexity and are not identical chemical products, SB 71 ensures there will be **transparent communication** between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. This information would be relayed after the prescription is dispensed to alleviate the need for waiting for pre-approval, as current law requires.

Why support SB 71:

- SB 71 recognizes the growing use of interoperable electronic health records and electronic prescribing records, allowing such systems to be used by a patient's health care team to communicate regarding a patient's medication history.
- **SB 71 will establish a clear substitution process** by allowing pharmacists to dispense an FDA approved interchangeable biologic without first seeking approval.
- SB 71 will increase access to lower cost drugs for patients. Biosimilars are forecast to lead to a $44.2 billion reduction in direct spending on brand-name biologics from 2014 to 2024, according to the Rand Corporation.

Many provider and patient groups have studied the issue of biologics and interchangeable biologic substitution and agree with the principles for safe substitution included in SB 71.

Vote YES on SB 71!

For further information, please contact Brock Herzberg 303-945-1076

Pharmacist Substitution of Interchangeable Biologics

Sounds complicated. What you *need* to know!

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

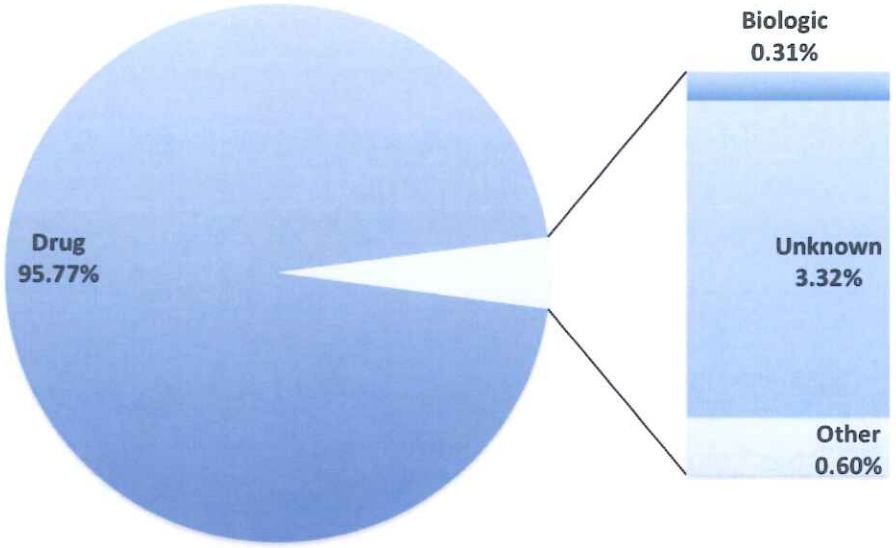
- The prescribing physician retains authority to use Dispense as Written, DAW. Identical to generic substitution.

- The patient is notified both orally and in writing of the substitution, the same as with generic substitution.

- Ensures communication between physician and pharmacist on what product is dispensed, for complete patient record.

- A record of the substitution is kept by the pharmacy for the same period as generic substitution records.

Colorado: Biologics Represented 0.31% of Prescriptions Dispensed by Retail Pharmacies in 2013



Rxs Filled	In 2013	Per month (average)	Per week (average)
Drugs	52,127,505	4,343,959	1,002,452
Biologics	168,747	14,062	3,245

There are 844 retail pharmacies in Colorado. On average a retail pharmacy dispenses **3.84** biologic prescriptions per week.

Sources: MarketScan, July 2014; Data for Jan 2013-Dec 2013 **Other** includes "Unapproved (Not Included)" "Others", "OTC, and vaccines; insulin is categorized as a drug. Vaccines are excluded from the biologics category. Data extrapolated to map to full universe using Kaiser State Health Facts. Retail may include specialty pharmacy data. Retail pharmacy count is from NPMS 2014, SK&A, A Cegedim Company

List of Biologics Approved via 505
1997 - Present

Active Ingredient	Approval Year	Therapeutic Area
teduglutide (rDNA origin)	2012	Gastrointestinal Disorders
taliglucerase alfa	2012	Metabolic Diseases
velaglucerase alfa	2010	Metabolic Diseases
liraglutide (rDNA origin)	2010	Endocrine Disorders
somatropin (rDNA origin)	2007	Endocrine Disorders
somatropin (rDNA origin)	2006	Endocrine Disorders
mecasermin rinfabate (rDNA origin)	2005	Endocrine Disorders
hyaluronidase human	2005	Pharmaceutical Aids
hyaluronidase	2005	Pharmaceutical Aids
insulin detemir	2005	Endocrine Disorders
mecasermin (rDNA origin)	2005	Endocrine Disorders
insulin detemir (rDNA origin)	2005	Endocrine Disorders
hyaluronidase	2004	Pharmaceutical Aids
lutropin alfa	2004	Endocrine Disorders
follitropin alfa	2004	Disorders of Sexual Function, Breast and Reproduction
hyaluronidase	2004	Pharmaceutical Aids
insulin glulisine (rDNA origin)	2004	Endocrine Disorders
follitropin alfa	2004	Disorders of Sexual Function, Breast and Reproduction
follitropin beta	2004	Disorders of Sexual Function, Breast and Reproduction
somatropin (rDNA origin)	2003	Gastrointestinal Disorders
pegvisomant	2003	Endocrine Disorders
teriparatide (rDNA origin)	2002	Musculoskeletal and Connective Tissue Disorders
nesiritide	2001	Cardiovascular Disorders
choriogonadotropin alfa	2000	Disorders of Sexual Function, Breast and Reproduction
somatropin (rDNA origin)	2000	Endocrine Disorders
insulin aspart (rDNA origin)	2000	Endocrine Disorders
gemtuzumab ozogamicin	2000	Cancer
insulin glargine (rDNA)	2000	Endocrine Disorders
insulin lispro (rDNA origin) protamine; insulin lispro (rDNA origin)	1999	Endocrine Disorders
insulin lispro (rDNA origin) protamine; insulin lispro (rDNA origin)	1999	Endocrine Disorders
thyrotopin alfa	1998	Cancer
rDNA Origin	1998	Endocrine Disorders
glucagon (rDNA origin)	1998	Endocrine Disorders
lepirudin (rDNA)	1998	Hematologic Diseases
follitropin alfa/beta	1997	Disorders of Sexual Function, Breast and Reproduction

September 2014 CA30140

Approved for external use

Note: all drug and biological approvals are publically available at Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/)

Colorado Pharmacy/Prescription Drug Information

Calculations to determine the estimates below were conducted using IMS Health claims data, a report from the Kaiser Family Foundation and internal mathematical extrapolation methods based on actual claims data. The numbers below are *estimates* based on these calculations.

Estimated Colorado Prescriptions Dispensed at Retail Pharmacies for Total Insulin Product Market, 2012[1]

Insulin Product Prescriptions Dispensed by Location	2012
Retail Pharmacies	217,732
All Other Pharmacies	43,051
Total	260,783

Total Number of Retail Prescription Drugs Filled at Pharmacies, 2011[2]

STATE	Total Retail Rx Drugs
Colorado	49,808,764

Based on the estimated data above, the total number of prescriptions for insulin products at Colorado retail pharmacies represents approximately **.4%** of the total of all prescriptions dispensed at retail pharmacies.

Number of Retail Pharmacies[3]

STATE	Total Number of Active Retail Pharmacies
Colorado	793

Based on the estimated data above, on average, a retail pharmacy in Colorado dispenses approximately one insulin product prescription per day.[4]

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[1] Estimates calculated using IMS Health prescription data and mathematical extrapolation and calculations based on actual internal claims data.

[2] Total Number of Retail Prescription Drugs Filled at Retail Pharmacies. Kaiser Family Foundation. 2011. IMS Health. Accessed January 23, 2014. Available: http://kff.org/other/state-indicator/total-retail-rx-drugs/?state=CO.

[3] National Council for Prescription Drug Programs. List of Pharmacies. Accessed January 22, 2014.

[4] Calculation equals slightly less than one prescription per day: Total estimated number of insulin prescriptions dispensed in retail pharmacies (217,732) divided by the total number of Colorado retail pharmacies (793). The total (275) was then divided by 365 days per year.

January 28th 2015

Senator Kevin Lundberg
Chair, Health & Human Services
Colorado State Capitol
200 East Colfax Ave
Denver, CO 80203

Dear Mr. Lundberg and Committee Leadership Members:

On behalf of all women and men who have been adversely affected by prostate cancer, Women Against Prostate Cancer (WAPC) respectfully urges the Colorado Senate Health & Human Services Committee to pass SB 71, which will mandate communication between prescribers and pharmacists regarding biosimilars.

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

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

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

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

We hope that you and your members of the Colorado Senate Health and Human Services Committee strongly consider passing SB 71 with prescriber-pharmacist communication to ensure patient safety for not only the patients living with prostate cancer but the women who are adversely affected as well.

Sincerely,

Torrey Ford Shallcross
VP, External Affairs: Women Against Prostate Cancer

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ican international cancer advocacy network

the virtual lifeline for proactive cancer patients

January 26, 2015

Chairman Kevin Lundberg

Vice-Chair Larry Crowder

Senator Irene Aguilar

Senator Beth Martinez Humenik

Senator Linda Newell

Colorado State Capitol

200 East Colfax Avenue

Senate, Room 346

Denver, CO 80203

Dear Chairman Lundberg, Vice-Chair Crowder, and Senators Aguilar, Humenik, and Newell,

We are in full support of CO SB 71 which provides the key component of prescriber communication which you will be hearing on Thursday, January 29th.

We represent the Colorado cancer patients working with ICAN, International Cancer Advocacy Network, www.askican.org, a charitable organization serving Stage IV cancer patients throughout the U.S. and 53 countries. ICAN has been following the biosimilars issue from day one.

If retail pharmacists do not inform the prescribing physician as to what drug the patient has been put on, it will lead to a very dangerous situation for Colorado patients not only fighting cancer but who are battling any chronic or lethal disease where a biosimilar may be prescribed. The pharmacist and physician must be on the same page so that when a patient reports side effects to his or her doctor, those side effects can be charted and dealt with effectively. A biosimilar drug may well have completely unexpected side effects, so to pull the rug out from under the physician and not include a prescriber communication provision would do terrible damage to Colorado patients and would do lasting damage to their relationships with physicians and pharmacies across the state.

We hope that you will enthusiastically support SB 71 and make sure that prescriber communication is a central part of Colorado's biosimilar legislation.

With kind regards and many thanks for your consideration on Thursday the 29th,

Marcia K. Horn, J.D., President and CEO

Robert H. Tamis, M.D., Chairman, Physicians Advisory Council

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January 27, 2015

Senator Kevin Lundberg
Chair, Health & Human Services
200 East Colfax Ave.
Denver, Co 80203

Senator Larry Crowder
Vice-Chair, Health & Human Services
200 East Colfax Ave.
Denver, Co 80203

RE: **SB 71 – *Support***

Dear Chairmen Lundberg and Vice-Chair Crowder:

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 75,000 chronically ill, several of which are your fellow Colorado 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 SB 71.

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 and transparency in the substitution process should be of paramount concern.

We believe that SB 71 takes positive steps toward updating Colorado law to cover biologics and biosimilars in a way that protects patients. Unlike traditional chemical drugs, biologics are very 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 either help or adversely impact the patient.

There are two provisions in SB 71 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 and the purchaser or patient within a reasonable time. Second, the pharmacist must keep a written record of the substitution for no less than two 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 insurers and prescription benefit managers through states' automatic substitution policies. We believe that the choice of therapy 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 physicians are in charge of the drugs prescribed and that patients are aware of what drugs they are taking. Patients and physicians are the primary individuals that 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 his or her patient. We urge the passage of SB 71 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, Senate Health & Human Services Committee
Members, House Public Health Care & Human Services Committee

AfPA Alliance for Patient Access | National Physicians Biologics Working Group

January 27, 2015

The Honorable Kevin Lundberg
Chairman
Senate Health & Human Services Committee
Colorado State Capitol
200 East Colfax Ave
Denver, CO 80203

RE: Support for SB 15-071 – Concerning the Ability of a Pharmacist to Substitute an Interchangeable Biological Product for a Prescribed Biological Product when Certain Conditions are Met

Dear Chairman Lundberg:

On behalf of our Colorado State members and their patients, the Alliance for Patient Access would like to express support for SB 15-071, allowing or the substitution of biological medicines when certain conditions are met. The legislation contains the patient safety principles that AfPA member physicians have identified as critical for safe access to biosimilar medications and is worthy of your support

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 NPBWG 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 pharmacists communicate to the prescribing physician any substitutions with in a reasonable timeframe, that physicians be allowed to specify no substitution, and that patients be notified of any substitution. This communication provision will help ensure a complete medical record and help ensure the patient safety in the case of an adverse event. AfPA is pleased that SB 15-071 contains provisions to implement these safeguards, most importantly physician and patient communication of substitution

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 15-071 attempts to provide this pathway for biosimilar medicines while maintain notification safeguards and is worthy of your support in its current form.

Sincerely,

Brian Kennedy
Executive Director

Cc: Members, Senate Health and Human Services Committee
Leadership, Colorado Senate
Leadership, Colorado House of Representatives
Sponsors, SB 15-071

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National
Kidney
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www.kidney.org

January 28, 2015

Senator Kevin Lundberg
Chair, Health & Human Services
Colorado State Capitol
200 East Colfax Ave
Denver, CO 80203

Dear Senator Lundberg,

The National Kidney Foundation (NKF) supports Senate Bill (SB) 71 to regulate the substitution of biosimilar biological products. NKF is America's largest and oldest health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We also provide professional and patient education, patient support services, and community health programs. We work with volunteers to offer the scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. NKF has local division and affiliate offices serving our constituents in all 50 states, including a division office located in Denver.

Given the lack of guidance from the Food and Drug Administration (FDA) on the distribution and tracking of biosimilar substitutions, NKF supports legislation to permit automatic substitution of biosimilar products only when they are classified as interchangeable by the FDA and when the substituted product is less costly for the patient. In addition, NKF supports the provisions SB 71 that protects the patient and physician decision making relationship by requiring notification to the patient of the substitution and allowing physicians to refuse substitution by indicating it on the prescription. Finally, we endorse the record-keeping requirement in this legislation. Identifying the specific product that a particular patient receives is crucial in the event that said patient has a negative reaction to the medicine or there is a quality control problem with the product.

National Kidney Foundation
30 E. 33rd Street
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www.kidney.org

With biosimilars, we know that individual patients can respond differently to even seemingly insignificant changes in drug formulation, manufacturing process, packaging, storage, or handling. These unintended consequences could be life threatening. Since biosimilars are produced without access to the innovator's proprietary manufacturing processes, differences in composition compared to the original innovator product are likely to occur.

A decade ago the FDA collected information on 82 patients worldwide who had developed pure red-cell aplasia as a result of changes in the manufacture and/or packaging of a reference biological product used by kidney patients. Most recently a synthetic erythropoietin stimulating agent – peginesatide was approved by the FDA in March of 2012 and nearly a year later pulled from the market due to an allergic reaction not seen in patients during the clinical trial. Because of those experiences, the kidney community has been especially cautious regarding the possibility of substituting or alternating between reference drugs and biosimilars or between biosimilars without physician and patient notification and absent any record keeping as to which biological product the patient received.

We respectfully encourage you to sign SB 71 into law. If you have any questions please contact me at tonya.saffer@kidney.org or at 202.244.7900 ext. 26

Sincerely,

Tonya L. Saffer

Tonya L. Saffer, MPH
Senior Health Policy Director

Cancer Action Network™ American Cancer Society

ACS CAN Principles for Biosimilars

ACS CAN Statement on Biosimilars

The development of biologic drugs has provided cancer patients and their physicians with access to improved therapeutic options. As generics have done for small-molecule drugs, interchangeable biosimilars have the potential to increase price competition on older biologic drugs, and result in lower cost burdens for cancer patients. As biosimilar policies are developed, they must focus on ensuring the safety and efficacy of all biologic drugs, whether innovator or biosimilar, and policies must also ensure access and affordability of biosimilars for cancer patients. These dual goals will be accomplished by a combination of federal and state policies. Federal policies will primarily be responsible for safety, efficacy, and interchangeability, while state laws will primarily affect access and affordability.

Consent: Physicians should have the ability to withhold or provide consent for biosimilar substitution. Each state varies in how this is done, but physicians can typically mark "Do not substitute" or "Medically necessary" to prevent substitution or conversely "Substitution allowed" to grant consent for substitution. The required consent for biosimilar substitution should be consistent between small molecule drugs and biologics. Patient consent is typically given at the time of dispensing and should mirror state patient consent requirements for generic small molecule drugs.

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.

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." 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.

STATEMENT

PhRMA
RESEARCH PROGRESS HOPE

Statement in Support of Colorado Senate Bill Number 71
January 29, 2015

Position: PhRMA supports Colorado Senate Bill 71 which would amend the law in Colorado to reflect recent changes to federal law that created an abbreviated pathway for FDA approval of biosimilar products. SB 71 will put into place several patient protections that recognize the unique attributes of biosimilar products. Because patient safety is paramount, we are pleased that SB 71 will ensure that patient safety is protected when interchangeable biosimilars become available.

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.

PhRMA represents innovative biopharmaceutical research and discovery companies devoted to advancing public policies in the U.S. and around the world that support innovative medical research, yield progress for patients today and provide hope for the treatments and cures of tomorrow. PhRMA companies spent an estimated $51 billion in 2013 to discover and develop new medicines.

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. Recent 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. SB 71 amends Colorado 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.

SB 71 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. SB 71 permits a prescriber to prevent substitution by expressly prohibiting product selection. 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.

SB 71 requires that a pharmacist provide notification to the prescriber of the substitution when dispensing an interchangeable biosimilar. 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 the pharmacy to keep records of the substitution.

Finally, SB 71 requires that records of substitutions be maintained by both the pharmacist and prescriber as specified by current law. 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 to best interpret any health changes and respond appropriately.

For these reasons, PhRMA respectfully urges Colorado legislators to support SB 71.

Senator Lambert:

Last week I testified FOR the passage of this bill on behalf of stroke survivors who inevitably end up with physical problems that range from physical to cognitive to aphasia, putting them at risk for all sorts of miscommunication and confusion. After stroke, chronic care is almost always a condition of life.

If I were to testify personally, my experience with pharmacists ran afoul when my first child developed epilepsy. The doc prescribed a brand name but did not note that no substitutions were to be made. Naturally the generic was less expensive and that's the direction we followed since it was offered to us by the pharmacists. As you might guess, the generic allowed breakthroughs and we worked with the doctor to understand why. It was a while before he followed it back to the generic (since the meds were taken as prescribed) and there we found our culprit. All is well now with this child and now I have another with epilepsy and a grandson as well. They also have to have the brand name for their type of epilepsy.

I'm not blaming anyone – that was the rule of the land at the time. BUT if there had been communication, my children would not have suffered embarrassment, school days missed, and a car accident.

Communication is a huge deal – everywhere –and if you should ever encounter an episode of miscommunication, you understand. In these days of electronic communication it should be simple. Eventually the rural pharmacies will get there too.

Please support SB71 as originally written.

Thank you.

Yvonne Baca
Patient Advocate

Representative Mitsch-Bush,

Attached please find a comment letter concerning Senate bill 71 which addresses the substitution of biologics and biosimilars. **We kindly request that you support this bill.** We believe that SB 71 takes positive steps toward updating Colorado law to cover biologics and biosimilars in a way that protects patients. There are two fundamental patient protection provisions in SB 71 that GHLF believes are key. First, the bill requires a pharmacist dispensing an interchangeable biosimilar to notify the prescribing physician and the purchaser or patient within a reasonable time. Second, the pharmacist must keep a written record of the substitution for no less than two years. Should a patient experience an adverse event from these immunosuppressant therapies, it is critical that their physician know exactly what drug they have been given.

We would welcome the opportunity to work with members of the Colorado House of Representatives and share the perspective of the chronically ill patients that we represent in Colorado, many of whom rely on biologics to live productive lives. 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.

Thank you for your time and attention to this extremely important matter.

All the best,

Stephen
Global Healthy Living Foundation

I represent ROCKY MOUNTAIN STROKE CENTER, ITS SURVIVORS AND THEIR FAMILIES. I ALSO REPRESENT MYSELF ON BEHALF OF TWO OF MY CHILDREN AND A GRANDSON WHO TAKE SEIZURE DISORDER MEDS.

In talking with stroke survivors and their families, I find that they don't always understand their meds but take them because the doctor said so. Because they are suspect of any change in routine, they are not inclined to trust their local pharmacist in the same way. Stroke almost leaves a cognitive impact, big or small, and so their hesitancy. They are so afraid of setbacks.

Two of my four children have tonic/clonic epilepsy (fall down and lose consciousness). My daughter was prescribed the brand name and did well. Then the pharmacist offered the change to generics and touted the same results for less money. So we did it. But it didn't work. Several seizures later, working with the doctor, the problem was finally resolved. Generics simply did not work the same. Back to the name brand and all was well. Both my son and grandson were made aware of this issue and watch it carefully.

I am a believer in communication (for all for whatever reason) and treat doctors as practically inviolable. Transparency is a huge part of that communication. At stroke, in the office and on the street, we promote talking to your doctor about your particular set of circumstances. We find that no two strokes are alike and absolutely are more than a limp! At the Center we do not pretend to know anything about meds. Our mission is to help stroke survivors and their families face the rest of their lives with a variety of therapies in small groups, to include socialization. Because young stroke is so much more prevalent today, isolation is a much bigger problem. They learn to know each other, take comfort in knowing they are not the only one with stroke, and eventually get comfort and hope for their own situations.

PLEASE do not amend SB 71, keep the communication in place, and hopefully it will become more efficient with the use of electronics. That world is here; let's make the best of it.

Yvonne Baca

Representative -

Attached please find a comment letter concerning Senate bill 71 which addresses the substitution of biologics and biosimilars. **We kindly request that you support this bill.**

We believe that SB 71 takes positive steps toward updating Colorado law to cover biologics and biosimilars in a way that protects patients. There are two fundamental patient protection provisions in SB 71 that GHLF believes are key. First, the bill requires a pharmacist dispensing an interchangeable biosimilar to notify the prescribing physician and the purchaser or patient within a reasonable time. Second, the pharmacist must keep a written record of the substitution for no less than two years.

We would welcome the opportunity to work with your office to share the perspective of the chronically ill patients that we represent in Colorado, many of whom rely on biologics to live productive lives. To that end, we invite you to view a recent CBS News segment our organization helped coordinate to share the story of one of our patient advocates and Louisville, Colorado residents, Mariah Leach: http://denver.cbslocal.com/2015/02/09/state-lawmakers-weigh-issue-of-biosimilars-new-life-saving-drugs/

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.

Thank you for your time and attention to this extremely important matter.

All the best,

Stephen
Global Healthy Living Foundation

Dear Representative Brown,

I wanted to thank you for meeting with me yesterday about SB71 - the biosimilars bill that will be heard in Committee next Thursday, March 5th. I truly appreciate you taking the time to consider the patient's perspective on this issue. As someone living with rheumatoid arthritis, a condition I will need to treat my entire life, I am very excited about the promise that biosimilars hold. However, I think this promise will be jeopardized if we do not pass legislation to create an accurate and transparent medical record for patients and their doctors. This is why the notification requirement of SB71 is so important.

I will be offering my testimony at the hearing next week, but if you have any other questions I can help with before then please do not hesitate to let me know.

Thank you again for your time. Have a great afternoon!

~Mariah Leach~

Dear Representative Landgraf,

I wanted to thank you for taking a few minutes to chat with me about SB71 last week. I really appreciate you sponsoring this bill and taking the time to consider the patient's perspective.

I look forward to testifying at the hearing on Thursday. If there's anything else I can do to help before then, please don't hesitate to let me know.

~Mariah Leach~

Dear Representative Ginal,

My name is Mariah Leach and I am a patient advocate with the Global Healthy Living Foundation's 50 State Network. I was diagnosed with rheumatoid arthritis at the age of 25 and have been living with this disease for the last six years. As someone who depends on biologic medications to function, I wanted to offer you my perspective on SB71, the biosimilars bill which will be considered at the hearing on Thursday afternoon.

Without biologic medications, I never would have gotten my condition well enough under control to graduate from law school and start my family. But as wonderful as biologic medications are, they can also be quite expensive. For that reason I am very excited about the promise that biosimilars hold - both for generating more options and providing less expensive treatment options.

However, I think this promise will be jeopardized if we do not pass legislation to create an accurate and transparent medical record for patients and their doctors. If a pharmacist substitutes a biosimilar for the biologic my doctor prescribed, I want to know about it and I want my doctor to know about it also. That is why the notification requirement if SB71 is so important.

I ask that you consider passing SB71 with no amendments. I will be offering my testimony at the hearing on Thursday, but if you have any other questions I can help with before then please do not hesitate to let me know.

Thank you again for your time. Have a great afternoon!

~Mariah Leach~

Dear Daneya,

It is extremely important for you to vote yes on SB71 with no amendments. This bill meets with important criteria for our patient population and should not be changed in any way. Thank you for sponsoring the bill and for continuing to support it.

Sincerely,

Anita Fricklas
Arthritis Foundation Ambassador

Representative McCann -

It is imperative that you vote yes on SB71 so that patients and their doctors can know when their drugs are being substituted. Biologics and biosimilars are not the same so it is important that the knowledge of substitution is made clear to the patient. The patient should be the one to decide if the substitution is okay with them and with their doctors. In order for you to be certain that the patient is protected, you must vote YES on SB71. Thank you.

Anita Fricklas
Arthritis Foundation Ambassador