Summary of Verbal Comments Against:

Greg Hoke – Biotechnology Innovation Organization

Want 5 things in relation to biologic substitutions

1. FDA Interchangeable Biologic products only allowed for direct substitution
2. Preserve the right of prescribers to specify that a product must be dispensed as written or do not substitute for the product.
3. Patient must be notified of the product they receive
4. Records must be kept for some period of time
5. Communication to prescriber which can be met by various methods such as HB1204 from the last session.

* The Board would note that #'s 1-4 are specifically outlined in this proposed language and example exemptions for #5 would be met 100% of the time by Board of Pharmacy estimates.

Scott Smith – Arkansas Medical Society

Wanted a requirement for notification within 5 days of a biologic substitution which could have a sunset clause for August 1, 2019.

*The Board would note that others wanting a passive notification that would be met in the filling process of any prescription would be against any type of sunset clauses in our proposed regulations.

Stephen Marmaras – Global Healthy Living Foundation

Communication to prescribers should be included but supportive of (Dispense as Written) DAW language to preserve the rights of prescribers to designate that a product cannot be substituted and fully supports the advent of biologic products.

Cummins Lue – Rheumatologist, Arkansas Rheumatology Association and Arthritis Foundation

Spoke on differences between small and large molecules. Opposed to HB1204 and these proposed regulation changes because he wants ACTIVE communication requirement back to prescribers. Acknowledged that biosimilars are different just like innovator products are different batch to batch. When asked he stated that he had not seen any adverse issues in his own funded biologic research from biosimilars when compared to innovator products.

Summary of Verbal Comments For:

Scott Pace – Arkansas Pharmacists Association

Read his letter offering comments from the Arkansas Pharmacists Association into the record. In his statement he pointed out that the FDA has stated specifically that when considering approval of any interchangeable product that there "should be no additional risk to a patient for switching between the innovator and the interchangeable products vs the switching from one batch to another of the innovator products." Dr. Pace also pointed out that no group had requested notification of changes of lot or batch designation on innovator products even though they vary for every batch.

ARKANSAS STATE BOARD OF PHARMACY
PUBLIC HEARING – REGULATION CHANGES
REGULATION 7

Speakers

Printed name (Individual)	Printed Name (Who you represent)	For	Against
GREG HOKE	BIO		✓
Scott Smith	Arkansas Medical Society		✓
Stephen Marmaras	Global Healthy Living Foundation		✓
Scott Pace	ARK. Pharmacist Association	✓	
Cummins Lee	Arkansas Rheumatology Association		✓

Arkansas Pharmacists Association

September 25, 2017

John Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy
322 S. Main #600
Little Rock, AR 72201

Re: Proposed Regulation Changes

Dear Dr. Kirtley,

The Arkansas Pharmacists Association would like to submit the following comments regarding the proposed regulation changes that will be reviewed by the Board Members during your September 2017 Board Meeting.

Regulation 9

The APA supports the changes to Regulation 09-00-0002 regarding medication administration. The changes eliminate language from 1997 and make the Board's regulations consistent with the language of Act 284 of 2017 passed earlier this year.

Additionally, the APA supports deregulating the requirement that any CPR course must be accredited by the American Heart Association, thereby allowing any CPR provider's course to count towards a pharmacist's CPR requirement.

Regulation 7

The APA supports the definitions that are proposed in Regulation 7. These definitions are consistent with, and may be identical to, the definitions from the Food and Drug Administration, thereby ensuring consistent application from the Federal to the State level.

As BIO, the trade association that represents the biologic manufacturers, noted in their letter to the Arkansas State Board of Pharmacy (obtained through FOI) "the standard for interchangeability in the law is stringent and consistent with the FDA's role in protecting patient safety." BIO goes further to correctly state the heighted scrutiny that interchangeable biosimilars much achieve before receiving interchangeable status from the FDA by stating "if a patient switches between two products, the FDA must determine that there is ***no (emphasis added)*** additional risk in such switching compared to using the reference product alone."

Simply put, for the FDA to approve a product as an interchangeable biosimilar, the risk posed to the patient between switching between the originator product and the interchangeable biosimilar must not be greater than the risk posed to a patient by continuing the originator product, which could include changing between various lots of the originator. This will necessarily require interchangeable biosimilar manufacturers to perform switching studies to obtain an approval for an interchangeable biosimilar.

417 South Victory Street | Little Rock, AR 72201-2923 | 501-372-5250 | Fax-501-372-0546 | www.arrx.org

Arkansas Pharmacists Association

Absent these studies, the FDA would never allow a non-single dose biosimilar to ever obtain interchangeable status.

While we do not always agree with Congress and the FDA, the agency is implementing a solid regulatory scheme to account for the manufacturing process variabilities that can occur when making large molecule drugs grown within living organisms. Congress knew when passing the Biosimilars Price Competition and Innovation Act (BPCIA) that it was not simply creating a new Hatch-Waxman generic drug type approval process; rather, they were creating a new process for more complex drugs that needs additional scrutiny before allowing interchangeability.

APA supports Congress' and the FDA's regulatory framework for determining interchangeability for biologic drugs and we do not believe any additional state-based regulatory burden should be placed on pharmacists, physicians or patients. We therefore are supportive of the changes to the Arkansas State Board of Pharmacy's Regulation 7.

Respectfully submitted,

Scott Pace, Pharm.D., J.D.

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September 22, 2017

Arkansas State Board of Pharmacy
322 S. Main Street, Suite 600
Little Rock, AR 72201

Sent via Hand Delivery

RE: Arkansas State Board of Pharmacy Proposed Changes to Regulation 7

Dear John Kirtley,

On behalf of Wal-Mart Stores, Inc. ("Walmart") and the more than 130 Walmart and Sam's Club Pharmacies we operate in the State of Arkansas, I am writing this letter to express Walmart's support of the proposed changes to Regulation 7, as put forth by the Arkansas State Board of Pharmacy.

As a matter of background, many studies have been published over the last several years that outline the benefits of biological products ("biologics") and biosimilar products ("biosimilars"). For example, biologics have been shown as effective in symptom control of rheumatoid arthritis, with which approximately 673,000 Arkansans[1] are afflicted.

Sincerely,

Michael Lindsey

Michael Lindsey
Director, Public Affairs
Walmart

[1] Arkansas Arthritis Foundation. See http://www.arthritis.org/arkansas/.

AMCP | Academy of Managed Care Pharmacy

September 26, 2017

John C. Kirtley, PharmD
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Re: Proposed Changes to Regulation 7 – Drug Products/Prescriptions

Dear Dr. Kirtley:

The Academy of Managed Care Pharmacy (AMCP) thanks the Arkansas State Board of Pharmacy (Board) for the opportunity to provide comments on the proposed changes to *Regulation 7 – Drug Products/Prescriptions* as they relate to biosimilar products. The introduction of biosimilars in the United States marketplace has the potential to save the United States healthcare industry billions of dollars in annual expenditures, and encourages a competitive marketplace that could result in substantial savings to patients and public and private payers. AMCP supports the implementation of a robust biosimilars pathway at the federal and state level to ensure that Americans continue to receive access to safe, effective, and affordable biologics and biosimilars.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners, including members in Arkansas, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

The proposed changes update several definitions, including biological product, biosimilar, and biosimilar product, to align with the Food and Drug Administration's (FDA) definitions of these terms. AMCP supports adoption of the FDA definition of these terms in state regulations to minimize confusion to prescribers, pharmacists, and patients and minimize differences between state and federal regulations. However, AMCP is concerned that the proposed changes include 'biological products' within the definition of 'drug.' By FDA definition, a biological product is not a drug and therefore this may result in unintended confusion for prescribers, pharmacists, and patients. AMCP recommends that the Board reconsider the inclusion of 'biological product' within the definition of 'drug' and maintain them as separate definitions to be consistent with the FDA and federal regulations.

The proposed changes would also allow the dispensing of an interchangeable biological product when available unless the provider specifically indicates that substitution is not permitted, which is consistent with the Biologics Price Competition and Innovation Act (BPCIA). AMCP supports the automatic substitution, without additional restrictions or recordkeeping requirements, of interchangeable biological products that are licensed by the FDA and determined to meet the safety standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4). Therefore, AMCP urges the Board to move forward with finalizing the proposed rule regarding interchangeability.

To make the interchangeability provisions more definitive, AMCP recommends that the Board consider revising *Section 07-00-0006—GENERIC AND BIOLOGICAL SUBSTITUTION* into two sub-sections, the first discussing generic substitution and the second discussing biological interchangeability. As written, the section may be confusing with its multiple references and therefore AMCP suggests dividing it to minimize any potential confusion and misinterpretation, especially regarding when the Orange Book versus the Purple Book is the appropriate reference.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with the Arkansas State Board of Pharmacy. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

Jennifer Burgin (Board of Pharmacy)

From: Haley Payne <HPayne@hmcw.org>
Sent: Tuesday, September 26, 2017 10:43 AM
To: John Kirtley
Cc: ASBP; Brenda McCrady; Luke Daniel
Subject: RE: Comments to Oppose the Proposed ASBP Rule to Permit the Substitution of Biologics Without Prescriber Communication

Hi John,

Thank you for your quick reply. The Digestive Disease National Coalition opposes this rule because it does not include an active communications provision. Like many boards of pharmacy, pharmacist associations, physician and patient organizations across the country, we believe that mandatory, active communications is essential to building confidence in biosimilars. We urge the Arkansas Board of Pharmacy to include such a provision.

Thanks for your time,

Haley Payne
Digestive Disease National Coalition
507 Capitol Court, N.E.
Suite 200
Washington, D.C. 20002
ph: (202) 544-7497
fax: (202) 546-7105
HPayne@HMCW.org

From: John Kirtley [mailto:John.Kirtley@arkansas.gov]
Sent: Tuesday, September 26, 2017 9:40 AM
To: ASBP <asbp@arkansas.gov>; Brenda McCrady <Brenda.McCrady@arkansas.gov>; Luke Daniel <Luke.Daniel@arkansas.gov>; Haley Payne <HPayne@hmcw.org>
Subject: RE: Comments to Oppose the Proposed ASBP Rule to Permit the Substitution of Biologics Without Prescriber Communication

Ms. Payne,
If you are okay with the Bio Language as it sits then why is our language problematic for your people? Every prescription filled in our state would meet the exemptions of this language which you are in support of? It appears to me that the request with the listed exemptions which I have seen in several states is a hollow ask. If it is done in a manner that the further notification is exempt then why does it truly matter? Would your organization also be supportive if there was an added clause requiring the prescriber to be directly available for such notification and that they must put it directly into the patient's chart to be maintained? Point being, the information is there currently and nobody is looking at it. Instead of looking at it or tying into it, you want a manual notification requirement of pharmacists and pharmacies.
I'll be interested to see your response,
Thank you,
John

From: ASBP
Sent: Tuesday, September 26, 2017 8:22 AM
To: John Kirtley; Brenda McCrady; Luke Daniel
Subject: FW: Comments to Oppose the Proposed ASBP Rule to Permit the Substitution of Biologics Without Prescriber Communication

From: Haley Payne [mailto:HPayne@hmcw.org]
Sent: Tuesday, September 26, 2017 8:18 AM
To: ASBP
Subject: Comments to Oppose the Proposed ASBP Rule to Permit the Substitution of Biologics Without Prescriber Communication

Good morning,

Please see the attached comment letter from the Digestive Disease National Coalition (DDNC) on the ASBP's proposed rule to permit the substitution of biologics without prescriber communication ahead of today's hearing.

Best,

Haley Payne
Digestive Disease National Coalition
507 Capitol Court, N.E.
Suite 200
Washington, D.C. 20002
ph: (202) 544-7497
fax: (202) 546-7105
HPayne@HMCW.org

ARKANSAS SENATE

89th General Assembly - Regular Session, 2013

Amendment Form

Subtitle of Senate Bill No. 149

TO REGULATE THE SUBSTITUTION OF BIOSIMILAR BIOLOGICAL PRODUCTS FOR CERTAIN PRESCRIBED PRODUCTS.

Amendment No. 1 to Senate Bill No. 149

Amend Senate Bill No. 149 as originally introduced:

Delete everything after the ENACTING clause and substitute the following:

"SECTION 1. Arkansas Code Title 17, Chapter 92, is amended to add an additional subchapter to read as follows:

Subchapter 5 — Biosimilar Biological Products

17-92-507. Biosimilar biological products.

(a) As used in this section:

(1) "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", and "reference product" have the meanings established under Section 351 of the Public Health Service Act, 42 U.S.C. § 262; and

(2) "Prescription" means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b).

(b)(1) Except as provided in subsection (c) of this section, when a pharmacist receives a prescription for a biological product, the pharmacist may dispense a lower cost interchangeable biosimilar drug product.

(2) The total amount charged for the substituted interchangeable biosimilar product or for dispensing the prescribed product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that prescribed product or for the dispensing of the prescribed product.

(3) A pharmacist, a pharmacist's employee, or agent of a pharmacist shall notify the prescriber of the substitution of an interchangeable biosimilar product, including the full name and manufacturer, in writing or electronically not later than three (3) days after the date the product is dispensed.

(4) A pharmacist, the pharmacist's employee, or agent of a pharmacist, before dispensing an interchangeable biosimilar as a substitute for the prescribed biological product, shall inform the person for whom the medication is prescribed and the label of the dispensed shall appropriately indicate the substitution.

(5) A pharmacist shall record and retain for a period of two (2) years such records, the substitution of a reference product, including the full name and manufacturer of the prescribed product and of the interchangeable biosimilar product substituted for the prescribed product.

(c) A pharmacist shall not dispense an interchangeable biosimilar product under subsection (b) of this section:

(1) Unless the purchaser agrees to the total charge, if the total charge for the interchangeable biosimilar product exceeds the total charge of the prescribed product originally prescribed;

(2) For a prescription in writing signed by the prescriber, if the prescriber indicates in his or her own handwriting by name or initial that a substitution shall not be made;

(3) For a prescription other than one in writing signed by the prescriber, if the prescriber expressly indicates that the prescription is to be dispensed as communicated;

(4) If the individual for whom the reference product is prescribed indicates that the prescription shall be dispensed as written or communicated; or

(5) If the Arkansas State Board of Pharmacy has determined that the product shall not be substituted and has notified all pharmacists of that determination.

(d) The Arkansas State Board of Pharmacy shall:

(1)(A) Determine which biosimilar biological products are interchangeable.

(B) The Arkansas State Board of Pharmacy shall make the determination under subdivision (d)(1)(A) of this section on the basis of the determination of the United States Food and Drug Administration regarding interchangeability with the prescribed biological product; and

(2) Notify each licensed pharmacist and the Arkansas State Medical Board of the determination and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion."

The Amendment was read the first time, rules suspended and read the second time and _____

By: Senator Files

MGF/NJR - 01-31-2013 09:02:50

MGF142

_____

Secretary

Arthritis Foundation

Yes

September 25, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

RE: Regulation 7 – Drug Products/Prescriptions

Dear Members of the Arkansas State Board of Pharmacy,

On behalf of the 54 million adults and children with arthritis in the United States, the Arthritis Foundation welcomes the opportunity to comment on the proposed changes to AR Regulation 7 – Drug Products/Prescriptions. The Arthritis Foundation is boldly pursuing a cure for America's #1 cause of disability, while championing the fight against arthritis with life-changing resources, science, advocacy and community connections.

For years, biological medical products have offered tremendous therapeutic benefits to thousands of people with arthritis, and have also helped many others living with complex chronic diseases. In Arkansas alone, there are 672,000 adults and 2,700 children with doctor-diagnosed arthritis.

While the Arthritis Foundation supports enhanced patient access to lower cost and innovative medicines like biosimilars, we are concerned with the recent notice on Regulation 7, which does not include a prescriber communication provision. People with chronic diseases like arthritis often require complex, nuanced treatment plans to address their symptoms, and in the event of an adverse side effect, a physician must know which medications their patient is taking in order to appropriately adjust the treatment regimen. As such, it is imperative that physicians and patients are aware of the specific biological product dispensed. Not only does this communication help capture an accurate medical record, but it also allows physicians to closely monitor the care and progress of their patients.

The Arthritis Foundation has long supported bipartisan legislation creating a pathway for the substitution of interchangeable biological products, including HB1204 filed by Representative Stephen Magie in 2017. Comparable legislation has successfully passed in 35 states across the country. As included in Representative Magie's legislation, timely prescriber notification of the dispensed biosimilar and manufacturer by electronic health record or other means is essential to the safety of the patient.

Consistent with HB1204, we respectfully ask that the Arkansas Board of Pharmacy consider adopting a requirement of prescriber notification by the pharmacist within five business days after the dispensing of a biological product.

The Arthritis Foundation requests that the Arkansas Board of Pharmacy work with the state legislature to craft a legislative solution that addresses patient and provider concerns with automatic substitution of interchangeable biological products. The Arthritis Foundation would

Arthritis Foundation

Yes

welcome the opportunity to represent the patient voice and work with the state legislature and Arkansas Board of Pharmacy on the development and implementation of substitution law. Please contact Michele Guadalupe, Arthritis Foundation Director of State Legislative Affairs at mguadalupe@arthritis.org or Courtney Kawelaske, State Director of Advocacy and Access at ckawelaske@arthritis.org with questions or for further information.

Sincerely,

Anna Hyde

Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation

Arthritis Foundation

Yes

Arthritis Foundation Position Statement on Interchangeable Biosimilar Substitution

Issue

The Affordable Care Act (ACA) created a regulatory pathway for approving a new group of biologic medications called "biosimilars." Biosimilars have the potential to provide safe and effective treatment to people with arthritis at a lower cost than name-brand biologic medications.

Background

For years, biologic medical products have offered tremendous therapeutic benefits to thousands of people with arthritis and have also helped many others living with complex chronic diseases.

Biosimilars have now started to enter the marketplace and many more are on the way. These complex products offer potentially more affordable treatment opportunities for people with forms of inflammatory arthritis. Through special review processes conducted by the Food and Drug Administration (FDA), some of these biosimilar products may be deemed therapeutically equivalent or "interchangeable" with an original biologic or reference product.

The Arthritis Foundation conducted a survey of adults with rheumatoid arthritis to determine their current state of awareness about biosimilars. Over 90 percent of respondents expressed a preference to receive a communication if a substitution for a biosimilar occurs. As both biologics and biosimilars are complex treatments requiring careful therapeutic monitoring, pathways for substitution should require communication and transparency in all pharmacy transactions.

Our Position

The Arthritis Foundation supports state legislation that provides a pathway for biosimilar substitution that includes the following:

- Permission for a physician to prevent substitution (with "dispense as written") for patients who are stable on a prescribed biologic.
- Communication to the patient prior to or when substitution occurs.
- Entry of the substitution into an electronic health record that may be accessed by the physician.
- Communication to the prescriber within 48 hours of the substitution via electronic health record or other means if an electronic health record system is not available.
- Retention of substitution records for a minimum of five years.
- An individualized and unique name for the biosimilar medication that is noticeably different from the name-brand innovator biologic.

Biotechnology Innovation Organization

Tgmes w/ Roll 1204

September 22, 2017

BY ELECTRONIC DELIVERY

John C. Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Dear Dr. Kirtley:

The Biotechnology Innovation Organization (BIO) would like to submit the following comments on the proposed Arkansas State Board of Pharmacy Regulation 7 concerning biologic product substitution. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. We oppose the proposed regulation because it does not include an important patient-safety requirement sought by prescribers, patients, and other members of the healthcare team that requires communication between the prescriber and pharmacist. We also believe the Arkansas Board of Pharmacy may not have proper authority to amend the pharmacy practice act through a rule making process rather than through a more deliberative legislative process. We believe these are valid concerns to raise before the Arkansas Board of Pharmacy given the complex nature of biologics and the increasingly significant role they play in treating patients.

Important Distinctions of Biologic Medicines

The Biosimilars Price Competition and Innovation Act (BPCIA), which was enacted as part of the national health reform law, provides the U.S. Food and Drug Administration (FDA) statutory authority to approve safe, effective lower cost biologic treatments for patients; however, the authority to determine how these medicines are dispensed at the pharmacy rests with individual states. To that end, BIO actively engages state policymakers across the country as part of an effort to help them better understand the complexity of biologics, their stark difference to chemically synthesized medicines, and the important distinctions between generic small molecule medicines, biosimilar biologic products, and interchangeable biologic products.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

Unlike traditional chemically synthesized "small molecule" medicines, biologics are manufactured from living cells by programming a particular cell line to produce a desired therapeutic effect and in a highly controlled sterile environment. Each individual biologic is complex. Because of this complexity, 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.

The FDA is developing guidance on 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 a reference biologic – meaning they are "highly similar" to a reference product – and biologic products that meet a heightened standard to be deemed "interchangeable." The standard for interchangeability in the law is stringent and consistent with the FDA's role in protecting patient safety. In order to deem a biologic product interchangeable with a reference product, FDA must determine that a biologic is not only "biosimilar," but also "can be expected to produce the same clinical result as the [reference] product in any given patient." Further, if a patient switches between two products, the FDA must determine that there is no additional risk in such switching compared to using the reference product alone.

Pharmacist/Prescriber Communication

The proposed Arkansas State Board of Pharmacy Regulation 7 concerning biologic product substitution lacks an important patient-safety requirement for the pharmacist to communicate back to the prescriber after a biologic was dispensed. Interchangeable biologics are expected to be safe and produce the same clinical result, but patients could react differently to an interchangeable biologic than if they were given the reference (innovator) product due to the complex nature of biologic products and how they work in the human body. In these circumstances, the prescriber must know what products were substituted shortly after the point of dispensing to appropriately assess a patient's experience and further treatment options. Moreover, it is in the interest of public health to be advised of which biologic is being administered as it will facilitate attribution to the proper product for adverse event reporting. With the implementation of interoperable electronic health records (EHRs), BIO believes entry into a patient's EHR by the pharmacist of the biologic product dispensed will make this process easy and more efficient. In instances where EHRs are not yet available, the pharmacist could communicate the dispensing of a biologic product to the prescriber using any prevailing means. We do not believe this communication should be required where: (a) There is no FDA-approved

interchangeable biologic for the product prescribed; (b) A refill prescription is not changed from the product originally dispensed.

Amending the Pharmacy Practice Act through Administrative Rulemaking

Additionally, we would like to briefly note that in our interpretation of Arkansas law, we believe that the Arkansas Board of Pharmacy may lack authority to issue these regulations. The Arkansas Code provides that pharmacists are permitted to substitute only "a lower cost generically equivalent drug product" as outlined in AR Code § 17-92-503(a) (1). Biosimilars and interchangeable biological products do not meet the law's definition of "generically equivalent drug product[s]" as defined in AR Code § 17-92-101 and there is no similar authorization in Arkansas statute permitting their substitution. We therefore maintain that a substantive change such as this requires legislation.

BIO appreciates the opportunity to comment on the proposed rule set forth by the Arkansas State Board of Pharmacy with respect to the substitution of interchangeable biologics. We look forward to working collaboratively with both the Arkansas State Board of Pharmacy and the Arkansas Legislature in developing sound public policy that promotes a transparent substitution process and safeguards primacy of the patient-physician relationship.

Sincerely,

Patrick J Plues

Patrick Plues
Vice President
State Government Affairs
The Biotechnology Innovation Organization

2017 – 2018

Tuesday, September 26, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

RE: Regulation 7 – Drug Products/Prescriptions

Dear Members of the Arkansas State Board of Pharmacy,

The Arkansas Rheumatology Association (ARA) is a non-profit, state medical society established to represent rheumatologists in Arkansas, whose mission is advocacy for patient access to rheumatology care. 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.

On behalf of the Arkansas Rheumatology Association (ARA), we urge the Arkansas State Board of Pharmacy to ensure the safe dispensing of biologic and biosimilar medications to patients. In response to the proposed changes to Rule 7 on drug products/ prescriptions, the ARA would like to offer the following comments:

The ARA believes that the Arkansas State Board of Pharmacy's proposal to allow pharmacists to automatically substitute interchangeable biological products at the pharmacy level exceeds the authority provided to the Arkansas Board of Pharmacy, and subverts the legislative process.

Arkansas code provides that the Arkansas State Board of Pharmacy may determine whether a drug is generically equivalent as defined in 17-92-101 of the Arkansas code. However, biosimilars and interchangeable biological products cannot meet the law's definition of "generically equivalent drug product[s]." While biosimilar products are colloquially understood to be the generic equivalent of an innovator biologic, there are significant distinctions between biosimilars and their reference products that preclude them from being considered "generically equivalent."

Biosimilar products, even those deemed interchangeable by the FDA, do not have the same active chemical ingredients as their reference products – a requirement set forth in Arkansas code for "generically equivalent" status. Indeed, Federal law recognizes the differences between small molecule chemically synthesized drugs and large molecule biologics made using biotechnology. That is why federal law provides that biosimilars, even interchangeable ones, will be "highly similar" to their reference products, whereas generic drugs must be the "same as" their reference products. These distinctions may present unique clinical challenges in a case-by-case basis, particularly when a patient's physician receives no notification of the switch. Only a physician maintains the full accounting of a patient's health history, and as a result is in a unique position to understand the impact and efficacy of certain drug components given each patient's unique medical history.

Arkansas Rheumatology Association, Inc. (ARA)
Two Woodfield Lake
1100 E Woodfield Road, Suite 350 | Schaumburg, IL 60173
Phone: (847) 517-7225 | Fax: (847) 517-7229

In addition, biosimilars, including interchangeable biological products, cannot meet the standards set forth in a nationally-recognized drug compendium, another requirement for meeting Arkansas' definition of "generically equivalent." Unlike with small molecule drugs, compendia do not include product-specific standards for biologics.

Arkansas Code 17-92-503, which authorizes the substitution of generically equivalent drugs, was written without the unique qualities of biologic drugs in mind, making any attempt to define biosimilars into this category of drug a misapplication of the language's intent. Thus, it would be inappropriate, and outside of the scope of the board's authority, to apply provisions written before the widespread use of biotechnology to substitution of the biosimilars at the pharmacy level.

Bypassing the Legislative Process and Bi-Partisan Efforts.

The Arkansas State Board of Pharmacy's use of administrative action to subvert the legislative process that has been successful in 35 states across the country is troubling. Bypassing the legislative process prevents a broad array of stakeholders from providing important input and expertise on the biosimilars issue. Contrary to the Arkansas Board of Pharmacy's assertion that the proposed rule change will be uncontroversial, the lack of a prescriber notification standard is deeply troubling. The proposed rule change does not address concerns universally shared by prescribers, patients, and others. 35 states have been able to pass bipartisan biosimilar substitution legislation in an uncontroversial manner, without resorting to administrative action that bypasses stakeholders concerns. Stakeholders in the state of Arkansas have been working collaboratively within the legislative process, with Representative Stephen Magie, MD sponsoring legislation on this issue in 2017. This process should be allowed to continue.

The Arkansas State Board of Pharmacy notes that it will not require substitution communications to prescribers under the auspices that such communications constitute "burdensome" regulation.

ARA, along with many other stakeholders, strenuously opposes the absence of a communication provision. The aforementioned distinctions between biosimilars and their reference products present the potential for adverse consequences on a patient-by-patient basis that necessitates quick intervention by prescribers. Timely substitution communications for prescribing physicians are essential to ensure patient safety with these uniquely innovative, but uniquely challenging products. We support the agreed upon timeframe for the communication to occur within 5 days of the substitution. This specific time period offers physicians a safer and more consistent window to understand and counter any adverse effects of medications.

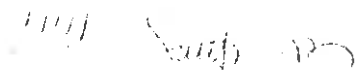
Rheumatologists are keenly aware of the dramatic long-term, life changing clinical improvements that biological agents have on some of the most crippling and disabling conditions. These biologic response modifying agents are available for the treatment of autoimmune diseases and have a significant impact on improving our patients' quality of life, preventing disability and lowering mortality.

Physicians must be involved in decisions regarding their patient's use of a biosimilar. Allowing health systems to impose an automatic substitution for biologics, without informing the prescribing physician of the product dispensed, makes it harder to determine which product is responsible for adverse events and may not be safe for patients.

In the best interest of the patient, physicians must know what medicine their patients receive and the prescribing physician must be notified in a timely manner whenever a patient's biologic medicine is substituted.

For these reasons, we ask that the Arkansas State Board of Pharmacy withdraw their proposal and allow for stakeholders to continue working through the legislative process.

Respectfully,



Mike Saitta
President
Arkansas Rheumatology Association

American Cancer Society Cancer Action Network
901 N University
Little Rock, AR 72207

Cancer Action Network℠
American Cancer Society

acscan.org

September 26, 2017

Arkansas State Board of Pharmacy
322 South Main Street
Suite 600
Little Rock, AR 72201

Members of the Board:

On behalf of the more than 134,000 survivors of cancer and their families, as well as on behalf of the more than 16,000 people that will be diagnosed with cancer this year, it is a privilege for me to provide written comment to the Board of Pharmacy regarding the proposed changes to Regulation 7.

ACS CAN appreciates the opportunity to comment on Proposed Regulation 7. Specifically, we recommend enhancing the accuracy and transparency of patient medical records to their physicians.

We appreciate that the rule limits biosimilar substitution to products that the Food and Drug Administration (FDA) has designated as an interchangeable biologic product. ACS CAN agrees that pharmacy substitution should only happen when the FDA has deemed a product to be interchangeable.

Patients undergoing treatment to fight cancer can be on a variety of biologic products as well as traditional small-molecule drugs. Therefore, we are very concerned that the proposed rule does not contain any requirement for prescriber notification when a biosimilar substitution is made.

Biologics are manufactured in living organisms and are therefore much more complex than manufacturing pharmaceutical generics. In addition, biosimilars are not necessarily exact replications of their reference biological product and, as such, a patient's response may be different to the substituted product. Any outcome difference due to a substitution may not be readily understood if either the patient or the prescriber are left uniformed of the biosimilar substitution.

Where possible, physician 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, but not more than 5 days. By utilizing automated means for physician notification, the burden on human resources is minimized. Phone calls, fax or email would be acceptable means of notification if automated means to directly import into the patient's medical record do not exist.

Finally, while ACS CAN routinely engages in a wide variety of regulatory work there are certain instances when it may not be the most prudent path of action. Biosimilar legislation has previously passed in 35 other states and that process has allowed for robust discussion and contributions from a wide and diverse range of stakeholders. We would encourage the Arkansas State Board of Pharmacy to consider allowing a similar process to play out here.

Thank you for the opportunity to provide these written comments.

Warmest regards,

Michael Keck

Michael Keck
Government Relations Director
American Cancer Society Cancer Action Network

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

September 25, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Re: Regulation 7 – Drug Products/Prescriptions

Dear Board Members,

My name is Philip Schneider, I am Professor and Associate Dean at the University of Arizona, College of Pharmacy at the new Phoenix Biomedical Campus and past president of the American Society of Health-system Pharmacists (ASHP) which represents more than 43,000 pharmacists, and serve on the Board of the International Pharmaceutical Federation, which represents 3 million pharmacists globally.

I also serve as Chair of the Advisory Board for the Alliance for Safe Biologic Medicines (ASBM) a group of patients, physicians, pharmacists, manufacturers of both originator and biosimilar biologics, and others working toward the safe introduction and use of biosimilars. ASBM has been working on biosimilar issues at the state, federal and international level for 5 years.

As you are aware, biologic medicines help patients with some of the most serious and chronic conditions like cancer, rheumatoid arthritis, diabetes, Crohn's disease, and MS. "Copies" of these medicines, called "biosimilars" are becoming available in the U.S. and they have the potential to offer new therapeutic options to these patients at lower cost.

Yet unlike generic versions of more simple chemical drugs, biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its biosimilar can have a significant impact on a patient- including reduced efficacy or unwanted immune responses.

For these reasons, regulators including the FDA and WHO have made it a priority to name these products distinguishably- so inadvertent substitution is less likely to occur and any problems can be traced to the correct product. With biosimilars, it is critical that everyone- physician, pharmacist, patient, and regulator- knows which medicine the patient actually received at the pharmacy.

Because biologic products differ from generics in complexity and are not identical chemical products, **clear and timely communication** between pharmacists and

prescribers is critical to ensure medical records reflect which specific product has been dispensed to the patient.

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

Our survey of 376 U.S. physicians found that 80% considered communication in the event of a biosimilar substitution "very important" or "critical".

Having an accurate patient record allows providers to assess the patient's response to a particular treatment, including proper attribution of any adverse events to the correct product, and help us make informed treatment decisions.

So far, 35 states and Puerto Rico have passed legislation permitting pharmacists to substitute an interchangeable biosimilar. All but two of these have included a communication provision allowing pharmacists a reasonable amount of time- typically 5 business days- to relay information on which medication is dispensed, so that all providers will have an accurate patient medical record. A similar bill was introduced in 2017 in the Arkansas State Legislature.

While we agree with the provision of informing the patient when a substitution of an interchangeable biosimilar is dispensed by a pharmacist, we think that the pharmacist should also communicate this substitution to the prescriber. Applying the same principles to biologics as those regulating the dispensing of generic medications may seem to make sense, but does not account for the fact that biologics are not the same as simple molecules, even if considered by the FDA to be interchangeable.

In fact, active communication among patients, prescribers, and pharmacists is the cornerstone to good patient care and codified in the Arkansas pharmacy practice act in section 07-00-0009—PROPER PRACTITIONER-PATIENT RELATIONSHIP that states "an in person physical exam of the patient performed by a practitioner, physician, doctor or other prescribing health professional ("a practitioner") prior to the issuance of any prescription is required in order to establish a valid prior patient-practitioner relationship ." This implies the importance of a prescriber-patient-pharmacist relationship when medications are prescribed. This relationship is strengthened when the pharmacist communicates professional decisions with prescribers in addition to patients.

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

For these reasons, it is ASBM's view that the lack of a communication provision in the proposed Regulation 7 language poses unnecessary risks to patient safety, and we respectfully urge the Board to reject the regulation without the inclusion of such a provision.

Thank you for the opportunity to comment on these proposed changes.

Philip Schneider, MS, FASHP
Advisory Board Chair, Alliance for Safe Biologic Medicines
Professor and Associate Dean
University of Arizona College of Pharmacy- Phoenix
650 East Van Buren St.
Room 3384
Phoenix, AZ 85004-2101
(602) 827-2446

ASBM Steering Committee
Alliance for Patient Access
American Academy of Dermatology
American Autoimmune Related Diseases Association (AARDA)
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
HealthHIV
Hepatitis Foundation International
International Cancer Advocacy Network
Kidney Cancer Association
Lupus and Allied Diseases Association
National Hispanic Medical Association
National Psoriasis Foundation
ZeroCancer

PhRMA
RESEARCH PROGRESS HOPE
950 F STREET, NW, SUITE 300 WASHINGTON, DC 20004 202-835-3400 PhRMA.org

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
asbp@arkansas.gov

September 26, 2017

Dear Arkansas Board of Pharmacy:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is writing in regard to proposed changes to Regulation 7 – Drug Products/Prescriptions that would amend existing statute to reflect changes to federal law that created an abbreviated pathway for the FDA approval of biosimilar products. As the association representing the country's leading innovative biopharmaceutical research companies, we are pleased to see that Arkansas has included many patient protections throughout the regulation. We encourage the Board of Pharmacy to include an additional patient protection that would require a pharmacist to notify a prescriber when a substitution has occurred.

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. The abbreviated regulatory pathway has led many states to adopt legislation and regulations to instate safeguards to ensure patient health and safety.

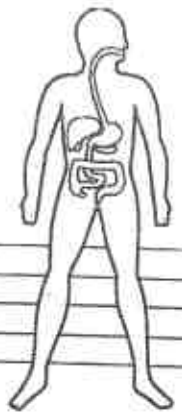
The proposed changes to Regulation 7 apply several important patient protections to the biosimilar substitution process. PhRMA supports provisions that place patient safety first, recognize the FDA as the only entity authorized to designate interchangeability, affirm the decision-making authority of physicians, and require that proper safeguards are in place in case of a future need for information on prior substitution of medicines.

PhRMA would encourage the Board of Pharmacy to consider adding language that would require a pharmacy to notify a physician when an interchangeable biological drug substitution occured. Informing prescribers of these substitutions 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.

PhRMA appreciates the opportunity to submit comments to the Board of Pharmacy on the proposed changes, and would be happy to answer any questions.

Sincerely,
Kristina M. Moorhead
Senior Director, State Policy

Digestive Disease National Coalition



507 Capitol Court, N.E., Suite 200, Washington, D.C. 20002
(202) 544-7497 (202) 546-7105 - Fax WWW.DDNC.ORG

September 26, 2017

Thomas Warmack, P.D.
President
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Re: Comments to oppose the proposed Arkansas Board of Pharmacy rule to permit the substitution of biologics without prescriber communication

Dear Dr. Warmack,

On behalf of thousands of Arkansas residents suffering from digestive diseases and the physicians who treat them, the Digestive Disease National Coalition (DDNC) respectfully opposes the Arkansas Board of Pharmacy's proposed regulation to permit the substitution of biologics without prescriber communication. Allowing the automatic substitution of interchangeable biological products at the pharmacy level goes against many in the patient community's position because of the impact it can have on proper patient access and safety.

DDNC represents dozens of major professional societies concerned with digestive diseases in order to further our goal of improving the quality and accessibility of health care options for patients. Biologic medicines, including biosimilars, are expanding treatment options for patients with digestive diseases and disorders, and we are advocating for their safe integration into the U.S. market. For the sake of our patients, it is important that the entire medical team, including physicians and pharmacists, communicate about the proper course of treatment.

Because of the complexity involved with manufacturing biologic medications, which interact with living cells, there is no way to create the "generic" medications that are so common in other

traditional pill-like drugs. While the development of biosimilars—which are similar to their innovator biologic medication, but not exactly the same—is important for creating robust choices for patients, there are safety issues that must be addressed. The best way to address these concerns is through clear communication between prescribers and pharmacists.

The proposed changes to Rule 7 circumvents the legislation process and creates a framework that does not ensure that there is transparent, open communication between prescribers and pharmacists, which is needed for patient safety. A patient's physician is well versed in a patient's treatment regimen and history, and a clear line of communication helps to ensure that patients have access to the best care.

With several biosimilars already on the market, it is crucial that we act quickly to ensure that there are clear guidelines for prescriber and pharmacists. We strongly urge the Arkansas Board of Pharmacy to retract the proposed rule and support the current legislative process in the Arkansas legislature that will allow for substitution with prescriber communication for the benefit of those who suffer from digestive illnesses and those who treat them.

Sincerely,

Lynn Seim, MSN, RN
Chairperson

Ralph McKibbin, MD
President

AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

1445 New York Ave., NW, Suite 800
Washington, DC 20005-2134

MAIN (202) 842-3555
FAX (202) 842-4355
www.aad.org

September 26, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Dear Members of the Arkansas Board of Pharmacy:

On behalf of the over 13,500 members of the American Academy of Dermatology Association (Academy), we write to oppose the Arkansas Board of Pharmacy proposed changes to Regulation 7- Drug Products/Prescriptions, which would affect a physician's ability to safely prescribe biologic products. Under the regulation's proposed definition of "interchangeable biological product," a pharmacist may substitute an interchangeable biological product without the intervention of the health care provider who prescribed the reference product, effectively removing the physician's medical judgment and jeopardizing patient safety. The Academy strongly supports communication between a pharmacist and physician concerning the substitution, and such communication should occur by the time of dispensing.

Dermatologists who treat severe psoriasis call the advent of biologic therapies a revolution, which has opened the pathway for the development of biosimilars. Manufacturing a biosimilar is much more complex than manufacturing generics for small molecule drugs. Because biologics are manufactured in living organisms, biosimilars are not exact replications of their reference biologic products. Due to this variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. Even minor changes in the manufacturing process can significantly affect the efficacy of the biosimilar. The treating physician must know of a biosimilar substitution in order to appropriately assess the patient's experience and further treatment options. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include a physician's medical judgment.

The prescribing physician, who has a thorough knowledge of the patient's medical history, could identify potential adverse outcomes among multiple biosimilar medications before the medication is dispensed to the patient. Further, concerns raised that notification by the time of dispensing would impede access or increase the administrative burden for the pharmacy are not justified as most dermatology

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.

In order to protect our patients, the Academy urges the Arkansas Board of Pharmacy to withdraw proposed Regulation 7 so that stakeholders can work through the legislative process to ensure biosimilars are dispensed in a safe manner and without impeding access to patients of such medications. Please contact Lisa Albany, JD, associate director, state policy, at lalbany@aad.org or (202) 842-3555 should you require any additional information or clarification.

Sincerely,

Henry W. Lim MD, FAAD

Henry W. Lim, MD, FAAD
President
American Academy of Dermatology Association

Alliance of Specialty Medicine

Sound Policy. Quality Care.

September 25, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Sent electronically to asbp@arkansas.gov

To whom it may concern:

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 to express our **concern that the proposed amendments to Regulation 7 – Drug Products/Prescriptions being considered by the Arkansas State Board of Pharmacy fail to include a requirement to notify the treating prescriber when a biosimilar is substituted for the prescribed product.**

The practice of automatic substitution that is seen with generic drugs is not appropriate for biosimilar products given that they are not simply "generic" versions of biologics. Each biologic product is unique, which is a fact that becomes even more significant when one considers the often fragile health of the patients who rely on these medicines. For this reason, notification of a substitution is critical because it will help ensure proper patient care and allow for accurate attribution of any adverse events that may occur. Physicians must know what medicine their patient receives and therefore, the prescribing physician should be notified whenever a patient's biologic medicine is substituted. Simply requiring that the patient is notified of a substitution without any communication to the prescriber falls far short of the safeguards needed to protect patients.

Advances in medical treatment have transformed the way we fight certain diseases. Biologics and biosimilars will continue to be an important treatment option for patients, but prescribers cannot be removed from decisions that can affect their patients' health. As such, **the Alliance of Specialty Medicine urges the Arkansas State Board of Pharmacy to include a notification requirement in its proposed substitution language.**

Sincerely,

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

Alliance for Patient Access

National Physicians Biologics Working Group

September 22, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

RE: Regulation Seven – Drug Products/Prescriptions

Dear Members of the Arkansas State Board of Pharmacy:

The Alliance for Patient Access (AfPA) would like to express concern regarding the recent proposed amendments to Regulation 7 that would allow pharmacists to substitute interchangeable biosimilar medicines. AfPA believes that biosimilar substitution policy should be enacted legislatively and must contain a patient and physician communication clause when interchangeable biosimilars are substituted at the pharmacy.

AfPA is a national network of more than 800 physicians with the shared mission of ensuring patient access to approved 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.

Biosimilars – even interchangeable biosimilars – are not identical to the reference product and are characterized by differences in immunogenicity, meaning patients may react differently to similar products. As such, biological products and their follow-on biosimilars cannot be treated in the same way as chemical drugs and their generics. Since the generic substitution laws are not applicable to biosimilars, over 30 states have enacted legislation updating pharmacy laws to permit biosimilar substitution when certain conditions are met.

AfPA has worked actively in many of these states to ensure that pharmacists have the ability to substitute interchangeable biosimilar medicines to increase treatment options and cost savings for patients. NPBWG members support legislation that contains key principles that biosimilar substitution must meet to ensure patient safety and promote prescriber confidence. They are as follows:

1. FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic.
2. Physician ability to specify no substitution or dispense as written.
3. Pharmacist communication to the prescribing physician and patient any substitution within a reasonable timeframe.

Alliance for Patient Access
1275 Pennsylvania Ave., NW | Suite 1100A
Washington, DC 20004

Such communication among a patient's health care team, which includes the pharmacist, allows for a complete medical record that helps ensure an individual's unique medical history is considered when dispensing biological products and facilitates the best medical response to a potential adverse event.

Earlier this year, Arkansas legislators introduced a bill to address revisions to the Arkansas Code in the General Assembly. HB 1204 included all three of the aforementioned principles, most notably the physician communication requirement:

Within five (5) business days after dispensing a biological product, the dispensing pharmacist or his or her designee shall enter the specific biological product provided to the patient, including without limitation the name of the biological product and the manufacturer of the biological product.

AfPA supports making potentially less costly medicines available to patients and physicians, but all efforts must be made to create policies that balance access, safety, and cost. AfPA advocates for the creation of appropriate biosimilar substitution policy, including a physician communication provision, through the legislative process.

Sincerely,

Brian Kennedy
Executive Director

Mon 9/25/2017 11:17 AM

Mr. Kirtley,

I can give you a more thorough comparison of biopharmaceutical companies' position to our own if you could point me to any specific model language or statutes that you have in mind. It has been my experience that smaller biotechnology companies developing biosimilars have been opposed to notification, while those manufacturing the innovator product have supported notification for their own reasons. In our estimation, the industry's position on this issue has not been uniform across all players.

For reasons of ensuring patient safety, the Arkansas Rheumatology Association supports the notification provision currently present in Arkansas HB 1204. Specifically, the language as follows:

"Within five (5) business days after dispensing a biological product, the dispensing pharmacist or his or her designee shall enter the specific biological product provided to the patient, including without limitation the name of the biological product and the manufacturer of the biological product."

Please let me know if there is any further clarification or information I can provide.

Best,

Brian Henderson
Government Affairs Specialist | WJ Weiser Association Management
Direct: 847.264.5910 | Main: 847.517.7225| Fax: 847.517.7229
Two Woodfield Lake | 1100 E Woodfield Road, Suite 350 | Schaumburg, IL 60173
brian@wjweiser.com | www.wjweiser.com

CSRO
COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

John Kirtley

From: John Kirtley
Sent: Tuesday, September 05, 2017 3:16 PM
To: Scott Pace
Cc: Debbie.Hayes@sanofi.com; ssmith@arkmed.org; dwroten@arkmed.org; stevemagie@Conwaycorp.net; smagie@comcast.net; ddsferg@aol.com; justin@colemanrx.arcoxmail.com; Brenda McCrady; Debra Wolfe; bill@phillipsmanagement.net; leo.hauser@sbcglobal.net; mlparks797@gmail.com
Subject: Re: Proposed Regulation 7 on Biologics

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600 (same building as Samantha's on 6th floor)
Wednesday, September 6
10:30AM -11:30AM
You can use our parking deck code below.

Our new offices are on the corner of 4th and Main and we have a parking deck behind the building at 4th and Louisiana if you need it. Since Louisiana is one way going West to East, you'll need to get on 4th somewhere before Louisiana. (One of the easiest ways is I-630 to Broadway, Broadway to 4th and then left into the parking lot.) You can use our parking deck using the code 7109# to get in – you must enter the pound sign at the end. This should be the best parking available in the area otherwise you are going back and forth around one way streets and turning restrictions. Please do not share our parking code. To get in the building, enter on 4th Street at the copper awning and walk down the hallway towards the elevators. To the right of those doors right before you enter the elevator lobby there is a video linked buzz system to our office so we can let you into the elevators. Then come on up to 6th floor and you will be right in front of the glass doors where we can buzz you into the office.
We will see everyone that can make it.
Thanks,
John

Sent from my iPhone

On Sep 5, 2017, at 3:49 PM, Scott Pace <Scott@arrx.org> wrote:

> I can do tomorrow at 1030.
>
> Sent from my iPhone
>
> On Sep 5, 2017, at 12:56 PM, "Debbie.Hayes@sanofi.com" <Debbie.Hayes@sanofi.com> wrote:
>
> > I can make either time work. I have another meeting on Thursday that starts at 10:45 AM.
> >
> > Debbie Hayes, Pharm.D.
> > Head, State Government Relations
> > Sanofi US
> > 5417 Chevaux Court

Little Rock, AR 72223
Debbie.Hayes@sanofi.com
TEL.:501-868-3380 - CELL.: 501-425-2270
55 CORPORATE DRIVE - BRIDGEWATER - New Jersey 08807

-----Original Message-----
From: John Kirtley [mailto:John.Kirtley@arkansas.gov]
Sent: Tuesday, September 05, 2017 11:48 AM
To: Scott Smith
Cc: David Wroten; Scott Pace; stevemagie@Conwaycorp.net; Dr. Steve Magie; Deborah Ferguson; Justin Boyd, Pharm.D., MBA; Brenda McCrady; Debra Wolfe (dwolfe@arpharmacists.org); bill@phillipsmanagement.net; Leo Hauser; Marvin Parks; Hayes, Debbie D. /US
Subject: Re: Proposed Regulation 7 on Biologics

Hello everyone,
I have yet to hear from anyone on this but thought I would check again in case tomorrow works best rather than Thursday. I am traveling today but will check email periodically.
Thank you,
John

Sent from my iPhone

On Sep 1, 2017, at 12:37 PM, John Kirtley <https://urldefense.proofpoint.com/v2/url?u=http-3A__John.Ki&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=uQ-WXY6yn7fHVst6qGRKZdC2mywIkDIBFlvb5U_rMLI&e= rtley@arkansas.gov<mailto:John.Kirtley@arkansas.gov>> wrote:

Hello Everyone,
In looking at my own calendar for next week it looks like I could meet Wednesday Morning from 10-11:30 or any time Thursday morning. I'll have to see which would get us the most folks in attendance and we can go from there. I will be out of state until late Tuesday night so unfortunately I could not meet Tuesday. Let me know your preference and I will send the specific place and time.
Thank you,
John

John Clay Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy

322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: 501-682-0190
Fax: 501-682-0195
John.Kirtley@arkansas.gov<mailto:John.Kirtley@arkansas.gov>

From: John Kirtley
Sent: Thursday, August 31, 2017 1:29 PM
To: 'Scott Smith'
Cc: 'David Wroten'; 'Scott Pace';
'stevemagie@Conwaycorp.net<mailto:stevemagie@Conwaycorp.net>'; 'Dr. Steve Magie'; 'Deborah Ferguson'
Subject: RE: Proposed Regulation 7 on Biologics

Scott,
I just realized that this wasn't part of our other chain so I'll put that below explaining part of this proposed change to ensure that prescribers have authority to prevent substitutions when it would be concerning. I will also add a couple of links to federal (FDA) sections that we are hoping to mirror as we discussed at the beginning of the month.

For everyone else, let me know if you have any questions on this beforehand that we can address and as I mentioned I will let you know when we can schedule as was offered earlier.
Other Resources:
FDA Glossary of Terms
https://urldefense.proofpoint.com/v2/url?u=https-3A__www.fda.gov_drugs_informationondrugs_ucm079436.htm&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=0bw6XTftTLTDqS3ShCteI1penVXTweUtCevZ7q9Q5y8&e=

Biological Product
Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

In general, the term "drugs" includes therapeutic biological products<https://urldefense.proofpoint.com/v2/url?u=https-

3A__www.fda.gov_drugs_informationondrugs_ucm079436.htm-23ther-5Fbiological&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=jcjo01tMHpLi7lEYTyDovbOge-Ay9q3GpJ5QNQpbdsE&e= >.

Drug
A drug is defined as:
· A substance recognized by an official pharmacopoeia or formulary.
· A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
· A substance (other than food) intended to affect the structure or any function of the body.
· A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
· Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

https://urldefense.proofpoint.com/v2/url?u=https-3A__www.fda.gov_downloads_Drugs_GuidanceComplianceRegulatoryInformation_Guidances_UCM537135.pdf&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=Y4coZ0Lv5sYozAoKewUDU3bmLQ7LKr-0ZZZdxhtP4Dg&e=
https://urldefense.proofpoint.com/v2/url?u=https-3A__www.pharmacist.com_sites_default_files_files_Biosimilar-2520Policy-2520Background-2520Paper-2520-2D-2520FINAL.PDF&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=YE7RU68jooGg2VSUzXdYKOi_NLT3eCwAlIO-A8JzPuU&e=
https://urldefense.proofpoint.com/v2/url?u=https-3A__legcounsel.house.gov_Comps_PHSA-2Dmerged.pdf&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=4_72hPvf_cMddgMIVcOn224DnUYz0KTpwJG0D17JxkM&e=
Section 351 page 370 Public Health Service Act
(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Page 372
(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.- Upon review of an application submitted under this subsection or any supplement

to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that-
(A) the biological product-
(i) is biosimilar to the reference product; and
(ii) can be expected to produce the same clinical result as the reference product in any given patient; and
(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Page 370
"biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means-
(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

Previous Emails:
From: John Kirtley
Sent: Thursday, August 31, 2017 1:01 PM
To: Scott Smith
Subject: FW: Proposed Regulation Changes

Scott,
Below you will see a message and links to the proposed regulation changes we were discussing a couple of weeks ago. I am not sure that a previous message went through on this but I wanted to make sure you saw this as well before it went out to the masses on our list serve for the Board meeting next month. I have additional documents on this relating to the federal approach on this but wanted to be sure you also knew that our approach on this is to get ahead of any drugs approved (so we can be prepared if they are 'coming any time' as we have heard for years) but also cover the manufacturer authorized generics that are currently only accepted for substitution by board policy but need further reinforcement in case of future issues. We also thought it was most important to protect the prescriber's authority to prevent substitutions by putting it in our coverage to show they can say do not substitute or name brand medically necessary.

Let me know if you have any questions and let me know if you would be

interested if we set up a meeting next week.

Thanks,
John

John Clay Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: 501-682-0190
Fax: 501-682-0195
John.Kirtley@arkansas.gov<mailto:John.Kirtley@arkansas.gov>

From: John Kirtley
Sent: Thursday, August 31, 2017 11:23 AM
To: 'mlparks797@gmail.com<mailto:mlparks797@gmail.com>'; 'Leo Hauser'
Subject: Proposed Regulation Changes

Leo and Marvin,
I am writing you today to be sure you have seen the following public notice regarding proposed regulation changes at the Board of Pharmacy. I imagine you guys will be interested in the fact that we are proposing regulations to follow federal guidelines on substitution, definitions and terms for biologics as well as manufacturer authorized generics. There is also language to remove the list of limited medications that pharmacists can administer. This ties in with the manufacturer requests for pharmacist to help with drug administration that we have heard over the last few years repeatedly.
Let me know if you guys want to discuss this next week sometime and I'll see if I can set it up.

https://urldefense.proofpoint.com/v2/url?u=http-3A__www.pharmacyboard.arkansas.gov_pharmacy-2Dlawbook&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=GOhho1RCefGjtNCq3E0vZUCWNaSuHSmO2BFtJGjPQe8&e=
https://urldefense.proofpoint.com/v2/url?u=http-3A__www.pharmacyboard.arkansas.gov_Websites_pharmacy_images_rules_Proposed-2520Regs_PUBLIC-2520NOTICE-2520August-25202017.pdf&d=DQIF-g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=EocW5pypPmMRaWNutAL86lEou67OJ6DYodHd2WH65mc&e=

Thanks,
John

John Clay Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: 501-682-0190
Fax: 501-682-0195
John.Kirtley@arkansas.gov<mailto:John.Kirtley@arkansas.gov>

From: John Kirtley
Sent: Thursday, August 31, 2017 1:10 PM
To: 'Scott Smith'
Cc: David Wroten; Scott Pace;
stevemagie@Conwaycorp.net<mailto:stevemagie@Conwaycorp.net>; 'Dr. Steve Magie'; Deborah Ferguson
Subject: RE: Proposed Regulation 7 on Biologics

Glad to. I am trying to set up one next week for everyone and will be glad to let you know when.
Thanks,
John

John Clay Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: 501-682-0190
Fax: 501-682-0195
John.Kirtley@arkansas.gov<mailto:John.Kirtley@arkansas.gov>

From: Scott Smith [mailto:ssmith@arkmed.org]
Sent: Thursday, August 31, 2017 1:06 PM
To: John Kirtley
Cc: David Wroten; Scott Pace;
stevemagie@Conwaycorp.net<mailto:stevemagie@Conwaycorp.net>; 'Dr. Steve Magie'; Deborah Ferguson
Subject: Proposed Regulation 7 on Biologics

John,

Could we set up a meeting to discuss the proposed regulation 7?

https://urldefense.proofpoint.com/v2/url?u=http-3A__www.pharmacyboard.arkansas.gov_Websites_pharmacy_images_rules_Proposed-2520Regs_REGULATION-5F07-5F8.17.pdf&d=DQIF-

g&c=Dbf9zoswcQ-CRvvI7VX5j3HvibIuT3ZiarcKl5qtMPo&r=11S_qZCWuH62MENmME97Vhs1R8Hx0srd8RxlarDuqVY&m=7wOkcxc2TPr-VbSTjrEGR3SrXKUTKocELF_jv0FcGbQ&s=6GmkbeuuK2hk_WHiHEFVRjvh1_PkM0A9Crc7_aQrimM&e=

Thank you,

Scott

H. Scott Smith, JD
Director of Governmental Affairs
Arkansas Medical Society

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

September 25, 2017

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Re: Regulation 7 – Drug Products/Prescriptions

Dear Board Members,

My name is Philip Schneider, I am Professor and Associate Dean at the University of Arizona, College of Pharmacy at the new Phoenix Biomedical Campus and past president of the American Society of Health-system Pharmacists (ASHP) which represents more than 43,000 pharmacists, and serve on the Board of the International Pharmaceutical Federation, which represents 3 million pharmacists globally.

I also serve as Chair of the Advisory Board for the Alliance for Safe Biologic Medicines (ASBM) a group of patients, physicians, pharmacists, manufacturers of both originator and biosimilar biologics, and others working toward the safe introduction and use of biosimilars. ASBM has been working on biosimilar issues at the state, federal and international level for 5 years.

As you are aware, biologic medicines help patients with some of the most serious and chronic conditions like cancer, rheumatoid arthritis, diabetes, Crohn's disease, and MS. "Copies" of these medicines, called "biosimilars" are becoming available in the U.S. and they have the potential to offer new therapeutic options to these patients at lower cost.

Yet unlike generic versions of more simple chemical drugs, biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its biosimilar can have a significant impact on a patient- including reduced efficacy or unwanted immune responses.

For these reasons, regulators including the FDA and WHO have made it a priority to name these products distinguishably- so inadvertent substitution is less likely to occur and any problems can be traced to the correct product. With biosimilars, it is critical that everyone- physician, pharmacist, patient, and regulator- knows which medicine the patient actually received at the pharmacy.

Because biologic products differ from generics in complexity and are not identical chemical products, **clear and timely communication** between pharmacists and

prescribers is critical to ensure medical records reflect which specific product has been dispensed to the patient.

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

Our survey of 376 U.S. physicians found that 80% considered communication in the event of a biosimilar substitution "very important" or "critical".

Having an accurate patient record allows providers to assess the patient's response to a particular treatment, including proper attribution of any adverse events to the correct product, and help us make informed treatment decisions.

So far, 35 states and Puerto Rico have passed legislation permitting pharmacists to substitute an interchangeable biosimilar. All but two of these have included a communication provision allowing pharmacists a reasonable amount of time- typically 5 business days- to relay information on which medication is dispensed, so that all providers will have an accurate patient medical record. A similar bill was introduced in 2017 in the Arkansas State Legislature.

While we agree with the provision of informing the patient when a substitution of an interchangeable biosimilar is dispensed by a pharmacist, we think that the pharmacist should also communicate this substitution to the prescriber. Applying the same principles to biologics as those regulating the dispensing of generic medications may seem to make sense, but does not account for the fact that biologics are not the same as simple molecules, even if considered by the FDA to be interchangeable.

In fact, active communication among patients, prescribers, and pharmacists is the cornerstone to good patient care and codified in the Arkansas pharmacy practice act in section 07-00-0009—PROPER PRACTITIONER-PATIENT RELATIONSHIP that states "an in person physical exam of the patient performed by a practitioner, physician, doctor or other prescribing health professional ("a practitioner") prior to the issuance of any prescription is required in order to establish a valid prior patient-practitioner relationship ." This implies the importance of a prescriber-patient-pharmacist relationship when medications are prescribed. This relationship is strengthened when the pharmacist communicates professional decisions with prescribers in addition to patients.

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

For these reasons, it is ASBM's view that the lack of a communication provision in the proposed Regulation 7 language poses unnecessary risks to patient safety, and we respectfully urge the Board to reject the regulation without the inclusion of such a provision.

Thank you for the opportunity to comment on these proposed changes.

Philip Schneider, MS, FASHP
Advisory Board Chair, Alliance for Safe Biologic Medicines
Professor and Associate Dean
University of Arizona College of Pharmacy- Phoenix
650 East Van Buren St.
Room 3384
Phoenix, AZ 85004-2101
(602) 827-2446

ASBM Steering Committee
Alliance for Patient Access
American Academy of Dermatology
American Autoimmune Related Diseases Association (AARDA)
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
HealthHIV
Hepatitis Foundation International
International Cancer Advocacy Network
Kidney Cancer Association
Lupus and Allied Diseases Association
National Hispanic Medical Association
National Psoriasis Foundation
ZeroCancer

Brenda McCrady

From: Nancy Sweet
Sent: Tuesday, September 26, 2017 3:31 PM
To: John Kirtley; Brenda McCrady; Luke Daniel
Subject: FW: Comments on Regulation 7, 9/26 BoP Hearing (Oppose)
Attachments: AR-Comments-Schneider-FINAL.pdf

Nancy Sweet

From: Ray Patnaude [mailto:ray@safebiologics.org]
Sent: Tuesday, September 26, 2017 10:36 AM
To: Nancy Sweet
Subject: Fwd: Comments on Regulation 7, 9/26 BoP Hearing (Oppose)

Dear Board of Pharmacy Members,

Please accept these comments in opposition to the proposed Rule changes (Regulation 7) concerning biosimilar substitution, from Philip Schneider MS FASHP. Professor Schneider is Associate Dean of the University of Arizona College of Pharmacy, past president of the American Society of Health-system Pharmacists (ASHP), and Chair of the Advisory Board of the Alliance for Safe Biologic Medicines. ASBM is a group of patients, physicians, pharmacists, manufacturers of both innovator biologics and biosimilars, researchers, and others working together to safely bring the benefits of biosimilars to patients.

Thank you for the opportunity to comment on this important matter.

Ray Patnaude
ray@safebiologics.org
(202)746-1469

Supporting documents for changes to Regulation 7
Rather than printing over a thousand pages of text for you, below are important links to guidance and referenced federal sources utilized in this proposed change.

FDA Glossary of terms from www.fda.gov under Drugs@FDA Glossary of Terms

Biological Product
Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available. In general, the term "drugs" includes therapeutic biological products.

Drug
A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

ALSO: FDA Industry Guidance on Biosimilars
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf
Considerations in Demonstrating Interchangeability With a Reference Product
Guidance for Industry
This guidance document outlines the FDA advice on what data and information will be needed to support a demonstration of interchangeability. Despite any information to the contrary, this guidance specifically outlines the following regarding switching studies:
Page 9
316 For biological products that are intended to be administered to an individual more than once,
317 sponsors generally will be expected to conduct a switching study or studies to address the
318 statutory provision "for a biological product that is administered more than once to an individual,
319 the risk in terms of safety or diminished efficacy of alternating or switching between use of the
320 biological product and the reference product is not greater than the risk of using the reference
321 product without such alternation or switch" set forth in section 351(k)(4)(B) of the PHS Act.
322 The main purpose of a switching study or studies is to demonstrate that the risk in terms of safety
323 or diminished efficacy of alternating or switching between use of the proposed interchangeable
324 product and the reference product is not greater than the risk of using the reference product
325 without such alternation or switch. A switching study or studies should evaluate changes in
326 treatment that result in two or more alternating exposures (switch intervals) to the proposed
327 interchangeable product and to the reference product.

VI. DATA AND INFORMATION NEEDED TO SUPPORT A DEMONSTRATION OF INTERCHANGEABILITY

FDA advises sponsors intending to develop a proposed interchangeable product to meet with FDA to discuss their proposed product development plan. Early discussions with FDA about product development plans, including adequate scientific justification for the proposed development program, will facilitate development of interchangeable products.[17]

A. Considerations for the Design and Analysis of a Switching Study or Studies Needed to Support a Demonstration of Interchangeability

For biological products that are intended to be administered to an individual more than once, sponsors generally will be expected to conduct a switching study or studies to address the statutory provision "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch" set forth in section 351(k)(4)(B) of the PHS Act. The main purpose of a switching study or studies is to demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between use of the proposed interchangeable product and the reference product is not greater than the risk of using the reference product without such alternation or switch. A switching study or studies should evaluate changes in treatment that result in two or more alternating exposures (switch intervals) to the proposed interchangeable product and to the reference product.

https://www.pharmacist.com/sites/default/files/files/Biosimilar%20Policy%20Background%20Paper%20-%20FINAL.PDF
Biologic, Biosimilar, and Interchangeable Biologic Drug Products Background Paper
Prepared for the 2015–2016 APhA Policy Committee Edward Li, PharmD, MPH, BCOP
Associate Professor University of New England College of Pharmacy

"Interchangeability Provisions within the BPCIA allow for a biosimilar to be designated interchangeable if it meets additional standards beyond biosimilarity. An interchangeable product is one that "can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.""

https://legcounsel.house.gov/Comps/PHSA-merged.pdf
Section 351 page 370 Public Health Service Act
(3) The term ''interchangeable'' or ''interchangeability'', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Page 372
(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—
(A) the biological product—
(i) is biosimilar to the reference product; and
(ii) can be expected to produce the same clinical result as the reference product in any given patient; and
(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Page 370
''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
(2) The term ''biosimilar'' or ''biosimilarity'', in reference to a biological product that is the subject of an application under subsection (k), means—
(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

Stricken language would be deleted from and underlined language would be added to present law.

State of Arkansas
91st General Assembly
Regular Session, 2017

As Engrossed: H2/8/17

A Bill

HOUSE BILL 1204

By: Representative Magie

For An Act To Be Entitled

AN ACT TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL PRODUCT SUBSTITUTIONS; AND FOR OTHER PURPOSES.

Subtitle

TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL PRODUCT SUBSTITUTIONS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code § 17-92-101, concerning the definitions relating to pharmacists, pharmacies, and the practice of pharmacy, is amended to add new subdivisions to read as follows:

(24) "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein that is not chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any trivalent organic sersenic compound applicable to the prevention, treatment, or cure of a disease or condition of a human being; and

(25) "Interchangeable biological product" means a biological product that the United States Food and Drug Administration has:

(A) Licensed and determined to meet the standards of interchangeability established by 42 U.S.C. § 262(k)(4), as existing on January 1, 2017; or

(B) Determined to be therapeutically equivalent to another biological product as set forth in the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations", also known as the "Orange Book", as existing on January 1,

2017.

SECTION 2. Arkansas Code § 17-92-503 is amended to read as follows:

17-92-503. Generic drug product and biological product substitutions.

(a)(1) Except as provided in subsection (b) of this section, when a pharmacist receives a prescription for a brand or trade name drug product or biological product, the pharmacist may dispense a lower cost generically equivalent drug product or interchangeable biological product.

(2) The total amount charged for the substituted generically equivalent drug product or interchangeable biological product, or for dispensing the drug product or biological product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that drug product or biological product or for the dispensing of that drug product or biological product.

(3) A pharmacist may not dispense a drug product or interchangeable biological product with a total charge that exceeds the total charge of the drug product *or biological product* originally prescribed unless agreed to by the purchaser.

(b) The pharmacist shall not dispense a generically equivalent drug product or interchangeable biological product under subsection (a) of this section if:

(1) The prescriber, in the case of a prescription in writing signed by the prescriber, indicates in his or her own handwriting by name or initial that no substitution shall be made;

(2) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates that the prescription is to be dispensed as communicated;

(3) The person for whom the drug product or biological product is prescribed indicates that the prescription is to be dispensed as written or communicated; or

(4) The Arkansas State Board of Pharmacy has determined that the drug product or biological product should not be substituted and has notified all pharmacists of that determination.

(c)(1) The Arkansas State Board of Pharmacy shall determine which drugs are generically equivalent as defined in § 17-92-101, relying on standards scientifically supported and generally accepted in the field of

pharmacy, and shall notify each licensed pharmacist and the Arkansas State Medical Board of this determination.

(2) In making this determination, the Arkansas State Board of Pharmacy may use a nationally recognized reference source that meets the requirements of this act, notifying each licensed pharmacist and the Arkansas State Medical Board of the reference source to be used and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.

(d)(1) Within five (5) business days after dispensing a biological product, the dispensing pharmacist or his or her designee shall enter the specific biological product provided to the patient, including without limitation the name of the biological product and the manufacturer of the biological product.

(2) The entry shall be electronically accessible to the prescriber through:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefit management system; or

(D) A pharmacy record.

(3) If the pharmacist is unable to make an entry as described in subdivision (d)(2) of this section, a pharmacist shall communicate to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means the biological product dispensed.

(4) An entry made into an electronic records system as described in subdivision (d)(2) or subdivision (d)(3) of this section is presumed to provide notice to the prescriber of the dispensing of the biological product.

(5) A communication is not required when:

(A) An interchangeable biological product does not exist for the prescribed biological product; or

(B) A refill prescription for a biological product is not substituted for an interchangeable biological product on a subsequent filling of the prescription.

(6) The pharmacist or pharmacy shall maintain a record of biological products dispensed for at least two (2) years.

SECTION 3. Arkansas Code § 17-92-505 is amended to read as follows:

17-92-505. Labeling.

(a)(1) The pharmacist filling a prescription for dispensing to an ultimate patient may affix to the container a label showing:

(A) The pharmacy name, address, and telephone number;

(B) The date of dispensing;

(C) The serial number of the prescription;

(D) The name of the patient;

(E) The name of the prescribing practitioner;

(F) The trade name of the ~~medication~~ drug product, if any, or the generic name and identity of the manufacturer of the dispensed ~~medication~~ drug product, if the medication appears generically listed on the drug formulary list as established by this subchapter, or in the case of a biological product, the trade name of the biological product, if any, or the proper name of the biological product and identity of the manufacturer of the dispensed biological product;

(G) The strength per unit dose of the medication;

(H) The quantity of the medication; and

(I) Directions for use.

(2) If a pharmacist dispenses a generically equivalent product, the person for whom the medication is prescribed shall be informed prior to dispensing or the label should appropriately indicate the substitution.

(3) However, this subsection shall not apply to the dispensing of medication to inpatients in hospitals.

(4) ~~Further, in an appropriate manner,~~ In the case of dispensing *a drug product*, the prescribing practitioner may indicate that the name, manufacturer, and strength of the medication dispensed shall be deleted from the label.

(b)(1) ~~Any authorized person filling a prescription~~ An authorized person who fills a prescription for dispensing to an ultimate patient shall affix to the container a label showing the trade name of the medication or the generic name of the medication unless directed to the contrary by the physician.

(2) Failure to comply with this subsection shall be grounds for disciplinary action.

(c) An authorized person who fills a prescription for dispensing to a patient shall affix to the container a label showing the trade name, if any, or the proper name of the biological product.

(2) Failure to comply with this subsection shall be grounds for disciplinary action.

SECTION 4. Arkansas Code § 17-92-506 is amended to read as follows:

17-92-506. ~~Price~~ Available drug product and biological product lists.

(a)(1) A pharmacist may display, within the confines of the pharmacy, lists of available drug products and biological products, other than controlled substances, and current charges for the drug products or biological products or for the dispensing of the drug products or biological products in specified quantities.

(2) Upon request, a pharmacy may make such lists available to its customers and other members of the public.

(b) The Arkansas State Board of Pharmacy shall maintain on the website of the board a link to the list of all interchangeable biological products approved by the United States Food and Drug Administration.

/s/Magie

State of Arkansas *As Engrossed: S2/4/13*
89th General Assembly **A Bill**
Regular Session, 2013 SENATE BILL 149

By: Senator Files

For An Act To Be Entitled

AN ACT TO REGULATE THE SUBSTITUTION OF BIOSIMILAR BIOLOGICAL PRODUCTS FOR CERTAIN PRESCRIBED PRODUCTS; AND FOR OTHER PURPOSES.

Subtitle

TO REGULATE THE SUBSTITUTION OF BIOSIMILAR BIOLOGICAL PRODUCTS FOR CERTAIN PRESCRIBED PRODUCTS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 17, Chapter 92, is amended to add an additional subchapter to read as follows:

Subchapter 5 — Biosimilar Biological Products

17-92-507. Biosimilar biological products.

(a) As used in this section:

(1) "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", and "reference product" have the meanings established under Section 351 of the Public Health Service Act, 42 U.S.C. § 262; and

(2) "Prescription" means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b).

(b)(1) Except as provided in subsection (c) of this section, when a pharmacist receives a prescription for a biological product, the pharmacist may dispense a lower cost interchangeable biosimilar drug product.

(2) The total amount charged for the substituted interchangeable

biosimilar product or for dispensing the prescribed product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that prescribed product or for the dispensing of the prescribed product.

(3) A pharmacist, a pharmacist's employee, or agent of a pharmacist shall notify the prescriber of the substitution of an interchangeable biosimilar product, including the full name and manufacturer, in writing or electronically not later than three (3) days after the date the product is dispensed.

(4) A pharmacist, the pharmacist's employee, or agent of a pharmacist, before dispensing an interchangeable biosimilar as a substitute for the prescribed biological product, shall inform the person for whom the medication is prescribed and the label of the dispensed shall appropriately indicate the substitution.

(5) A pharmacist shall record and retain for a period of two (2) years such records, the substitution of a reference product, including the full name and manufacturer of the prescribed product and of the interchangeable biosimilar product substituted for the prescribed product.

(c) A pharmacist shall not dispense an interchangeable biosimilar product under subsection (b) of this section:

(1) Unless the purchaser agrees to the total charge, if the total charge for the interchangeable biosimilar product exceeds the total charge of the prescribed product originally prescribed;

(2) For a prescription in writing signed by the prescriber, if the prescriber indicates in his or her own handwriting by name or initial that a substitution shall not be made;

(3) For a prescription other than one in writing signed by the prescriber, if the prescriber expressly indicates that the prescription is to be dispensed as communicated;

(4) If the individual for whom the reference product is prescribed indicates that the prescription shall be dispensed as written or communicated; or

(5) If the Arkansas State Board of Pharmacy has determined that the product shall not be substituted and has notified all pharmacists of that determination.

(d) The Arkansas State Board of Pharmacy shall:

(1)(A) Determine which biosimilar biological products are interchangeable.

(B) The Arkansas State Board of Pharmacy shall make the determination under subdivision (d)(1)(A) of this section on the basis of the determination of the United States Food and Drug Administration regarding interchangeability with the prescribed biological product; and

(2) Notify each licensed pharmacist and the Arkansas State Medical Board of the determination and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.

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