mississippi Pharmacist

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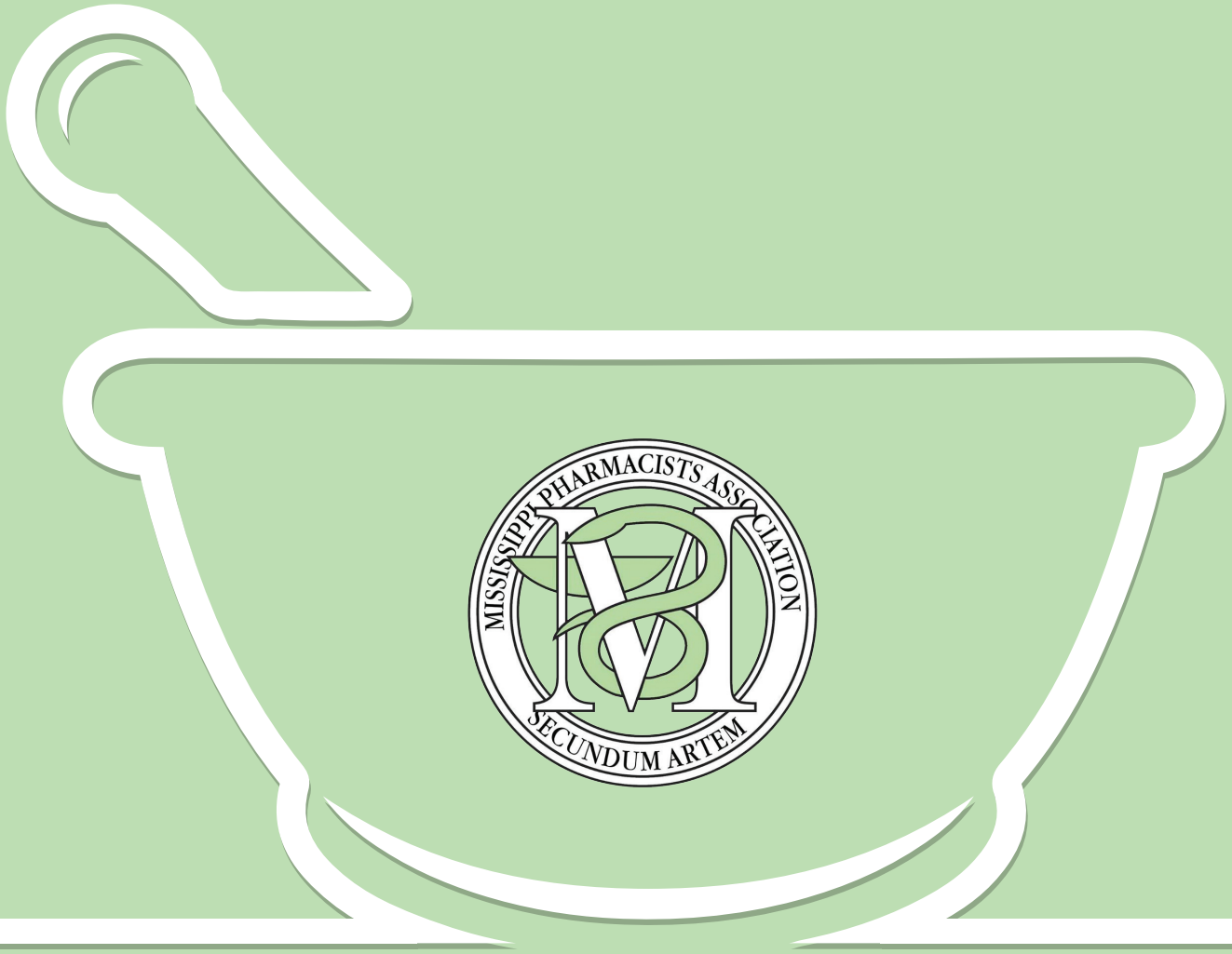

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PRESIDENT'S NOTE

To the Members of MPhA,

Thank you for the opportunity to serve you as President of this historic and proud organization. I am excited about what the future holds not only for MPhA, but for our profession and for our patients as well. With renewed focus on member opportunities, advocacy, and partnerships with fellow pharmacy and other professional organizations, we stand poised to do great things.

To say that 2020 has been challenging so far would be an understatement. Winston Churchill once said, "A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty." I would like to take this time to invite you to share with me in the optimism I have for our profession and for MPhA. Although we have been faced with difficulties, we have collectively risen to the challenge and been successful, specifically with our recently completed 149th Annual Convention in a virtual format and with the Pharmacy Prompt Pay Act, which is also known as House Bill (HB) 708. HB 708 stands to provide much needed relief for patients and pharmacies from Pharmacy Benefit Managers. As I am writing this letter, HB 708 passed concurrence between the House and Senate and is on the Governor's desk to be signed into law.

Another success we can celebrate is the recent appointment of Beau Cox as our new Executive Director. Beau is a native of Nettleton and a 2005 graduate of The University of Mississippi School of Pharmacy. He has been active within Mississippi's pharmacy community since his time as a student. Beau has worked in a variety of pharmacy practice areas including independent community, chain community, infusion, and long-term care. Beau is currently Pharmacy Director for Tara Pharmacy, a long-term care pharmacy in Pearl. In addition to being active in MPhA as a former Executive Committee Member at Large, Membership Committee Chair, and Political Action Committee Co-Chair, Beau has served in leadership roles with the Ole Miss Pharmacy Alumni Association, the MS Medicaid DUR Board, and the MS PMP Advisory Committee. Beau continues to serve as a Clinical Assistant Professor with the UM School of Pharmacy. Recently, Beau stood in the gap and served MPhA as our Interim Executive Director and proved himself to be a strong and dependable leader during a time of transition. Please join me in welcoming Beau into his role as our permanent Executive Director. If you do not already know Beau, you are in for a treat when you do get to cross paths with him.

To complete our staff changes at MPhA, we welcomed Corrie Sigler to our team as Office Manager. Corrie has brought a renewed energy, exceptional organizational skills, and a can-do attitude to MPhA. Please join me as well in welcoming Corrie to MPhA. You should also be looking forward to meeting Corrie.

In closing, I would like to thank our Executive Committee for their tireless work and creativity to navigate through uncharted waters. To our committee members and chairs, congratulations on a job well done this year. You have certainly risen to the occasion and delivered in the face of many challenges. It has truly been an honor to be part of such a great team. To Ross Guastella, thank you for your leadership this past year as our President. It is good to know that we will have one more year of your insight and wisdom on the Executive Committee as you transition to Past-President. To Lauren Bloodworth, a very special thank you as you complete your service on the Executive Committee. It has been inspiring to see your tenacity and attention to detail while working alongside you as you have led our organization.

Thank you again for placing your trust in me. Here's to a great year ahead.

Sincerely yours,

Wes Pitts, Pharm.D., BCPS, FASHP, FMSHP

MPhA President

2020

BOWL OF HYGEIA
ANN FRANKLIN, PHARMD

SPIRIT OF PHARMACY
REGAN TYLER

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DISTRICT I

EXCELLENCE IN INNOVATION AWARD
JEFF KING, PHARMD

MPhA Awards

HALL OF FAME
CINDY NOBLE

MEMBER OF THE YEAR
OLIVIA L. STRAIN, PHARMD

PHARMACY TECHNICIAN AWARD
GAIL SIAS

STUDENT PHARMACY AWARD
ELIZABETH DEMOSS

DISTINGUISHED YOUNG PHARMACIST AWARD
BRIAN EDWARD HUBBARD, PHARMD, MBA

EXCELLENCE IN INNOVATION AWARD
JEFFREY CLARK

EXECUTIVE DIRECTOR'S MESSAGE

"Why should I join MPhA?" Before becoming Executive Director, I served a few years as the MPhA Membership Committee Co-Chair, and this is a question I heard a lot. I would give them reasons relating to legislative advocacy, making connections, and CE opportunities. I understand. Pharmacists don't feel like they can make a difference at the capitol. They feel like they have plenty of friends. They feel that it's normal to spend the last week of December cramming in CE. They feel there is nothing that can be done to change what bothers them about the profession; understaffing, underpayment, underappreciation. I'm a pharmacist-I get it! I've worked chain retail, independent retail, infusion, and long-term care pharmacy. I know the frustrations. I want to assure you through MPhA that your voice is being heard at the capitol, that job opportunities are being created through connections, that it feels good to have your CE completed in June, and that we are working on issues to increase pharmacist quality of life.

"What do you want from your association?" This is the question I have asked in the past and this is the question I ask you today. You don't have to look very far to see in recent years that there is uneasiness in our profession. Third party reimbursements decreasing, DIR fees and clawbacks increasing, available jobs decreasing, and the fight for provider status at a seeming standstill. This is why now more than ever our pharmacy associations are critical in representing and protecting our profession. There are over 3,300 licensed pharmacists in the great state of Mississippi and MPhA represents ALL of them. If you are receiving this journal, then you are one of the 600 MPhA members that have answered the call to be involved and we are grateful.

So, what has MPhA been doing this year for its membership? I am very proud of how the associations have been working together this year on issues with COVID-19 and HB 708. MPhA, MIPA, MSHP, and MSPS sent a letter to the governor on a joint letterhead requesting pharmacists be allowed to order and administer COVID-19 testing. We have been working with the MS Board of Pharmacy, the MS Department of Health, and MS Medicaid to see where pharmacists can play an impactful role in the pandemic and get reimbursed for it. We were able to get a segment on WJTV promoting pharmacists as healthcare professionals and their current roles and risks during the pandemic. MPhA, MSHP, and MSPS went to the capitol to show unified support for the work that MIPA has been doing on HB 708. I am eagerly looking forward to future collaboration between the associations. We have hired a lobbyist to help us have a greater presence at the capitol during the legislative session and throughout the year.

So, what is MPhA going to do for you in the future? With your help, we are going to increase our membership. With increased membership comes more influence at the capitol, more connections we can offer to members, and more events we can off with increased dues collection. We are going to be making our Career Center much more robust. We want to be the place where employers and prospective employees look first for qualified pharmacists and technicians. We are going to continue working with the MS Board of Pharmacy and the MS Legislature on regulations and laws that affect how we practice our profession. And we are going to offer several events and opportunities for our membership to be interactive and get involved.

So, what can you do, you ask? Personally, reach out and get your friends and colleagues to join MPhA. Get and stay involved and informed. We have several opportunities for involvement with committees and district events. Join us for our upcoming events; the consultant pharmacist seminar, the MPhA/MSHP Fall Seminar and Residency Showcase, last chance seminar, mid-winter, and capitol day. Donate to our Political Action Committee, even better, set up a recurring payment to the PAC. Consider getting a Pharmacists license plate (all proceeds go to the Amie Lynn Ewing Memorial Scholarship for a pharmacy student at Ole Miss). Let me know what is important to you, what regulations need to be negotiated for you to perform at the top of your degree? You can call the office at 601-981-0416, you can email me at beau@mspharm.org, or you can visit the MPhA website at www.mspharm.org where we have resources on COVID-19, legislative advocacy, CE programs, upcoming meetings, and how you can get involved. From the website, you can easily fill out a membership application, renew your membership, subscribe to emails, and make PAC donations.

I would like to thank everyone for making this year's virtual convention a success. It would not have been possible without the hard work from Olivia Strain and the Education Committee, the team at the UM SOP- Division of Pharmacy Professional Development, Drs. Stuart Haines, Randy Pittman, and Gary Theilman, and our office manager, Corrie Sigler. We had around 170 participants which is almost double previous year's conventions. Next year's convention will be our 150th Annual Convention June 3rd – 5th at Centennial Plaza in Gulfport, MS and we look forward to seeing everyone there.

Finally, I would like to thank Corrie for all of her hard work and I would like to thank the Executive Committee for giving me this opportunity. I look forward traveling around the state catching up with friends, making new ones, and working with you promoting this great profession of ours.

Sincerely,

Beau Cox, PharmD
Executive Director, MPhA

NEW PRACTITIONERS COMMITTEE UPDATE

Jordan Marie Ballou, PharmD, BCACP

Dear MPhA Members,

The New Practitioner Committee has been off to a great start during our first year as a committee. I'd like to thank the committee members over the past year for their engagement and participation: Kim Bradley, Jonathan Doles, Michelle Ha, Joseph Nosser, Regan Tyler, and Anna Touchstone. We first decided that MPhA would define a new practitioner as a pharmacist who graduated less than or equal to 7 years ago. We also decided on our three priority areas for New Practitioners for the year would be: 1) Recruitment and Engagement of New Practitioners, 2) Marketing and raising awareness of New Practitioners, and 3) Student Member Development in hopes of retaining them as future New Practitioners. We conducted a survey of New Practitioner Members that received some good feedback. We were able to have a presence at the University of Mississippi graduating student event to share the benefits of MPhA Membership and as of the time of this writing, we have had nearly 40 graduates join the Association. The Membership Committee and New Practitioner Committee jointly presented a proposal to the Executive Committee to cover these student membership fees for their first 18 months of practice to line up with our new calendar year membership cycle. I am fortunate to get to stay on as committee chair for the upcoming year and we plan to focus on New Practitioner Spotlights and developing a student/New Practitioner mentoring program. If you graduated in 2013 or later, be on the lookout for more communication about New Practitioner opportunities. We'd love to have your participation!

Sincerely,
Jordan Marie Ballou, PharmD, BCACP
New Practitioner Committee Chair

THE ROLE OF A PHARMACIST IN THE USE OF BIOSIMILAR PRODUCTS

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Article Topic
Novel new medications and place in therapy

Goal

The goal of this article is to educate pharmacists, pharmacy technicians, and student pharmacists about the opportunities and challenges associated with the use of biosimilar products.

Objectives

1. Describe the approval process for biosimilar products.
2. Identify opportunities for pharmacy staff in the use of biosimilar products.
3. Recognize challenges associated with the use of biosimilar products.

Faculty Disclosure

The authors declare no conflicts of interest regarding this article.

Introduction

The national health expenditure totaled $3.6 trillion in 2018. This number is forecasted to increase at an annual rate of 5.4% from 2019 – 2028, reaching $6.2 trillion within the next ten years.1 The use of biologic products alone accounted for 38% of national prescription drug spending in 2015 and 70% of prescription drug spending growth between 2010 – 2015.2 In 2009, Congress passed the Biologic Price Competition and Innovation Act (BPCIA) in an attempt to increase treatment options for patients, expand access to lifesaving medications, and potentially lower healthcare costs through increased competition. The act created an abbreviated licensure pathway for biologic products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biologic.

An estimated $54 billion will be saved annually through the use of biosimilar products following approval through this alternate licensure pathway.2 Cost savings have been demonstrated following the use of the first FDA-approved biosimilar Zarxio® (filgrastim-sndz) in 2015. Filgrastim-sndz, along with a second filgrastim product, Granix® (tbo-filgrastim), accounted for 30% market share by the end of 2016. In addition, filgrastim-sndz and tbo-filgrastim had pre-rebate prices 30% and 45% below the reference product price, respectively.2

The Food and Drug Administration (FDA) has continued to approve additional biosimilar products for the treatment of various conditions such as cancer, colitis, rheumatoid arthritis, psoriasis, and supportive care (see **Table 1**)[3]. The increased approval and use of these biosimilar products offers a unique opportunity for pharmacy staff to facilitate their use within various patient populations and improve value-based care.

Table 1. FDA-approved biosimilar products (as of 05/15/2020)

Biologic	Reference Product	Approved Biosimilar Products	Approval Date	Commercially Available in US?
Filgrastim	Neupogen®	Zarxio®	2015	Yes
		Nivestym®	2018	Yes
Infliximab	Remicade®	Inflectra®	2016	Yes
		Renflexis®	2017	Yes
		Ixifi®	2017	No
		Avsola®	2019	No
Etanercept	Enbrel®	Erelzi®	2016	No
		Eticovo®	2019	No
Adalimumab	Humira®	Amjevita®	2016	No
		Cyltezo®	2017	No
		Hyrimoz®	2018	No
		Hadlima®	2019	No
		Abrilada®	2019	No
Bevacizumab	Avastin®	Mvasi®	2017	Yes
		Zirabev®	2019	Yes
Trastuzumab	Herceptin®	Ogivri®	2017	Yes
		Herzuma®	2018	Yes
		Ontruzant®	2019	Yes
		Trazimera®	2019	Yes
		Kanjinti®	2019	Yes
Epoetin-alfa	Epogen® Procrit®	Retacrit®	2018	Yes
Pegfilgrastim	Neulasta®	Fulphilia®	2018	Yes
		Udenyca®	2018	Yes
		Ziextenzo®	2019	Yes
Rituximab	Rituxan®	Truxima®	2018	Yes
		Ruxience®	2019	No

What is a Biosimilar Product?

Biologic products are large, complex molecules produced using natural and living sources (see **Figure 1**).[3] The FDA defines a biosimilar product as a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the originator biologic or reference product).3 The biosimilar must have the same mechanism of action,

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THE ROLE OF A PHARMACIST IN THE USE OF BIOSIMILAR PRODUCTS

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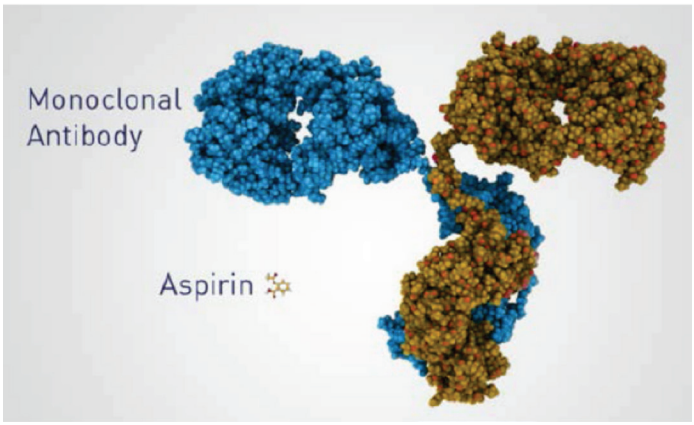
amino acid sequence, route of administration, dosage, strength, processing, packaging, and storage requirements.3

Figure 1. Structural differences between small molecules and biologic products



Aspirin (shown on the left) is a small molecule. A monoclonal antibody (shown on the right) is an example of a biologic product, which is a large molecule. A single monoclonal antibody weighs more than 800 times what an aspirin molecule weighs.3

Biosimilar Products vs. Generic Medications

Biosimilar products and generic medications are versions of brand name medications that offer more affordable treatment options for patients. Although biosimilar products and generic medications are both approved through abbreviated licensure pathways, there are important differences between biosimilar products and generic medications (see **Table 2**).[3]

Table 2. Generic medications vs. biosimilar products

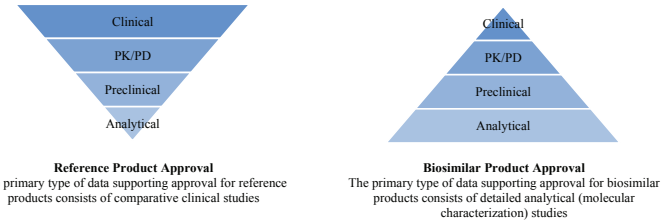
Generic Medications	Biosimilar Products
Identical to the reference product	Similar, but not identical, to reference product
80% - 90% price reduction	20% - 30% price reduction
Low development costs	High development costs
Short development timeline	Long development timeline
Interchangeable with reference product	Not interchangeable with reference product
No specific nomenclature requirements	4-letter suffix nomenclature requirement

For example, active ingredients of generic medications are the exact same as their reference product. In contrast, biosimilar product manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components. Biosimilar product manufacturers must also demonstrate that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness. In addition, there are differences in the naming processes for biosimilar products and generic medications; as of November 2019, a 4-letter suffix that is devoid of meaning must be added to the core name of all biologic and biosimilar products.3

Biosimilar Approval Process

All FDA-approved biological products, including reference and biosimilar products, undergo a rigorous evaluation to ensure that patients can rely on their efficacy, safety, and purity. However, there are slight differences in the approval process for reference products compared to biosimilar products (see **Figure 2**).

Figure 2. Approval of biosimilar products



Reference Product Approval
The primary type of data supporting approval for reference products consists of comparative clinical studies

Biosimilar Product Approval
The primary type of data supporting approval for biosimilar products consists of detailed analytical (molecular characterization) studies

A biosimilar product application must demonstrate biosimilarity to the reference product through providing the following data: (1) analytical studies that demonstrate that the biosimilar product is highly similar to the reference product, in spite of slight differences in their inactive ingredients, (2) animal studies which include an assessment of adverse effects of the biosimilar product, and (3) a clinical study which demonstrates safety, purity, and potency of the proposed biosimilar product in one or more of the indications for which the reference product is already licensed.3

The primary type of data supporting approval for biosimilar products consists of detailed analytical studies. However, randomized, controlled trials comparing the efficacy and safety of biosimilar products to reference products have been conducted within select indications. For example, a randomized, double-blind study comparing Inflectra® (infliximab-dyyb) and Remicade® (infliximab) in patients with Crohn's disease demonstrated non-inferior efficacy outcomes following six weeks of therapy and similar rates of treatment-emergent adverse events following fifty-four weeks of therapy.4

While reference product applications require clinical studies for each desired indication, biosimilar products can be approved for use in indications held by the reference product using the concept of extrapolation. A biosimilar product must have clinical data to establish efficacy and safety in at least one "key indication" suitable to detect clinically relevant differences between the biosimilar product

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and the originator biologic.5,6 Once approved, biosimilar products may be granted labeling that is identical to that of the reference product for clinical use, unless an indication is patent-protected (i.e., orphan drug designations), without requiring direct clinical studies of the biosimilar product in all indications the reference product holds. Ultimately, extrapolation is critical to the success of an abbreviated approval pathway for biosimilar products.

Pharmacists' Role in the Use of Biosimilar Products

Pharmacists can serve many roles in the use of biosimilar products, including educating providers and patients, creating policies for biosimilar product use at an institutional level, and participating in biosimilar product post-marketing surveillance.

The American Society of Clinical Oncology (ASCO) released a statement that endorses the use of biosimilar products and provides strategies for educating providers and patients.7 Key education points include clarifying the difference between biosimilars and generics, defining interchangeability and substitution, explaining naming issues, and emphasizing the need for post-market surveillance. Many resources are available to aid in education efforts, including online webinars and patient-facing infographics created by the FDA.3 Because of the wide variety of settings in which a pharmacist may practice, pharmacists are uniquely positioned to provide education to all parties affected by biosimilar product utilization.

Additionally, pharmacists may play a major role in creating policies to increase biosimilar product utilization at their institutions. Interchangeability of biologic products is established at the federal level based on the regulations set forth by the BPCIA. For a biosimilar product to be deemed interchangeable with its reference biologic product, additional information must be submitted to the FDA to demonstrate that the product is expected to produce the same clinical result as the reference product in any given patient.3 Furthermore, the risk of adverse events and diminished efficacy from switching from a reference product to a biosimilar must not be greater than the risk associated with using the reference product without switching.5 Whereas biosimilar product approval only requires demonstration that there are no clinically meaningful differences in outcomes compared to the reference product, designation of a biosimilar product as interchangeable requires that equivalent clinical results occur within the same patient if the biosimilar replaces the reference product (may require a "switching study").5 The FDA's Purple Book is an online resource that provides information about whether a biological product is a reference product, biosimilar, or interchangeable product. To date, no biosimilar product has been granted interchangeable status by the FDA. In contrast to interchangeability, substitution of biologic products is regulated at the state level. Currently, Mississippi does not have specific regulations regarding pharmacist substitution of interchangeable products. Ultimately, if a provider prescribes a biologic reference product, he/she must be contacted for approval prior to dispensing a biosimilar product instead. Within health-systems, pharmacists can be involved with creating institutional policies that allow for therapeutic interchange of a biosimilar product when a reference product is prescribed. Notably, the National Comprehensive Cancer Network (NCCN) guidelines support the use of biosimilar products across many oncology and supportive care indications. When creating institutional policies, it is important to consider if patients who are currently receiving a reference product will be switched to a biosimilar product, or if biosimilar product implementation will begin exclusively with new patients.

Finally, pharmacists can play a role in the post-marketing surveillance of biosimilar products. These efforts are vital for tracking the effectiveness, safety, and usefulness of biosimilars once deployed in clinical practice.8 Because biosimilar product approval is largely based on pharmacokinetic and pharmacodynamic data, there is a need for real-world data and monitoring of new trends in adverse events or differences in clinical outcomes. Inconsistencies in storage requirements, packaging, and compatibility with other products should also be reported. While post-marketing surveillance of biosimilar products is not required by the BPCIA for healthcare professionals, systems for collection of post-marketing data include the FDA Sentinel Initiative, FDA MedWatch, post-marketing safety registries, and integrated health information systems such as the ASCO CancerLinQ.7

Challenges Associated with the Use of Biosimilar Products

Despite the potential for cost savings and increased access to biologics through the use of biosimilar products, there are multiple challenges that must be overcome for widespread biosimilar product implementation. Barriers to implementation include patient and provider perceptions, third-party payer coverage and reimbursement, and necessary electronic medical record changes.

In order for biosimilar products to offer cost savings, the regulatory process for their approval is largely based on preclinical studies.8 Providers may have concerns about reduced efficacy or increased immunogenicity when switching from a reference product to a biosimilar product.9 Immunogenicity is the process in which a patient's body

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recognizes a biological product as foreign and produces antibodies against the drug, leading to decreased medication efficacy and/or increased risk of adverse effects.7 While there is a theoretical concern for increased potential of immunogenicity when switching between products, the PIONEER study, a phase 3 trial in which patients alternated use of biosimilar and reference filgrastim products, found that repeated switching between products did not impact efficacy, safety, or immunogenicity.10 Some providers may welcome use of biosimilar products in the supportive care realm, but may have less confidence for their use in the curative oncology setting.11 However, it is important to emphasize the rigorous scientific approval process that biosimilar products undergo, as well as provide reinforcement that the lower cost does not imply inferiority of these products.11 Patients may also need reassurance regarding the safety and efficacy of biosimilar products. Pharmacy staff can utilize the following FDA statement when educating patients: "biosimilar products are made with the same types of natural sources as the original medication they were compared to; they are given the same way, have the same strength and dosage, and have the same potential side effects. A biosimilar product provides the same treatment benefits as the original biologic."3 An important issue to consider is whether patients need to be re-consented if switching from a reference biologic product to a biosimilar product.

Another potential challenge associated with utilization of biosimilar products is the issue of third-party payer preferences and reimbursement. For instance, if multiple biosimilar products are approved for one reference biologic, will insurance plans mandate that a specific biosimilar product be utilized? Will different plans prefer different biosimilar products? If so, this may create difficulties in maintaining a streamlined inventory within health-systems. Additionally, biosimilar products may not obtain all of the indications a reference product holds due to patent protection regulations; therefore, payers may prefer a biosimilar product for some indications and a reference product for other indications. For example, Mvasi® (bevacizumab-awwb) obtained all indications its originator product Avastin® (bevacizumab) holds except for use in ovarian cancer, since bevacizumab's manufacturer has orphan drug exclusivity protection for ovarian cancer indications until 2021.5 From a reimbursement perspective, reference products and their biosimilar counterparts previously had the same Healthcare Common Procedure Coding System (HCPCS) code; thus, reimbursements were uniform regardless of what product was prescribed (i.e., higher profit margins for medications with lower acquisition costs). However, the Center for Medicare and Medicaid Services (CMS) now requires that each biosimilar product have its own specific HCPCS code. Additionally, the Affordable Care Act stipulates Medicare Part B reimbursement for a biosimilar product be based on the biosimilar's average selling price (ASP) plus 6% of the reference product's price (i.e., profit margin will now be similar for the reference product and its biosimilar products).12

Even after regulatory approval of biosimilar products, commercial availability can be delayed due to patent infringement litigation initiated by the reference product manufacturer.8 These delays to market may limit price competition and the potential cost savings achieved with biosimilar product utilization. A final challenge associated with use of biosimilar products is the changes required within electronic medical record systems. Medication orders and order sets must be updated, which may be labor-intensive and require specialized information technology training.

Conclusions

Biosimilar products have the potential to offer significant cost savings and increased access to care. Pharmacy staff are uniquely equipped to facilitate the use of biosimilar products through provider and patient education, creation of institutional policies, and post-marketing surveillance. Challenges associated with use of biosimilar products include provider and patient perceptions, third-party payer issues, patent infringement litigation, and necessary updates to electronic medical records. Despite these challenges, increased use of biosimilar products has the potential to make a significant impact on today's treatment paradigm of value-based care.

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EXAMINATION QUESTIONS

1. What is the most appropriate description of a biosimilar product?
    a. Must be pharmaceutically equivalent and bioequivalent to reference product
    b. Highly similar to reference product with no clinically meaningful differences
    c. Expected to produce the same clinical result as the reference product in any given patient
    d. Large molecule created through identical manufacturing processes as the reference product

2. Which act created the regulatory process for biosimilar approval?
    a. Federal Food, Drug, and Cosmetic Act
    b. Drug Price Competition and Patent Term Restoration Act
    c. Omnibus Budget Reconciliation Act
    d. Biologic Price Competition and Innovation Act

3. Which of the following studies is not required for biosimilar product application?
    a. Analytical
    b. Preclinical
    c. PK/PD
    d. Randomized Controlled Trial

4. To be deemed a biosimilar product, all of the following must be the same as the reference product except:
    a. Inactive ingredients
    b. Dosage form
    c. Route of administration
    d. Mechanism of action

5. Which of the following is true regarding the difference between a generic medication and biosimilar product?
    a. Biosimilar products take less time to develop
    b. Biosimilar products cost less money to develop
    c. Generic medications offer higher price reductions
    d. Biosimilar products and generic medications are both interchangeable

6. What is the recommendation regarding the naming convention for biosimilars' suffix?
    a. Suffix identifies the manufacturer
    b. Suffix identifies the batching facility
    c. Suffix is four letters that are devoid of meaning
    d. Suffix is four numerals that are devoid of meaning

7. Which type of trial supplies the primary data supporting approval for biosimilar products?
    a. Analytical
    b. Preclinical
    c. PK/PD
    d. Clinical

8. What is the term to describe the approval of a biosimilar for use in an indication held by the reference product but not directly studied in a comparative clinical trial with the biosimilar?
    a. Extrapolation
    b. Substitution
    c. Interchangeability
    d. Bioequivalence

9. What is the FDA resource for information regarding biologics, biosimilars, and interchangeability?
    a. Orange Book
    b. Red Book
    c. Blue Book
    d. Purple Book

10. Which of the following reporting systems are required for use by healthcare professionals (HCPs) by the BPCIA for post-marketing surveillance of biosimilars?
    a. MedWatch
    b. Sentinel Initiative
    c. CancerLinQ
    d. No specific post-marketing surveillance of biosimilars required for HCPs by FDA

11. Which term is used to describe the process in which a patient's body recognizes a biologic product as foreign and creates antibodies against it, which may lead to reduced efficacy of the medication?
    a. Immunology
    b. Immunogenicity
    c. Immunotherapy
    d. Immunization

12. Which was the first FDA-approved biosimilar product?
    a. Kanjinti® (trastuzumab-anns)
    b. Ruxience® (rituximab-pvvr)
    c. Udenyca® (pegfilgrastim-cbqv)
    d. Zarxio® (filgrastim-sndz)

13. All of the following medications currently have an FDA-approved biosimilar product except:
    a. Infliximab
    b. Atezolizumab
    c. Trastuzumab
    d. Bevacizumab

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EXAMINATION QUESTIONS

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14. Which biosimilar product is not currently commercially available within the US?
    a. Hadlima® (adalimumab-bwwd)
    b. Inflectra® (infliximab-dyyb)
    c. Mvasi® (bevacizumab-awwb)
    d. Retacrit® (epoetin alfa-epbx)

15. Per the Affordable Care Act, how is reimbursement for biosimilars calculated?
    a. Wholesale acquisition cost of biosimilar + 6% of reference product's price
    b. Wholesale acquisition cost of biosimilar + 6% of biosimilar product's price
    c. Average selling price of biosimilar + 6% of reference product's price
    d. Average selling price of biosimilar + 6% of biosimilar product's price

16. Which of the following pairs has been deemed interchangeable by the FDA?
    a. Rituximab → Rituximab-abbs
    b. Filgrastim → Filgrastim-sndz
    c. Epoetin alfa → Epoetin alfa-epbx
    d. None of the above

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Please submit your questions or comments to: sthaines@olemiss.edu

STOP BREAKING INSULIN PEN BOXES

PAAS National® sent out an URGENT Email Alert February 18, 2020 regarding the FDA's involvement in the breaking of insulin pen boxes. The pharmacy industry has long debated whether one box of insulin pens is considered "unbreakable". The **debate** appeared to be settled January 22nd, 2019 when the U.S. Department of Justice issued a press release1 stating Walgreens agreed to a $209 million fraud settlement with the federal government regarding its billing and dispensing of insulin pens to Medicaid, Medicare Part D and TRICARE patients. Prior to the settlement, Walgreens' policy was to not dispense any insulin pens in quantities less than one full box, forcing their staff to falsely understate the days' supply on thousands of claims. They then enrolled many of these patients on its refill reminder program, causing patients to get early refills. The government labeled that billing activity as widespread FRAUD and required Walgreens to enter into a Corporate Integrity Agreement with the Office of the Inspector General. Consequently, both Walgreens and CVS have been breaking insulin pen boxes when appropriate.

Since that time, PAAS has seen OptumRx, Express Scripts, Humana, Prime Therapeutics, and EnvisionRx dramatically increase their audit recoupments on insulin pens being dispensed that exceed plan limits.

To complicate the matter, the FDA got involved June 20, 2019 when it sent a "Safety-Related Supplement Request" to Eli Lilly, Sanofi, and Novo Nordisk requesting:

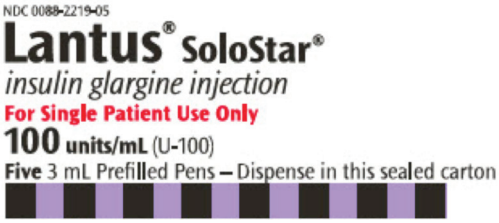
"…updates to the Prescribing Information (PI) and carton labeling to specify that pens be dispensed in the original sealed carton…"

Consequently, the manufacturers submitted supplemental new drug applications (sNDAs) to update the information accordingly and on **November 15, 2019 the FDA published updated labeling[2].** PAAS National® has been in correspondence with the FDA and manufacturers to better understand the June 20th request. From a Freedom Of Information Act (FOIA) request through the FDA, PAAS has learned that the request was due to a Tracked Safety Issue (TSI) opened June 25, 2018 for insulin pen products and medication errors (packaging confusion – opening cartons to dispense single insulin pens)

It is important to note that PBMs are aware and will likely enforce the revised standard during audits (**i.e. do not break insulin pen boxes)**. PAAS just received audit results where the PBM expected insulin pen boxes to have been broken between 1/22/2019-11/15/2019, and post-11/15/2019 they are expecting full insulin pen boxes to be dispensed. The absurdity is not lost on PAAS, but PBMs will use anything they can to deny paying claims - especially high dollar insulin claims.

Updated Section 16.2 of the package insert, and the exterior carton, will now state to dispense in the original sealed carton. Your supply chain and inventory management will dictate when you start seeing the revised product labeling, if you haven't already.

6.2 Storage
Dispense in the original sealed carton with the en closed Instructions for Use.



PAAS has been able to confirm ALL insulin pen products on our **Insulin Medication Chart** (a PAAS member benefit) have updated product labeling on the Carton and in Section 16.2 (with the exception of Insulin Lispro (AG) and Novolog Cartridges). This includes combination products, Soliqua® and Xultophy®. We have not seen any revisions with GLP-1 Receptor Agonist products (e.g. Victoza, Trulicity, etc).

PAAS Tips:

- Pharmacies should always try to first bill an accurate days' supply based on the prescribed quantity– many insurers have accommodated days' supply limits well in excess of 90 days
- If plan limits are exceeded follow the guidance below:
  - o Multiple cartons – reduce the # of cartons and corresponding days' supply until the claim will adjudicate. Document Insurance Limits Quantity (e.g. ILQ = 30 days) on the hard copy.
  - o Single carton (in order of prefecence):
- Call the help desk and request an override
- If no override is available, adjust the days' supply to the Plan Limit

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- Best practice: note the actual days' supply in the patient sig – and make patients/staff aware of the process
- Do NOT refill the product early. When overriding the accurate days' supply to meet plan limits, pharmacies can no longer rely on adjudiction to properly reject claims that are refill too soon. All PBMs (including Caremark) will recoup for early refills on an audit. Since the original claim was rejected with an accurate days' supply, PBMs know the actual day's supply and will be looking for pharmacies that refill it earlier than allowed.

- Open boxes in inventory – PAAS recomends using up any open boxes as soon as possible prior to transitioning. Be sure to include a Patient Instructions for Use.

PAAS Members are encouraged to visit the Tools & Aids section of the PAAS Member Portal to find updated versions of our popular tip sheets:

1. Can You Bill It As 30 Days?
2. Insulin Medication and Injectable Diabetic Medication Charts
3. Diabetic Injectables FAQs

FAQs answered

We have received many questions from pharmacies regarding this important change. Here are the most common questions:

Claim Processing

1. **Will PBMs allow claims with a days' supply greater than 90?**
   Many pharmacies report that claims will successfully process for greater than 90 days. Pharmacies should always start by submitting an accurate days' supply for a full box and follow plan messaging, See *Can You Bill It As 30 Days?* in the PAAS Member Portal for additional guidance.

2. **Does the pharmacy need to get a new prescription for a larger quantity?**
   In general, we advise pharmacies to avoid increasing the dispensing quantity (even if enough refills exist) and obtain new prescriptions. Failure to do so could result in an increased audit risk (even if legally allowed to do so in your state).

3. **Can the pharmacy change to insulin vials?**
   There may be scenarios where patients want to switch to vials because they cannot afford the copay associated with a 90-day or 140-day supply. If clinically appropriate, we suggest that pharmacies contact prescribers to obtain authorization for a new prescription for vials (and syringes).

4. **What if patients cannot afford the copay?**
   In general, patients may request a smaller quantity to avoid paying two or three copays, however this is no longer an option with insulin pens as the "smallest package size" is one full box. Patients or pharmacies may be able to call PBM to request copay overrides – for example, if one full box is a 45-day supply and the patient is being charged two copays. Document any helpdesk advice with a 4-element clinical note. Additionally, patients may consider the pros and cons of switching to vials.

5. **Why is my reimbursement going down?**
   We suspect that pharmacies are processing more insulin pen claims for extended day's supply (> 30 days). PBM contracts have more aggressive rates for extended days' supply dispensing. Pharmacies may consider contacting their PSAO or the PBM to try to opt out of these networks. Submitting a false days' supply (e.g. 30 days) when the product should really last 90 days, and the plan allows 90 days, is a contractual violation and would probably be considered fraudulent.

LTC Pharmacy

6. **Does this apply to LTC practice?**
   Yes, FDA-approved labeling applies to all practice settings and pay types.

7. **Can I open the box to label individual pens for LTC facilities?**

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STOP BREAKING INSULIN PEN BOXES *Continued from page 17*

The revised outer carton labeling and section 16.2 of the product labeling indicate "*dispense in the original sealed carton*" which implies that pharmacies cannot even open the box to label individual pens for LTC facilities that may mandate such labeling for medication carts. Part of the decision appears to be concern over supply chain security & counterfeit product entering the supply chain. Sealed boxes make it more difficult for counterfeiters. Consider labeling an unopened box inside a labeled plastic bag (that's TWO labels). Facility staff can then open the sealed box and put one pen into the labeled bag for administration, while keeping the remaining pens in the labeled box in the fridge. To avoid medication errors, nurses would need to use extreme caution with this method to ensure the right insulin, for the right patient, is in the right bag.

Audits

8. **Will PBMs recoup on claims where we opened boxes after November 15, 2019?**
   The revised FDA labeling wasn't well known in the community pharmacy industry until February 2020. While PAAS hopes for PBM discretion (i.e. a 4 month grace period where pharmacies are okay to break or not break the boxes), we saw no such leniency granted to pharmacies when the Walgreens' DOJ decision was publicly announced on January 22, 2019 – in fact, we continue to see audits where PBMs are expecting pharmacies to have broken boxes back into 2018. An argument can be made that existing stock did not have the revised labeling – PAAS will help you make those arguments on audits should it come to that.

9. **Will PBMs issue written guidance such as fax memos or update Provider Manuals?**
   There was no explicit guidance issued subsequent to the Walgreens' DOJ decision, but most PBMs were quick to audit claims and enforce. We continue to encourage various audit departments to provide clear expectations on audit policies. On March 20, OptumRx sent a one-page memo entitled "Accurate Billing for Insulin Pens" confirming the FDA labeling update and reminding Network Pharmacies how to correctly submit claims. In particular, Optum states:

- Pharmacy Provider must request an override through the pharmacy help desk when rejected for plan limits and dispensing in the smallest commercially available package size (typically 15 mL per carton).

- If an override is not available and the days' supply is altered, pharmacies must ensure the refill interval is based on the actual days' supply, not the submitted days' supply (or risk audit recoup ments).

PAAS is not aware of additional PBM guidance; and much like MAC pricing, the more vague and opaque policies are, the more broadly they can be applied to benefit the PBM.

PAAS Tips:

- Please alert PAAS of any PBM communications that you receive so that we can aggregate and share with other members
- We expect that PBMs will be forced to update their adjudication claims logic to allow days' supply in excess of the standard limits and possibly implement hard edits to require quantities in multiples of full boxes at some point

Here at PAAS National®, we are committed to serving your needs and want to help you run your Pharmacy efficiently. Upon receiving notification for an audit or results, (608) 873-1342 or info@paasnational.com members are encouraged to reach out to us immediately so we can assist them through the whole audit process.

By Trenton Thiede, PharmD, MBA, Chief Operating Officer at PAAS National®, expert third party audit and contract advice. For more information, call (888) 870-7227 toll-free or visit paasnational.com.

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