

Biosimilar Policy Positions

1. Support use of biosimilars
2. Naming
 - a. Biologics and biosimilars share same non-proprietary name
 - b. Use of suffix in naming
3. Labeling – biosimilar label requirements are the same as those for innovator projects (i.e., no additional unique requirements for biosimilars)
4. Support pharmacists’ ability to substitute an interchangeable biosimilar for reference product without provider notification
5. Position on pharmacy recordkeeping requirements and provider notification requirements
6. Support extrapolation of indications for which the innovator product is approved
7. FDA Purple Book as official reference on biologics and biosimilars

Organization	Information Relating to above	Related to topics listed above	Link
APhA	<p>2016 - Biologic, Biosimilar, and Interchangeable Biologic Drug Products</p> <ol style="list-style-type: none"> 1. APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products. 2. APhA urges the Food and Drug Administration (FDA) to expedite the development of standards and pathways that will evaluate the interchangeability of biologic products. 3. APhA recognizes the Food and Drug Administration's (FDA) Purple Book as an authoritative reference about biologic product interchangeability within the United States. 4. APhA opposes interchangeable biologic product substitution processes that require authorization, recordkeeping, or reporting beyond generic product substitution processes. 5. APhA encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes. <p><i>(JAPhA 56(4); 369 July/August 2016)</i></p> <p>2012, 2007 - Biologic Drug Products</p> <ol style="list-style-type: none"> 1. APhA encourages the development of safe, effective, and affordable therapeutically equivalent generic/biosimilar versions of biologic drug products, including clinical trails that assess safety. 2. APhA encourages the FDA to develop a scientifically based process to approved therapeutically equivalent generic/biosimilar versions of biologic drug products. 3. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products. 	1, 2, 3, 4, 6, 7	<p>https://pharmacist.com/policy-manual?key=biosimilar&op=Search</p> <p>https://www.pharmacist.com/apha-advocacy-issues</p>

	<p>4.APhA should initiate educational programs for pharmacists and other health care professionals concerning the determination of therapeutic equivalence of generic/biosimilar versions of biologic drug products <i>(JAPhA NS40(5):Suppl. 1:58 September/October 2000) (Reviewed 2002) (Reviewed 2007)(Reviewed 2012)(Reviewed 2016)(Reviewed 2017)</i></p> <p>APhA strongly supports the development of biologics and biosimilars as well as state biosimilar substitution practices that mirror those for small-molecule drugs unless science dictates otherwise. APhA has advocated against unique names and/or suffixes for reference biologics and biosimilars for reasons including such distinction could contribute to confusion regarding biosimilar interchangeability.</p> <p>2004, 1971 - Anti-substitution Laws: Pharmacists' Responsibility APhA supports state substitution laws which emphasize the pharmacists' professional responsibility for determining, on the basis of available evidence, including professional literature, clinical studies, drug recalls, manufacturer reputation and other pertinent factors, that the drug products they dispense are therapeutically effective. <i>(JAPhA NS11:260. May, 1971) (JAPhA NS 44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)(Reviewed 2017)</i></p>		
AMCP	AMCP supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies by the U.S. Food and Drug Administration (FDA). Biological products play an increasingly important role in the country's health care system - both in terms of scientific improvements in the treatment of disease and increased drug costs.	1,2,3,4,6	http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20018 http://www.amcp.org/BBCIC/
ASCP	Supports the work of the Biologics & Biosimilars Collective Intelligence Consortium (BBCIC)	1	https://www.biosimilarsresourcecenter.org/about-brc/
ASHP	<p>1816 – Biosimilar Medications (page 24 of policy positions)</p> <p>1.To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,</p> <p>2.To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,</p> <p>3.To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore supports substitution for the reference product without the intervention of the prescriber; further,</p> <p>4.To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,</p>	1,2,4,5,6	https://www.ashp.org/-/media/assets/policy-guidelines/docs/browse-by-document-type-policy-positions-1982-2018-with-rationales-pdf.ashx?la=en&hash=86E6F53637C770606B8AF5D914380978A4B68AD0

	<p>5. To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,</p> <p>6. To support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; further,</p> <p>7. To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,</p> <p>8. To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA; further,</p> <p>9. To promote and develop education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,</p> <p>10. To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.</p> <p>1716 – Greater competition among generic and biosimilar manufacturers (page 54 of policy positions) To advocate for legislation and regulations that promote greater competition among generic and biosimilar pharmaceutical manufacturers.</p> <p>1535 – Nonproprietary naming of biological products (page 108 of policy positions) 1. To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further, 2. To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.</p>		<p>Search with control + F (windows) “biosimilars”</p>
<p>HOPA</p>	<p>Importance of Biosimilar Naming Health care providers, patients, manufacturers, and regulatory agencies must be able to identify that a product is biosimilar to the original branded medication, and they must be able to associate the medication with the appropriate therapeutic class to assure appropriate prescribing. Naming is important to avoid prescribing and dispensing errors. Further, biosimilars must be able to be easily tracked to monitor safety and quality. Pharmacists are uniquely positioned to understand the important role that naming will have in ensuring appropriate medication substitutions take place when biosimilars are used.</p> <p>Recommendations: Standards to Ensure Access, Safety, and Affordability Legislation defining the parameters by which pharmacists may substitute a biosimilar for the reference product is currently</p>	<p>1, 2, 3, 4, 6, 7</p>	<p>http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/HOPA_Biosimilars_Issue_Final_Dec_2015.pdf</p>

	<p>premature because issues such as naming and interchangeability have yet to be resolved. Future biosimilar substitution legislation should be developed with input from the State’s Board of Pharmacy, local pharmacy organizations, and from other healthcare providers, taking into consideration parameters within their current law regarding generic substitution as a starting point for discussion.</p> <p>Recommendations: Standards to Ensure Access, Safety, and Affordability</p> <p>The conceptual framework for determining when biosimilar indications may be extrapolated</p> <p>Criteria and clinical use standards for the automatic interchangeability of the biosimilar for the innovator medication</p> <p>Naming standards to ensure appropriate prescribing and safe dispensing—while the preferred naming convention would include using the current nonproprietary name associated with the reference product and modifying it with a prefix, HOPA supports the use of a meaningful four-letter suffix for FDA-designated non-interchangeable biosimilars</p> <p>Publishing a reference manual similar to that of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations but unique to biological medications; this reference should compare the quality attributes of a biosimilar product to the reference biologic and rate the comparability of the two products.</p>		
NABP Model Pharmacy Practice Act	Nothing is specifically mentioned about biosimilar products in the Model Pharmacy Practice Act		
NASPA	Supports the work of the Biologics & Biosimilars Collective Intelligence Consortium (BBCIC)	1	https://naspa.us/restopic/specialty-drugs-and-specialty-pharmacy/
NACDS	Biosimilars: NACDS supports policies that promote confidence in and encourage increased use of more cost-effective biosimilar medications. FDA should adopt naming policies for biosimilar drugs and biologics that are consistent with the naming conventions for brand and generic small molecule drugs, that is assigning the same individual nonproprietary name (“INN”) to a biosimilar drug product that is assigned to the reference biologic drug counterpart. Special naming policies for biosimilar drugs (and other biological drugs) that deviate from the traditional naming scheme can undermine prescriber and patient confidence in biosimilar products, thereby discouraging their use and	1,2,6,7,	https://www.nacds.org/pdfs/comm/2017/ways-means.pdf https://www.nacds.org/pdfs/government/2018/NACDS-Azar-RFI-7-16-18.pdf

	<p>jeopardizing the savings that could otherwise be achieved through increased use of more cost-effective biosimilar products.</p> <p>In a letter to Secretary of health and Human Services, Alex Azar – July 16, 2018</p> <p>8. Policy Solutions to Promote the Use of Cost-Effective Biosimilars</p> <p>NACDS strongly supports policies that will facilitate timely access to biosimilar products and promote the development of a robust biosimilars market. To that end, it is imperative that policies be implemented by FDA and other federal and state policymakers to facilitate the dispensing of less expensive biosimilar medications. This is critically important to ensuring patient access to biosimilar medications and to lower costs within the healthcare system.</p> <p>a. Biologic Naming Policies</p> <p>To further support adoption and use of biosimilar products in the broader healthcare system, NACDS urges revision of FDA’s current naming policies for biological products wherein biosimilar medications are assigned a “core name” plus a nonsensical four-letter suffix. This naming practice deviates from historical naming conventions and can lead to general confusion relative to the appropriate use, safety, and efficacy of these medications, as well as therapeutic duplication that would be detrimental to patients’ health. Moreover, naming practices for biological and biosimilar products that are different from other medications undermines healthcare provider and patient confidence in biosimilars and perpetuates the notion that biosimilars are not comparable to the innovator biologic.</p> <p>To remedy this, FDA naming policies for biological medications should be updated so that they are consistent with naming practices for small molecule medications and assign each biological medication the same nonproprietary name. This naming paradigm is familiar to healthcare providers and patients alike and promotes confidence in and use of biosimilar medications.</p> <p>b. Biologic Interchangeability</p> <p>We believe that FDA should prioritize efforts that clarify that interchangeability is merely a requirement for additional data and does not mean that the product has met some degree of higher standard of safety and efficacy. FDA does not have more than one standard of product quality for the approval of biologics.</p>		Pg 16-18
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Over the years, state generic substitution laws have enabled pharmacists to dispense cost-effective generic medications. While the overwhelming majority of states have enacted legislation to similarly allow pharmacists to substitute biosimilar products that FDA has deemed to be interchangeable, none of the biosimilar products approved by FDA have been designated as interchangeable. Consequently, pharmacists remain limited in their ability to substitute more cost-effective, interchangeable biosimilar medications given that currently available biosimilars have not been approved simultaneously with an “interchangeable” designation.

Notably, the current system disincentivizes biosimilar manufacturers from seeking an interchangeability designation for approved biosimilar products. Instead, biosimilar manufacturers are likely to only seek biosimilar approval and not complete the required studies to demonstrate interchangeability, as completing the studies necessary to demonstrate interchangeability may not be a cost-effective strategy for many manufacturers. To resolve this conundrum, NACDS urges Congress, AHRQ and/or FDA to take appropriate action to encourage and expedite the availability of interchangeable biosimilars. Recognizing that it may not be cost-effective for many biosimilar manufacturers to perform the studies necessary to demonstrate interchangeability, we encourage Congress, AHRQ, and/or FDA to explore new approaches to facilitate the performance of the required interchangeability studies. FDA could achieve this by securing federal funding for interchangeability studies of approved biosimilars, or by accepting studies performed by health systems or other private entities that demonstrate interchangeability.

Additionally, in the meantime, we urge HHS and other policymakers to encourage federal and private programs to recognize the benefit of pharmacist therapeutic interchange for biosimilars as a cost savings measure.

c. Improvements to Increase the Utility of the Purple Book

Policies and resources to facilitate the dispensing of more affordable biosimilar medications. Enabling pharmacists to substitute more affordable therapeutic alternative biological products, it is critical that FDA provide tools and resources, like the *Purple Book*, to support such dispensing.

The format of the *Purple Book* must be designed to clearly group and identify both therapeutic alternative biosimilars and interchangeable biological products with their respective reference products. This is especially important given that there are unlikely to be a significant number of interchangeable products on the market for years due to the market disincentives discussed above, and pharmacists will need to

	<p>know which products relate to a specific reference product and may therefore be appropriate for therapeutic interchange.</p> <p>Finally, we believe that the terms describing biosimilars in the <i>Purple Book</i> are confusing to most laypersons. We recommend that FDA use the simplified term “Clinically Equivalent” to mean “no clinically meaningful differences.”</p> <p>d. Educating Providers and Patients</p> <p>As HHS noted in the RFI, physician and patient confidence in biosimilar and interchangeable products is critical to the increased market acceptance of these products. NACDS supports the education and outreach efforts to physicians, patients, and others to facilitate awareness, understanding, and adoption of biosimilars. We encourage FDA to continue efforts to educate healthcare providers and the public about biosimilar medications. Initiatives such as continuing education programs designed to familiarize healthcare providers with biosimilar medications and multi-media public awareness campaigns can be useful to promote further understanding and adoption of biosimilar medications.</p> <p>Specifically, biosimilar education should stress that biosimilars are designed to match the structure and function of the reference biologic; patients should be assured that FDA-approved biosimilars have the same safety and efficacy as their reference products. Moreover, FDA should convey that the Agency approves biosimilars utilizing the same high standards for manufacturing and quality that apply to all biologics. The Administration should educate that the availability of biosimilars is anticipated to lower cost burdens for the U.S. health care system.</p> <p>e. Development and Product Review</p> <p>To foster timelier biosimilar development and uptake, we recommend that FDA prioritize hiring to fill the remaining Biosimilar User Fee Act positions to ensure that manufacturer and FDA plans for the biosimilar market may be fully realized. Moreover, a fully-staffed biosimilar team at FDA is critically important for the development and evolution and FDA biosimilar policy, as well as education efforts, considering the need to counter ongoing misinformation campaigns that are frustrating the uptake and utilization of biosimilars.</p>		
NCPA	<ul style="list-style-type: none"> • NCPA generally supports the biosimilars initiative to promote innovation, increase competition, and possibly result in cost savings. NCPA supports the movement to educate health care professionals and patients. • NCPA is part of the Biosimilars Roundtable and as a group we developed a two-pager that is essentially a fact sheet. • NCPA’s main concern/push is on the interchangeability aspect, which permits pharmacist substitution of a biosimilar without the involvement of the prescriber. <ul style="list-style-type: none"> ○ Currently, the FDA has not yet approved an interchangeable product, but 45 states and Puerto Rico have passed legislation allowing for substitution at the pharmacy level if the biosimilar has been designated by the FDA as interchangeable. ○ In line with what our interchangeability position statement says, we would caution against proposals that would place special requirements on pharmacies for the interchange of biosimilars. • In reference to the naming comments, the FDA finalized this guidance on Jan 2017, but NCPA opposed adding a suffix to the name of a biosimilar because: <ul style="list-style-type: none"> ○ confusing and complex naming conventions may lead healthcare providers to question the perceived safety and efficacy of these products; ○ decreased patient access to these products may occur; and 	1,2,4	http://biosimilarforum.org/PDFs/The%20Basic%20Facts%20About%20Biosimilars%20-20-Biosimilars%20Forum.pdf

	<ul style="list-style-type: none"> ○ there may be an increased opportunity for medication errors related to the dispensing and use of these products. 		
Pharmaceutical Care Management Assc. (PCMA)	<p>In finalizing guidance, the FDA should promote an interchangeability policy that will allow for greater patient access to these important drugs. Increasing competition through the approval of biosimilar, brand and generic drug competitors is the key to lowering prescription drug costs for consumers, employers, and public programs.”</p> <p>With numerous specialty drug patents expiring in the next five years, manufacturers are readying new biosimilars for introduction into the market. By 2020, 12 biologic products with global sales of more than \$67 billion could face biosimilar competition. A biosimilar is a biologic product that is approved and judged by the FDA to be highly similar to another FDA-approved biologic product (known as a reference product) and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilars.</p> <p>Patient advocates and payers anticipate biosimilars will foster competition and deliver increased savings from negotiated discounts. Biosimilars are generally priced about 20 percent below their brand-name counterparts and after several years of competition would be priced as much as 40 percent below the reference product.</p>	1	<p>https://www.pcmanet.org/pcma-statement-on-fda-biosimilar-action-plan/</p> <p>https://www.pcmanet.org/policy-issues/biosimilars/</p>
National Association of Specialty Pharmacy	Nothing specifically available online regarding their policy stances.		
ACCP	Supports the technological advances (e.g., genome sequencing, enhanced diagnostic testing capabilities) that have fundamentally altered pharmaceutical sciences research and new product development and fostered unprecedented therapeutic innovation in specialty drugs, including those targeting specific biomarkers or genotypes, novel agents for rare diseases (e.g., cystic fibrosis or Gaucher disease), biosimilars, and interchangeable biologic products.	1	https://www.accp.com/docs/positions/positionStatements/Specialty%20Drug%20Use%20Final%203.1.17.pdf
CPNP	No specific information available online regarding biosimilar policy positions.		