Your Generics & Biosimilars Industry

Biosimilars Council
A Division of AAM

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Comments from The Association for Accessible Medicines (AAM) and the Biosimilars Council on behalf of our member companies, regarding Docket FDA-2018-N-2689, Facilitating Competition and Innovation in the Biological Products Marketplace, Public Hearing; Request for Comments

The Association for Accessible Medicines ("AAM"), and its Biosimilars Council ("Council") (collectively referred to in these comments as AAM), are pleased to provide comments to the FDA regarding the biosimilars action plan and ways to facilitate competition in this critical industry.

AAM represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Generics represent greater than 90% of all prescriptions dispensed in the U.S. by volume, but only 23% of the cost expended on prescription drugs. AAM is the sole association representing America's generic pharmaceutical sector in the United States. The Council, a division of AAM, works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and educate stakeholders and patients about the safety and effectiveness of biosimilars. Member organizations include companies and stakeholder organizations working to develop biosimilar products with the intent to participate in the U.S. market.

AAM appreciates and supports FDA's continued efforts to foster biosimilar competition in the interest of building a sustainable marketplace for these new medicines for America's patients. Absent additional measures to build healthy biosimilar competition, AAM and its members are concerned that the development of this nascent industry is in jeopardy, a perspective echoed by Commissioner Gottlieb when he noted, "Our ability here at the FDA to build a market of safe, effective biosimilar products is key for patients, and its key for the nation's health care system. It's also a key to us to promoting access and reducing health care costs. And it's a key to advancing public health. But we are worried, and I'm worried in particular, that the market for these products is still not firmly established. And the ability of these products to penetrate clinical practice and gain acceptance in clinical practice isn't yet firmed up. That doesn't mean that the future doesn't hold a lot of promise for biosimilars. It just means in my view that the future is

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uncertain, and the policy, and the regulatory decisions that we make, here in the present day, are going to have a lot to do with whether or not we realize the promise from this new category of products. Or whether we see the opportunities we once envisioned from biosimilars, go unrealized."

A robust biosimilars market is vital to spur future innovation while ensuring health care costs benefit from the competition of lower-priced alternatives. Yet, the few launched biosimilar medicines in the United States have been slow to gain market share, to the detriment of patients and payors. This is largely due to tactics used by some originator biologic companies that abuse their dominant market position to create as many barriers as possible to biosimilar approval and uptake, for example: restricting access to samples needed for biosimilars development; establishing "patent thickets" intended only to make the cost of litigation prohibitive and thereby prevent competition; and sowing seeds of doubt regarding the safety and efficacy of FDA-approved biosimilars through misleading communication to prescribers and patients.

In the Federal Register of July 25, 2018,[1] FDA published a notice announcing that on September 4, 2018, it intended to hold a public hearing under 21 CFR Part 15 to solicit input from the public on "how to facilitate greater availability of biosimilar and interchangeable products while retaining the balance between competition and innovation that Congress intended to achieve under the [Biologics Price Competition and Innovation Act of 2009] BPCI Act."[2]

AAM and its members participated in the hearing and made the following recommendations to FDA of steps to take to help realize the full potential of the U.S. biosimilars market:

- Work within HHS to advance incentives to ensure further market penetration and timely adoption of lower-priced, life-saving biosimilar medicines;
- Work with the Patent and Trademark Office (PTO) to stem the issuance of non-innovative patents used to extend monopolies, and support the use of Inter-Partes Review;
- Work with the Office of the United States Trade Representative and advocate for the rejection of provisions in the announced trade understanding between the U.S. and Mexico to extend brand name biologic data protection to ten years;
- Continue to work to prevent the misuse of restricted access programs to block biosimilar development;
- Accelerate the education of physicians, patients and other key stakeholders regarding the safety and effectiveness of FDA-approved biosimilars, and address misinformation campaigns designed to deter switching to biosimilars;
- Improve the Purple Book to make it more useful for pharmacists and others who will look to it to obtain information
- Help combat patent abuse by brand manufacturers, where appropriate, including by allowing biosimilar applicants to seek licensure for fewer than all indications for which a reference product is licensed;
- Allow use of non-U.S. licensed reference product during biosimilar development without requiring the use of unnecessary bridging studies; and

[1] 83 FR 35154.
[2] Id. at 35155.

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- Advance biosimilar interchangeability through issuing revised or final interchangeability guidance that addresses stakeholder comments regarding the scientific and economic concerns of pursuing the designation. [3]

Below, AAM provides additional detail on some of these as well as other potential ways FDA can help biosimilars and interchangeable products reach patients more quickly in response to the specific questions FDA posed in the notice. AAM also anticipates providing supplemental comments to the docket following the release of the Part 15 Hearing transcript, in response to comments by stakeholders as well as questions from FDA panelists.

Improving the Purple Book

The current version of the Purple Book contains very little information about exclusivity for most currently marketed biological products. FDA has explained that "[a]lthough FDA has not made a determination of the date of first licensure for all 351(a) biological products included on the lists, it does not mean that the biological products on the list are not, or were not, eligible for exclusivity. A determination of the date of first licensure and of when any remaining reference product exclusivity will expire for a biological product submitted under section 351(a) of the PHS Act will generally be made for reasons of regulatory necessity and/or at the request of the 351(a) application license holder."[4]

AAM requests that FDA update the Purple Book to clarify which products have been determined not to have exclusivity (e.g., those where any exclusivity period would have expired, if it applied in the first place) and those that are still subject to pending decisions. This will provide greater clarity to sponsors considering the development of biosimilar and interchangeable biologics and allow them to request exclusivity determinations for specific reference products, if necessary. We suggest that a mechanism be created whereby FDA makes an exclusivity determination upon the request of a biosimilar applicant, not just the BLA holder or on the Agency's own initiative.

Additionally, at present, the Purple Book is comprised of static tables. To improve the usability and user experience of the Purple Book, we suggest that the Purple Book be converted into a single searchable electronic database combining the current separate CDER and CBER list of approved products with a preamble/introduction that defines basic terms. Moreover, it is not clear which biological product served as the reference product for a biosimilar product and AAM believes it would also be helpful if the Purple Book identified the reference product for the approved biosimilars product.

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[3] AAM & Biosimilars Council Comments on "Considerations in Demonstrating Interchangeability With a Reference Product; Draft Guidance for Industry" Available at: https://www.regulations.gov/document?D=FDA-2017-D-0154-0028

[4] FDA. "Background Information: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)." Available at: https://bit.ly/2tWK07F. Accessed: July 5, 2018.

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Facilitating the Evolution of the Biosimilar and Interchangeable Product Marketplace

To facilitate the evolution of the biosimilar and interchangeable product marketplace, FDA should revise the approach proposed in its draft guidance on interchangeability[5] to ensure that manufacturers can obtain an interchangeability designation through an economically viable process. .[6] . Current draft guidance from FDA indicates that manufacturers will need to conduct complex and costly multi-switch clinical trials with U.S. sourced reference product to demonstrate interchangeability.[7] AAM provided comments to the docket on the draft guidance and hopes that the final guidance will address some of its concerns so that the interchangeability designation will contribute to manufacturers' ability to directly deliver lower-cost options to patients.

Additionally, it remains critical for stakeholder confidence that the FDA continue to educate patients, healthcare providers and other stakeholders regarding biosimilarity and interchangeability, including explaining the concept of interchangeability in easily understandable terms. To do so, the FDA must underscore that the product quality requirements for all biological products, including originator biologics, biosimilars and interchangeable biologics are identical. The FDA can also educate physicians why pharmacy level substitution for interchangeable biologics is as medically sound and justified as it is for generic drugs.

Building Stakeholder Confidence

As FDA has recognized abroad range of health care professionals will be engaged in biosimilar prescribing, dispensing and utilization. This includes doctors, physician assistants, nurses and pharmacists, and education tailored to each role is important. Similarly, collaboration with patient advocacy groups and disease-specific organizations to improve understanding is essential to acceptance of biosimilars. Provider and patient acceptance will be key to enabling market adoption.

We commend FDA for introducing provider educational materials about the FDA approval pathway for biosimilar products, the data and information that FDA reviews to determine biosimilarity, and basic definitions of key terms.

Such efforts must continue in tandem with the emerging marketplace. As the FDA works to develop additional resources for stakeholders, we urge that the agency expand efforts focused on: promoting and instilling confidence in biosimilar safety, efficacy and quality; defining and utilizing terminology and key concepts in a manner that is easily comprehended by a variety of stakeholders; prioritizing and targeting stakeholder audiences who stand to benefit most from a comprehensive understanding of biosimilar and interchangeable products, and tailoring resources for their unique information needs.

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[6] FDA: Considerations in Demonstrating Interchangeability with a Reference Product: Draft Guidance for Industry, Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf.
[7] Id.

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Unfortunately, misinformation threatens to slow biosimilar uptake and undermine confidence in these FDA-approved products. These efforts, often driven or silently funded by originator reference biologic manufacturers, are intended to sow doubt among patients and prescribers regarding biosimilars' safety and efficacy, and construct regulatory, policy and legal roadblocks to competition, as was highlighted in a recent Citizen Petition sent to the Agency.[8] We note that the recent Citizen's Petition focuses on misinformation materials from companies, incorrect or misleading information has also been promulgated by other organizations.[9][10] This misinformation often takes advantage of the unfamiliarity stakeholders have with biologic medicines, including biosimilar medicines, and the important role these medicines play in addressing serious or life-threatening conditions. Such misinformation threatens the health of the patients who stand to benefit most from these treatments. It is important to focus on the facts about biosimilar medicines, including their safety, efficacy and lack of clinically meaningful differences from reference products and FDA should not only disseminate truthful and non-misleading information regarding biosimilars as broadly and effectively as possible.

In this regard, we believe FDA should clearly address the fact that transitioning, or "switching" patients who are stable on a reference medicine to a biosimilar is safe. As more biosimilars enter the U.S. market, branded biologic makers are raising the concerns that such switching is dangerous, either as a result of immunogenicity, adverse reaction to a new medicine, or based on some other unfounded assertion. This transition is often referred to as "non-medical switching", an ambiguous term that many brand biologics stakeholder organizations use, disingenuously, to highlight the scientifically unsound point that transitioning from an originator to a biosimilar medicine is not safe and is done to save money for payors at the expense of patient outcomes. FDA can address this misleading tactic directly, by clarifying that use of the term "non-medical switching" in the context of transition to biosimilar medicines is inappropriate. The use of this term also highlights a gap in stakeholder understanding of the basic science on which biosimilarity is based, and FDA should consider this an education opportunity. FDA should work with stakeholder groups to ensure understanding of important facts about biologic medicines, including biosimilars. For instance, FDA can further clarify that any variation between the originator and biosimilar is within the bounds of variability established by the originator across various lots, and that FDA carefully assesses data regarding the risk of immunogenicity related to both the originator and biosimilar medicine. Greater provider and patient confidence are needed in the fact that only those patients responding well to an originator biologic medicine are candidates for a transition to a corresponding biosimilar, contrary to misleading 'fail-first' policies seen in formularies because of originator tactics.

Another opportunity arising for FDA education because of originator tactics to undermine confidence in transition to biosimilar medicines is to highlight on the FDA website and in

[8] https://www.regulations.gov/document?D=FDA-2018-P-3281-0001

[9] Michael Reilly, Opinion: Patients on biologics need to be wary of substitutions, Vancouver Sun (December 25, 2017), available at https://vancouversun.com/opinion/op-ed/opinion-patients-on-biologics-need-to-be-wary-of-substitutions.

[10] https://www.centerforbiosimilars.com/contributor/carlos-sattler/2018/06/letter-to-the-editor-european-pharmacovigilance-for-biosimilars-is-robust-and-provides-meaningful-information

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interaction with stakeholders the wealth of data available on patient use of biosimilar medicines, including after product transition. A recent systematic literature review found that switching to a biosimilar carried a low risk of safety issues or loss of efficacy and was not dangerous to patients.[11] In Europe, transition from a brand biologic to a biosimilar is a common medical practice, and there is a significant amount of data from the EU that shows that a switch from a brand biologic to a biosimilar does not carry increased risk of an adverse event. The review comprised 90 biosimilar switching studies conducted on more than 14,000 individuals and involving seven molecular entities used to treat 17 disease indications. The review concludes, "Overall, the results suggest a low risk of either a safety concern or a loss of efficacy after switching to a biosimilar."[12] One of the study's co-authors, Avalere Senior Vice President Gillian Woollett, M.A., DPhil, stated the study is aimed at reassuring all biosimilar stakeholders that, "even though no clinical differences are expected when patients are switched from a reference product to a biosimilar, indeed none are found. Hence, we confirm the expectation already established through the application of sound regulatory science."[13]

The conclusions of this large systematic review were corroborated by another review that included 53 biosimilar switching studies[14] and are also confirmed by routine postmarketing data, which has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine.[15] In Europe, patients have used biosimilars for more than 10 years, resulting in more than 700 million patient days of safe, effective use.[16] .

To increase confidence in biosimilars, as part of its educational efforts, FDA should publicize the evidence that shows that switching from a reference medicine to a biosimilar is common with no clinical differences in safety or efficacy

AAM is proud to partner with such organizations as the American Cancer Society Cancer Action Network (ACSCAN) and American Pharmacists Association (APhA) to provide accurate and detailed information related to biosimilars.

Reducing Biosimilar Development Costs

AAM appreciates FDA's recognition of the significant investment required to develop a biosimilar medicine and its ongoing efforts to ensure development programs are efficient and right-sized to meet FDA's robust scientific standards for approval. In the context of the number of lots that should be used in analytical studies to support licensure of a proposed biosimilar product and how observed variability should be accounted for, AAM urges FDA to maintain a flexible

[11] Cohen, H.P., Blauvelt, A., Rifkin, R.M. et al. Drugs (2018) 78:463.
[12] Id.
[13] The Center for Biosimilars: "We Do Not Need to Reinvent the Wheel on Biosimilar Safety, Says Avalere's Gillian Woollett." Available at: https://bit.ly/2KrgMDS.
[14] Moots R, Azevedo V, Coindreau JL, et al. Curr Rheumatol Rep (2017) 19:37-53. Available at: http://dx.doi.org/10.1007/s11926-017-0658-4.
[15] Id.
[16] IMS Institute for Healthcare Informatics, Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets, (March 2016). Available at: https://bit.ly/2eTu1NP.

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approach that is tailored to the product and program. Maintaining flexibility in the use of statistical tools, as outlined in the previous AAM submission to the now-withdrawn draft guidance titled Statistical Approaches to Evaluate Analytical Similarity ,[17] is an important component to ensuring development programs are not inappropriately disadvantaged by observed variability in the reference product. Depending on the product, biosimilar sponsors will likely require different numbers of lots to conduct the analytical assessment required to confidently address uncertainties. For some specific reference products, lots may be infrequent and extremely expensive, creating difficulties in procurement of lots for biosimilar development; in these cases, product-specific guidance may be needed. FDA flexibility regarding the number of batches required for reference and biosimilar and the scale of test batches, is critical to ensure programs are tailored and efficient while meeting the FDA's robust scientific standards.

An additional challenge faced by biosimilar sponsors related to cost of development and approval is the substantial investment risk associated with developing commercial scale capacity, and the current lack of clarity on scientifically sound and enabling policy to allow rapid post-approval scale-up. The cost of full-scale capacity presents a significant barrier early in the development and approval process, in many cases necessitating post-approval site transfers. In the interest of bringing biosimilar competition to patients in a timely manner following approval, AAM encourages FDA flexibility in working with biosimilar sponsors to accept scientifically justified reductions in stability programs for Drug Substance and Drug Product and requirements for site transfers and scale-up. We also ask that FDA consider reducing the number of lots for the U.S. reference listed drug (RLD) vs EU RLD.

Biosimilar manufacturers must not be held accountable for variability among the quality attributes of a reference biologic. However, given that marketed batches of reference product are all deemed to be clinically acceptable, we consider such batches as helping define the acceptable range of a given quality attribute that must be met by a biosimilar.

Supporting Biosimilars Development

AAM appreciates FDA's continued prioritization of efforts to improve the efficiency of the biosimilar and interchangeable product development and approval process. The ability of U.S. biosimilar manufacturers to use development data for biosimilars generated with reference products licensed outside of the U.S. has been particularly helpful in realizing improvements to efficiency of the development and approval process.

Currently, biosimilar sponsors must submit analytical and clinical bridging studies between the proposed biosimilar, the non-U.S. -licensed reference product used during the biosimilar development, and the U.S.-licensed reference product, per FDA guidance on the issue. These additional studies add significant expense to a development process that is estimated to cost between $100 and $300 million. Further, these bridging studies do not bring any added scientific value, nor increase the safety profile of the biosimilar product or the safety of the patient. Bridging between reference products sourced outside of the U.S. reference products potentially also exposes subjects to unnecessary, and costly, clinical trials.

[17] Docket FDA-2017-D-5525: Draft Guidance on *Statistical Approaches to Evaluate Analytical Similarity.*

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FDA Commissioner Gottlieb has recently indicated that the Agency is actively exploring eliminating the requirement for sponsors to conduct these expensive and unnecessary studies. AAM supports such efforts. The BPCIA does not require these studies to be conducted, rather they are recommended as FDA's policy in the Agency's own discretion. Therefore, AAM recommends the Agency expeditiously reconsider its current regulatory requirements for these bridging studies. Removing this requirement would reduce the development cost for sponsors of biosimilars and interchangeable products, in turn leading to increased patient access to more-affordable alternatives to costly reference biologics.

The bridge between the US-licensed reference product version and the non-U.S. reference (comparator) product version can indeed be established by the applicant in most cases without bridging studies, while remaining within the regulatory biosimilars framework. We consequently invite the FDA to develop, together with industry, a new regulatory framework by adopting the concept of global comparator product and allowing the waiving of bridging studies unless warranted by scientific data.

AAM proposes that[18] ,in order to qualify as a comparator product, the product must have been authorized by a Stringent Regulatory Authority (SRA) i.e. "in a jurisdiction that has a well-established regulatory framework and principles, as well as considerable experience of evaluation of the biotherapeutic products and post-marketing surveillance activities"[19] (i.e. former ICH countries, called currently Stringent Regulatory Authorities by the World Health Organization[20]). This means that the comparator product should be from "a jurisdiction that has formally adopted International Council for Harmonization (ICH) guidelines. This criterion ensures that any comparability studies that have been conducted to support manufacturing changes of the reference have been conducted according to an internationally accepted process and standard, and that the reviewing authority is experienced in operating this standard."[21]

Additionally, the comparator product should have been approved according to international ICH standards with a complete registration dossier. An evaluation report related to the comparator product's application should ideally be publicly available in the country of origin of the comparator product (e.g. the European Public Assessment Report (EPAR) issued by the EMA; the Summary Basis of Approval (SBA) issued by the FDA; the Regulatory Summary Decision (RSD) issued by Health Canada). The comparator product must be fully identifiable by the approved product name, pharmaceutical form and qualitative composition.

In terms of circumstances where bridging studies between the US-licensed Reference Product and the chosen Comparator Product can be waived; the comparator product must meet the criteria of the comparator product as described above; must have the same concentration of active pharmaceutical ingredient (API) as the US-licensed reference product; must have the same

[18] https://www.igbamedicines.org/doc/IGBA%20Submission%20%20HHS%20Blueprint%20RFI%20Response%20Document%2007-12-2018.pdf
[19] WHO/SBPQ&A/Draft/Dec 2017
[20] WHO Guidance Document 15 February 2017 Clarification with respect to a Stringent Regulatory Organization as applicable to the Stringent Regulatory Authority (SRA) Guideline
[21] A "Global Reference" Comparator for biosimilar development – Christopher Webster, Gillian Woollett; BioDrugs-published online: 19 May 2017 https://bit.ly/2Cn4g3H

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pharmaceutical form and route of administration as the US-licensed reference product (relevant for the biosimilar application) must have the same qualitative composition of excipients as the US-licensed reference product and, if the qualitative compositions of excipients are different, a justification should be provided ensuring that they have been assessed and are not expected to impact clinical efficacy and safety; was approved in the respective jurisdiction based on essentially the same original data package as the U.S. licensed-reference product, including clinical safety and effectiveness data, and additionally demonstrated via evidence in the public domain; Subsequent manufacturing changes were regulated according to ICH Q5E principles to ensure that the clinical properties remain unchanged.

AAM also notes that the draft guidance on interchangeability specifies that reference products batches to be used in the multiple switch study must be sourced from the U.S. As we understand the draft guidance, even clinical bridging studies would not be sufficient. The stated premise is that there may be differences between U.S. and ex-U.S. sourced reference product that are acceptable for establishing biosimilarity but which may be dangerous if used in a multiple switch scenario. AAM believes that this hypothetical concern is not supported by any data and that it is even illogical. The most basic underpinning of the biosimilar concept is that advances in analytics have progressed where we can analyze critical quality attributes to a sensitivity and specificity never before possible. With this now possible, it is difficult to understand how analytics are sufficient to characterize reference product for biosimilarity but not for interchangeability.

Confidentiality arrangements between regulatory agencies provide a framework for crosschecking product information and making bridging studies obsolete in most cases. The existing U.S. FDA, European Commission DG Santé and EMA confidentiality arrangements could serve as a template for confidentiality agreements with other regulatory agencies, falling within the scope of this framework. Such a confidentiality commitment allows for the exchange of confidential information related to licensed products as part of regulatory and scientific processes. To avoid unethical clinical bridging studies, as well as the multiplication of bridging studies in general by several sponsors for the same reference product, FDA and EMA now have an established and highly confidential avenue to cross check information provided by the applicant regarding the comparator and the local reference product. By doing so, the FDA and the EMA will be able to confirm the veracity of this information. The updated statements of authority and confidentiality commitment from the United States Food and Drug Administration not to publicly disclose non-public information shared by the European Commission's Director General for Health and Food Safety and the European Medicines Agency, and vice versa, are clear regarding the possibility of exchanging information on licensed products. FDA is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the European Commission's Directorate General SANTE and to the EMA regarding FDA-regulated drugs, including pre-and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities.[22] Equally, the European Commission's Directorate-General SANTE and the EMA are authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding EU-regulated drugs, including pre-and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities.[23]

[22] EMA website-United States-Confidentiality arrangement https://bit.ly/2N1mTRv; accessed on 28 June 2018
[23] FDA to EMA and DG Santé, Confidentiality Commitment https://bit.ly/2lE12D9; accessed on 28 June 2018

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Balancing Innovation and Competition – Product Changes

AAM is concerned that reference product (RP) sponsors will use product changes strategically during the lifecycle of reference products to delay or block licensure of competing biosimilar and interchangeable biological products without any meaningful benefit to patients. Brand name companies have a history of using this tactic in the Hatch-Waxman context to harm the public health by generating barriers to generic competition through the use of, inter alia, eleventh-hour formulation and labeling changes and product-hopping strategies. Although both FDA and Congress have taken strong action to counter these tactics in certain circumstances, such corrective actions often occur many years after the anti-competitive conduct has become a routine lifecycle management strategy for brand companies. AAM thus requests that, in this case, FDA take immediate, proactive measures to ensure that RP sponsors cannot game the system through minor product changes that are designed to delay the licensure of safe and effective biosimilar and interchangeable biological products.

AAM believes there are several proactive measures that can be implemented. First, FDA should adopt policies that facilitate the timely approval and continued marketing of biosimilar and interchangeable products regardless of changes to the RP during the review process or after biosimilar or interchangeable product approval. For example, FDA should presume that changes to the RP accomplished via a supplemental application would not be significant enough to affect the biosimilarity or interchangeability of an approved or pending 351(k) application. Likewise, FDA policies regarding differences in labeling between the RP and the biosimilar product should be applied in a manner that minimizes delays to licensure of a biosimilar or interchangeable biological product when the labeling for the RP is revised late in the review cycle.

Second, FDA should require RP changes that are significant enough to affect biosimilarity, interchangeability or licensure decisions to be accomplished via a new BLA rather than through a supplement to the original BLA. This will help ensure that the original RP remains intact and that the status of 351(k) products as biosimilar or interchangeable is not affected by licensure of the modified RP, or in the alternative, provide the same "interchangeability" treatment as between the interchangeable product and the modified RP as it does when it compares the modified RP with the RP. There is no basis for declining biosimilarity or interchangeability of the biosimilar with the RP or the modified RP if the modified RP is deemed interchangeable with the RP. When paired with policies described below limiting an umbrella policy to Hatch-Waxman exclusivity, it also will help ensure that brand companies cannot easily "game the system" through product-hopping tactics by replacing the original reference product with a new version at strategic times.

Balancing Innovation and Competition – Labeling Carve-outs and Changes

FDA should expedite the review and approval of carved-out indications and conditions of use by allowing applicants to rely on the prior findings of biosimilarity or interchangeability for the molecule. In many cases, a determination of biosimilarity or interchangeability will apply, as a scientific matter, to all of the RP's approved indications. Indeed, in some cases, FDA's original review of the 351(k) application and/or advisory committee recommendations may specifically determine that a proposed product is biosimilar or interchangeable to the RP for an indication that

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is not ultimately licensed because of patent or exclusivity protection. In other cases, studies to demonstrate biosimilarity or interchangeability may be conducted in an indication for which the 351(k) applicant is not seeking approval. Where a biosimilarity or interchangeability determination applies to indications for which the 351(k) applicant did not initially seek licensure, the applicant should be able to obtain approval of a carved-out indication in an expedited manner after expiration of patents or exclusivity periods with minimal regulatory red tape. In fact, AAM believes it would be appropriate to allow such indications to be approved without prior approval supplements via a changes being effected (CBE) supplement.

In addition, FDA should give 351(k) applicants broad leeway to make labeling changes to the RP's labeling in order to retain as many indications or conditions of use as possible without infringing patents or violating exclusivity rights. For example, in some cases it may be possible to avoid patent infringement by narrowing an approved indication to a certain subset of patients. Because there is no "same labeling" requirement for biosimilars, FDA should allow this type of revised labeling "carve-out" even if it entails additional labeling language establishing new limitations or different cut-offs for required tests. While the BPCIA requires that the conditions of use included in the labeling of a biosimilar must have been "previously approved" for the RP, FDA should consider a narrower indication or patient population that is included within the RP's broader indication to be "previously approved" for purposes of the statutory requirement. For example, FDA approved Erelzi (etanercept-szzs) for polyarticular juvenile idiopathic arthritis (JIA) in juvenile patients, but only those weighing more than 63 kilograms, even though the RP was also approved for juvenile patients weighing less than 63 kilograms. Although this labeling difference was the result of Erelzi's different presentations rather than patent or exclusivity protection, FDA should allow similar labeling differences to avoid patent or exclusivity protections.

Rejecting "Umbrella Exclusivity" for Biosimilars' Reference Products

FDA should not apply "umbrella exclusivity" in the context of Reference Product (RP) exclusivity because there are significant differences between the Hatch-Waxman Act and the BPCIA with respect to the role of patents and non-patent exclusivity. As a result of these differences, AAM believes that an umbrella policy (1) is explicitly foreclosed by the clear statutory language of the BPCIA, and (2) would provide undue opportunities for RP sponsors to "game the system" through product-hopping and other anti-competitive tactics, contrary to the intent of Congress. Accordingly, AAM requests that FDA announce that it will not apply an umbrella policy to RP exclusivity.

Although there are clear similarities between the Hatch-Waxman Act and the BPCIA, FDA has recognized that there also are "notable differences between the framework for follow-on biologics subject to the BPCI Act and small-molecule drugs subject to the Hatch-Waxman Amendments." One such difference is the role played by patents and non-patent exclusivity to incentivize innovation. In the Hatch-Waxman context, innovations are protected by a variety of carefully calibrated exclusivity and patent protections designed to ensure that all innovative enhancements receive an appropriate level of protection – not too much and not too little. Under this "Goldilocks" system, molecules that were never previously approved receive five years of "new

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chemical entity" (NCE) exclusivity; innovative changes to previously approved molecules receive three years of exclusivity (but only if new clinical studies are required for approval); and innovative features of a drug product that are covered by patents are protected from competition for up to 30 months to permit patent rights to be adjudicated.

In the BPCIA context, by contrast, Congress provided a single exclusivity period of unprecedented length (i.e., 12 years) instead of a series of carefully calibrated exclusivity periods. Tellingly, Congress did not provide any special protection via either exclusivity or patent certification rules for subsequent product enhancements, including significant innovations such as new indications, dosage forms or dosing regimens. Quite the opposite, Congress specifically indicates that the BPCIA does not provide any special protections for product enhancements. With respect to exclusivity, for example, the BPCIA contains an explicit limitation stating that the 4- and 12-year exclusivity periods that cover the original product "shall not apply" to (a) an approved supplement, or (b) an approved BLA filed by the same sponsor for any non-structural change (e.g., new indication, route of administration, dosing schedule, dosage form, delivery device) or any structural change that does not result in a change in safety, purity or potency. Moreover, although the BPCIA contains detailed rules for the sharing of patent information, it does not contain any patent linkage provisions whereby the timing of approval of a biosimilar or interchangeable biological product depends upon the patent status of the RP (such as a 30-month stay).

Taken together, these differences between the Hatch-Waxman Act and the BPCIA indicate that Congress was interested in incentivizing the "first licensure" of a new biological product but not subsequent product enhancements, including new indications. Instead, Congress intended RP sponsors to avail themselves of the typical protections that apply under United States law to all new inventions: patent protection. Accordingly, there is no basis for FDA to apply an umbrella policy that protects a particular "innovation" through multiple, subsequent iterations (e.g., new dosage form, new indication) since RP exclusivity does not protect any particular "innovation," and Congress clearly intended RP sponsors to rely upon the patent system to protect subsequent product enhancements.

AAM, in fact, believes that an umbrella policy is explicitly foreclosed by the clear statutory language of the BPCIA. First, RP exclusivity under the BPCIA attaches to the first licensure of the "reference product." The term "reference product" is defined as "the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." Because a 351(k) application must be evaluated not just against the RP's active ingredient or active moiety but against the entire biological product – it must have the same route of administration, dosage form, strength and conditions of use as the RP – the term "reference product" clearly refers to the biological product, not the active moiety. This differs from the Hatch-Waxman Act, where FDA justified its "umbrella policy" based upon its interpretation of the term "drug" in the bar clause to mean "active moiety." By defining "reference product" to mean product rather than active moiety, Congress indicated that RP exclusivity protects only the first licensed version of the biological product.

Second, as noted above, the BPCIA clearly states that the 4- and 12-year RP exclusivity periods "shall not apply" to (a) an approved supplement, or (b) an approved BLA filed by the same

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sponsor for any non-structural change or any structural change that does not result in a change in safety, purity or potency. This language erects a statutory bar not only to the award of a new exclusivity period to affected supplements or BLAs but also to the application of the original exclusivity period under a so-called umbrella policy. Moreover, it further confirms the intent of Congress to define "reference product" to mean biological product rather than active moiety and to protect only the first licensed version of the biological product, not subsequent versions approved via supplements or new BLAs.

The necessity of this interpretation is most clearly seen in the context of new BLAs. Under the BPCIA, exclusivity is awarded to and protects the single reference product that a 351(k) applicant relies upon for approval. If FDA were to apply that exclusivity to a new version of the RP approved via a separate BLA, FDA would be violating the statutory rule that a 351(k) application "may not be evaluated against more than 1 reference product." This is because the new product clearly would be a different "reference product" yet FDA would be applying the exclusivity of the first-licensed RP to block licensure of 351(k) applications referencing the new product. Under the BPCIA's "single reference product" rule, this is not permitted.

For the reasons set forth above, the statutory language evinces a clear Congressional intent to carefully circumscribe the scope of RP exclusivity in the biosimilar context, including rejecting application of FDA's umbrella policy. There are compelling policy reasons for this decision. When the BPCIA was passed, Congress was aware of the brand industry's widespread and unjustified "gaming" of the Hatch-Waxman system in the years since FDA announced its umbrella policy. Congress thus may have believed it was more important to limit opportunities for gaming than to provide additional incentives to innovate beyond the incentives already provided by the patent protection system. Indeed, Congress may have been especially sensitive to the opportunities for gaming provided by the unprecedented 12-year exclusivity period granted to RPs. This extremely long period of exclusivity could provide many more opportunities for brand companies to, for example, engage in product hopping tactics involving multiple, well-planned and well-timed product hops to impede biosimilar competition. Indeed, the sole purpose of the limitation's provisions described above appears to be to guard against gamesmanship and evergreening that could delay licensure of biosimilar and interchangeable biological products.

For the reasons discussed above, Congress concluded that further expanding the 12-year exclusivity period via application of the umbrella policy was unwarranted in the very different biosimilars context. Accordingly, FDA should confirm that it will follow the language and structure of the BPCIA and will not apply an umbrella policy to RP exclusivity.

Addressing Other Challenges

AAM believes there are numerous other regulatory challenges that have the potential to interfere with patient access to these important products by disrupting the balance between innovation and competition in the biological product marketplace and that are within the power of FDA to address. These include REMS abuse, non-proprietary naming, and FDA's proposed policy regarding transitional biologics. AAM and several of its members already have submitted

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detailed comments on these issues so we will simply summarize our continuing concerns below and incorporate our prior comments by reference.

Patent "thickets": As FDA noted, many biosimilar products approved by FDA are nonetheless not yet marketed or available to patients. This is due, in part, to efforts by the brand-name pharmaceutical industry to manipulate the patent system by building "patent thickets" of potentially non-innovative patents to extend their market exclusivity beyond Congressional intent. Such efforts are explicitly designed to increase litigation and development costs for potential would-be biosimilar competitors. These patent thickets chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating meritless patents.

AbbVie's Humira® is a glaring example. Humira was first approved in 2002 and treats a variety of disease states including arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease and ulcerative colitis. While Humira has been a boon for patients suffering from these conditions, it can also be prohibitively expensive, at more than $38,000 per year.[24] Although Humira's 12-year statutory market exclusivity expired in 2014 and its principal patent expired in 2016, AbbVie filed more than 75 late-stage patents in the three years prior to the 2016 expiration to delay biosimilar competition. As a result, the last Humira patent won't expire until 2034. While two Humira biosimilar competitors have been approved to date by FDA, none is available to patients. One remains in litigation and the other's manufacturer has settled out of court to mitigate the risk of prolonged, expensive litigation. AbbVie reported net revenues of $12 billion in 2017 for Humira in the U.S. alone, an increase of 18.5 percent over 2016.[25] In contrast, the EU has approved 4 biosimilars to Humira that are all set to launch later this year.[26]

This is not an isolated example. Many other brand biologic companies use this tactic of creating "patent thickets" to prevent biosimilar competition.[27] If action is not taken now to address this issue, AbbVie's example will become the playbook for how originator companies can block competition for decades.

It is critical that the patent system and regulatory approval pathway incentivize true innovation, rather than innovative gamesmanship. We urge FDA to work with the PTO to ensure a more stringent review of patents prior to their approval by the PTO as well as economically reasonable and efficient means for competitors to challenge patents that do not meet the necessary legal standards of innovation in the first place.

FDA and the PTO should support the use of inter-partes review (IPR). IPRs lend high value to biosimilar companies by providing a more accurate picture of the patent landscape in a timely and less expensive manner than typical biosimilar litigation. When biosimilar manufacturers can file IPRs earlier in the development process so that there is certainty in how to proceed, they provide even more value.

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[24] New York Times: "Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher." January 6, 2018. Available at: https://nyti.ms/2m63Byl.
[25] AbbVie Reports Full-Year and Fourth-Quarter 2017 Financial Results. Available at: https://bit.ly/2rHAWCE.
[26] https://www.reuters.com/article/us-abbvie-biosimilars/europe-ready-to-cash-in-on-cheap-copies-of-abbvie-biotech-drug-idUSKCN1LE1JO
[27] I-MAK - "Overpatented, Overpriced 2018" http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

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Exclusivity and Trade Agreements: As it relates to market exclusivity for innovator products, we are concerned that the announced trade understanding between the U.S. and Mexico to extend brand name biologic data protection to ten years will harm patients who seek more affordable medicines. This provision would harm the nascent biosimilar industry, which aims to provide price competition to some of the most expensive prescription drugs and allow patients to benefit from affordable medicines. We hope FDA will continue to work with the Office of the United States Trade Representative and advocate for the rejection of these provisions, which would benefit brand name drug companies to the detriment of public health and the affordability of medical care.

REMS Abuse & Restricted Distribution Systems: AAM is concerned that brand companies will take advantage of existing regulatory requirements, such as drug safety provisions, to stifle legitimate biosimilar competition in the same way they have done so to thwart legitimate generic competition. One of the most notable anti-competitive tactics used by brand companies in recent years involves abuse of REMS requirements and restricted distribution systems. In particular, brand companies use their REMS or self-imposed restricted access programs to deny generic or biosimilar companies access to the brand company's RLD samples needed to support ANDAs or aBLAs. Indeed, FDA acknowledges this on the webpage[28] "Reference Listed Drug (RLD) Access Inquiries", where it states "This list reflects the RLD access inquiries FDA has received from prospective generic applicants about marketed RLD products. **FDA has also received RLD (or reference product) access inquiries from prospective applicants who intend to submit new drug applications under section 505(b)(2) of the FD&C Act or biologics license applications under section 351(k) of the Public Health Service Act.** This webpage, however, is focused on providing transparency about the potential impact of this issue on generic drug market competition."

AAM is concerned that the problem of access to samples is likely to be even more acute for biosimilar development as biosimilars are more complex and difficult to develop than traditional generic drugs. Because biosimilars must demonstrate that they are "highly similar" to the brand product, multiple lots of the brand product produced over time will be required. If access to the variability that is inherent in brand lot development of biologics is impeded, the development of the biosimilar will be greatly delayed. Plus, unlike with small molecule generic drugs, the development of biosimilars is more likely to involve clinical trials requiring even more samples of the reference product. Restricted access to samples at any point during the clinical trial could cause a study to fail if patients are forced to drop out of the study due to unavailability of reference product.

AAM believes there are a number of administrative actions FDA could take to address this issue. For example, FDA could affirmatively state that REMS do not apply to studies designed to demonstrate biosimilarity or interchangeability or, more broadly, to any clinical trial conducted pursuant to an IND. Likewise, FDA could include a REMS violation clause in all approved REMS requiring the timely provision of RP samples to 351(k) applicants. These and other suggestions previously have been described in detail in AAM's previous comments, which are incorporated herein by reference. Finally, although AAM believes FDA can and should do more

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to exercise its existing authority to counter REMS abuse, AAM also believes that the problem will not be solved without additional legislation. Accordingly, AAM urges FDA to support passage of the CREATES Act to supplement FDA's existing administrative authority.

Nonproprietary Naming: For the reasons discussed in AAM's prior comments, AAM strongly opposes the naming convention FDA has adopted for biosimilar products, which requires the use of distinguishable nonproprietary names for biosimilar products by appending a meaningless, four-letter suffix to the otherwise applicable official name. Although this policy has been adopted to enhance pharmacovigilance, it is not necessary (since tracking could done with brand names or NDC numbers) and may, in fact, be counter-productive. This policy creates complex, difficult-to-remember nonproprietary names that are neither simple nor useful, contrary to applicable statutory requirements. Moreover, the use of distinguishable names suggests that there are meaningful structural and clinical differences between biosimilars and their RPs. This suggestion is highly misleading because, under the statutory standards, biosimilars must be "highly similar" to their reference products, with no clinically meaningful differences in terms of safety, purity, or potency.

The use of a distinguishable suffix in the United States is at odds with the EU, which does not require a suffix, instead using identification tools that already exist within its pharmacovigilance system including INN, brand name and batch number. The EU has approved the greatest number of biosimilar medicines worldwide and has acquired considerable experience around their use and safety.[29] "Over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine."[30] Further, the preliminary results of an ongoing EMA pharmacovigilance study showed that 95.5 percent overall product identification has been achieved for classes of biologicals for which biosimilar medicines have been approved.[31] In other words, the absence of a suffix for biosimilar products has not resulted in an increase in adverse events due to prescriber confusion or the misidentification of products that are involved in such an event.

However, predictably, RP sponsors already have started weaponizing FDA's suffix requirement to cast doubt upon the safety and effectiveness of licensed biosimilars and undermine the marketplace for such products. For example, in its recent Citizen Petition, Pfizer highlighted a recent tweet by Amgen which used FDA's requirement that biosimilars must use an appended, meaningless suffix to suggest misleadingly that there are meaningful differences between biosimilars and their RPs. In particular, Amgen urged patients to "See what you're missing without the suffix." Accordingly, FDA's naming convention will, as the Federal Trade Commission has warned, impair competition and cost savings by impeding the uptake of biosimilars and interchangeable biological products. AAM thus renews its request that FDA revise its policy so that biosimilar products share the same INN or proper name as the RP, without an appended suffix.

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[29] https://www.medicinesforeurope.com/docs/20170713%20%20Biosimilar%20Medicines%20Group,%20EU%20experience-AVH-US%20FDA%20Adcom.pdf

[30] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/05/news_detail_002739.jsp&mid=WC0b01ac058004d5c1

[31] https://www.medicinesforeurope.com/wp-content/uploads/2017/10/E.-Wolff-Holz_ESMO-satellite_2017_release.pdf

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Additionally, AAM is concerned with recent FDA comments related to the requirement that originator biologics non-proprietary names will not have to include a suffix (in both retroactive naming for past products and future products), as biosimilars do. We believe this issue was resolved in the final guidance "Non-proprietary Naming of Biological Products", in which FDA explicitly requires both originator biologics and biosimilars to have a randomized suffix added to their non-proprietary name. AAM has serious concerns that if an originator biologic is not required to have a suffix, it will seriously impact the development of the biosimilars market in United States as well create confusion regarding safety and efficacy of biosimilars by providers and patients.

Transitional Biologics: In prior comments, AAM expressed its view that FDA's proposed policy to implement the "deemed to be a license" provisions of the BPCIA is contrary to law and would impair patient access to affordable alternatives to brand name biologics. In particular, AAM warned that FDA's policy, if implemented, would create a "regulatory dead zone" for important products like insulin by creating unnecessary roadblocks to the development of transitional biologics. AAM thus requested FDA to withdraw its proposed policy and instead implement policies designed to ensure that the transition of NDAs to BLAs is accomplished with minimal disruption to the marketplace and minimal prejudice to the firm's subject to the transition.

Unfortunately, FDA has not taken action to rescind its proposed policy and, as a result, the industry is now squarely within the predicted regulatory dead zone. AAM is aware of several programs for the development of important new transitional biologics that have been delayed or put on the back burner until after March 23, 2020 because of concerns that (a) 505(b)(2) approval could not be obtained before March 23, 2020, and (b) there is no available 351(k) pathway until after March 23, 2020. This is contrary to the public health and to the goals of the BPCIA to increase patient access to safe, effective and affordable biosimilar and interchangeable biological products, including transitional biological products. Accordingly, AAM respectfully renews its request for FDA to amend its proposed policy to facilitate a streamlined transition for pending applications in a manner that minimizes the impact to ongoing development programs.

The BPCIA established the pathway for biosimilar treatments to provide an affordable alternative to costly biologic products. AAM appreciates the FDA's efforts to establish the pathway, clarify policy and educate healthcare stakeholders but more must be done.

AAM looks forward to continued dialogue with the agency on these critical topics. The public meeting was an excellent opportunity to discuss outstanding issues from all stakeholders. However, the comment period was too brief, AAM reserves the right to expand on these comments in the future after a robust scientific and technical discussion.

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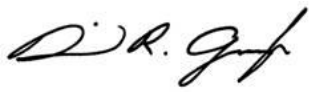
We thank you for your consideration of these comments and look forward to a continued dialogue. If you have any questions, please do not hesitate to contact the undersigned.

Sincerely,



David R. Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs

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