



February 28, 2014

Federal Trade Commission  
Office of the Secretary  
Room H-113 (Annex X)  
600 Pennsylvania Avenue NW  
Washington, DC 20580

**Re: Workshop on Follow-On Biologics: Project No. P131208**

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to the Federal Trade Commission's (the FTC's) request for comment entitled "Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition."<sup>1</sup> PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In 2012, PhRMA member companies invested an estimated \$48.5 billion in the discovery and development of medicines, representing the majority of all biopharmaceutical R&D spending in the U.S.

Although PhRMA appreciates the FTC's interest in fostering increased competition from biosimilar products, ensuring patient safety is essential in the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and the amendment of State substitution laws to permit the substitution of interchangeable biosimilars. It is the Food and Drug Administration's (FDA's) role, as the expert agency statutorily charged with regulating biologics, to apply a science-based approach to approving and naming biosimilars that is grounded in patient safety. This approach will not only protect public health but also provide patients with access to additional therapeutic options. Policies that are developed with the recognition that biosimilars are fundamentally different from generic drugs and that promote clear and accurate communication about biosimilars will increase confidence in biosimilars and thus facilitate their uptake. These policies should also aim to address current and future challenges related to patient safety and pharmacovigilance.

With these general principles in mind, PhRMA offers comments on five issues addressed in the FTC's Federal Register notice and workshop. First, we support the adoption of distinguishable but morphologically related nonproprietary names for all biologics. We strongly object to speaker claims that industry's views on distinguishable nonproprietary names and pharmacovigilance are new, pretextual positions intended to suppress competition. As a matter of fact, PhRMA has been on the record for years discussing the need for distinguishable

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<sup>1</sup> 78 Fed. Reg. 68840 (Nov. 15, 2013).

nonproprietary names to facilitate the attribution of adverse events to the correct biologic(s), which in turn will enable detection of safety differences among and between biologics. Rather, we believe that some speakers at the workshop neglected to acknowledge the patient safety considerations associated with naming, while exaggerating concerns about the potential impact of distinguishable nonproprietary names on competition.

Second, despite speaker claims to the contrary, the BPCIA does not preempt State pharmacy substitution laws, and instead preserves the States' traditional authority over the practices of pharmacy and medicine. As States amend their substitution laws to address interchangeable biosimilars, PhRMA believes that States should respect both the physician-patient relationship and the physician's authority in making treatment decisions. State legislation providing for substitution of biosimilars deemed interchangeable by FDA should include ministerial safeguards, including physician and patient notification regarding automatic substitution, to ensure accurate medical records and facilitate patient safety. We believe that some speakers incorrectly asserted that these ministerial safeguards would negatively affect competition, and underemphasized the importance of State amendments to build in safeguards to protect against inappropriate biosimilar substitution.

Third, although there is some uncertainty about market dynamics resulting from the entry of biosimilars, spending on specialty medicines, of which most definitions include biologics, must be placed in context.

Fourth, PhRMA believes that an *FDA-maintained* reference guide listing FDA-approved biologics and FDA's determination of interchangeability, or lack thereof, for FDA-approved biosimilars to their reference products would be valuable.

Fifth, the European biosimilars experience is not directly relevant to the (future) competitive environment for biosimilars in the United States.

Finally, we firmly disagree with the United States Pharmacopoeia's (USP's) suggestion at the workshop and elsewhere about the potential significance of USP monographs to the nonproprietary names of biologics.

## **I. Background: The Generic Model Is Inappropriate for Biosimilars.**

During the workshop, numerous speakers emphasized the generic drug model as precedent for their positions on naming conventions for biologics and State biosimilar substitution laws, among other things. These comments ignore the substantial ways in which biologics differ from small molecule drugs. Biologics are much more complex and heterogeneous than small molecule drugs. Further, contrary to comments made during the workshop, biologics are inherently subject to structural variation for a number of reasons, including the fact that they are manufactured in living cells and their function is heavily dependent on proper folding and stability of higher order structure. Even small changes to a biologic's manufacturing process, formulation, or packaging can potentially affect the product's structural, functional, and clinical properties. In addition, biologics change or "drift" over their life cycles as manufacturers implement process changes. Manufacturers must therefore comply with rigorous regulatory requirements to establish and complete comparability exercises to show

that biologics remain safe, pure, and potent after manufacturing changes. These requirements ensure a continued understanding of the clinical profile of the biologic that is based on experience and extensive monitoring and testing of the product.

Biosimilarity exercises share some scientific principles with the comparability exercises described above for manufacturing changes, but are even more complex because of the fundamentally different process for designing a biosimilar. The biosimilar manufacturer must independently design its manufacturing process de novo, which will differ from that of the reference product with respect to facilities and cell lines, among other things. Additionally, biosimilar manufacturers will not be privy to the manufacturing process history for the reference product. For the above reasons, unlike generic drugs, biosimilars cannot be proven to be the “same” as their reference products by current analytical techniques. Accordingly, the BPCIA requires biosimilars to be “highly similar” to their reference products instead.<sup>2</sup> Individual biosimilars also will not be proven biosimilar to each other, as FDA lacks statutory authority to require this showing, and the scientific standards and regulatory pathway for such a showing are undefined. And meaningful differences between reference products, biosimilars, and even interchangeable biosimilars could develop over time as each manufacturer implements process changes.

Moreover, in comparison with small molecule drugs, biologics are more likely to cause unwanted immunogenicity, i.e., an untoward immune response that can include serious consequences such as anaphylaxis, counteraction of drug effectiveness or, most seriously, blocking of both the drug and the endogenous protein. We disagree with statements made at the workshop that immunogenicity issues—such as those seen with Eprex® (epoetin alfa)—are unlikely to occur now due to improved analytics and that the effects of immunogenicity are typically inconsequential. The potential for immunogenicity is a function of human biology, not the level of sophistication of analytical assays. We believe that it is irresponsible, from a patient safety perspective, to downplay the potential for serious immunogenic events, recent examples of such events, and the critical need for immunogenicity testing to protect patients. For example, when Binocrit, a European biosimilar erythropoietin product, was tested in the chronic renal failure patient population for subcutaneous administration, two patients developed neutralizing anti-erythropoietin antibodies—with pure red cell aplasia confirmed in one patient—and the clinical trial was suspended.<sup>3</sup> Recognizing the need to protect patients, Congress mandated FDA to require immunogenicity testing for biosimilars as a general matter, and FDA has stated in draft guidance that “[e]stablishing that there are no clinically meaningful differences in immune response between a proposed [biosimilar] and the reference product is a key element in the demonstration of biosimilarity.”<sup>4</sup>

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<sup>2</sup> Public Health Service Act (PHSA) § 351(i)(2) & (k)(2)(a)(I)(aa).

<sup>3</sup> “Safety study for subcutaneous epoetin alfa biosimilar Binocrit/Epoetin alfa Hexal/Abseamed suspended,” Generics and Biosimilars Initiative (Jul. 10, 2009).

<sup>4</sup> PHSA § 351(k)(2)(A)(i)(I)(cc); FDA, Draft Guidance: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (Feb. 2012), at 14.

## II. Naming

Some presenters at the hearing questioned the legitimacy of calls by various stakeholders for distinguishable nonproprietary names for all biologics as a means for effective pharmacovigilance and to ensure patient safety. As FDA and HHS have noted for years,<sup>5</sup> distinguishable nonproprietary names are in the interest of patient safety, as they will facilitate accurate attribution of adverse events and allow for the detection of safety differences among and between biologics. They also will guard against misattribution of adverse events, which can impede or delay analysis and correction of problems. Accurate attribution of adverse events is especially critical for detecting latent safety signals associated with biologics, such as some immunogenic signals that first present long after the product is administered to the patient.

Only product names reliably appear in adverse event reports. Despite claims at the workshop that National Drug Codes (NDCs) and lot numbers permit accurate pharmacovigilance, empirical data—including those discussed in Pfizer’s presentation at the workshop—show that these numbers often do not appear in adverse events reports and, when they do, they are often inaccurate. For example, in Pfizer’s case study of adverse event reports for a company biologic, only nine percent of reports contained an NDC, and the reported NDC numbers were inaccurate in one-third of them.<sup>6</sup> NDCs are recorded by pharmacists, who are not common reporters of adverse events, but are not widely used outside of the pharmacy setting. Similarly, brand names are not required under U.S. law, and it remains to be seen whether adverse event reporters will consistently identify biologics’ proprietary names after the introduction of biosimilar competition. Distinguishable but morphologically related nonproprietary names will facilitate pharmacovigilance and improve the ability to identify and track all biologics.

PhRMA strenuously objects to speaker claims that innovators are now raising pharmacovigilance concerns as a pretext for suppressing competition. This statement is flatly inconsistent with our stated policy positions, both prior to and after enactment of the BPCIA. We have consistently supported the establishment of an abbreviated pathway for biosimilars to foster competition. PhRMA has underscored the importance of assigning distinguishable non-proprietary names in comments submitted to FDA dockets for draft guidances, public meetings,

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<sup>5</sup> FDA, Approval Pathway for Biosimilar and Interchangeable Biological Products, 75 Fed. Reg. 61497, 61499 (Oct. 5, 2010) (“[i]n the interest of patient safety and for the purpose of pharmacovigilance, the agency must be able to distinguish between a reference product, a related biological product that has not been demonstrated to be biosimilar, a biosimilar product, and an interchangeable product”); Letter from Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, FDA, to the Hon. Frank Pallone, Jr., Chairman, Subcomm. on Health, Comm. on Energy and Commerce, U.S. House of Representatives (Sept. 18, 2008), at 3 (“FDA believes that legislation should recognize the potential impact on pharmacovigilance and prescribing and require that [biosimilars] be assigned a distinguishable, non-proprietary name for safety purposes”); Letter from Michael O. Leavitt, Secretary of Health and Human Services, to the Hon. Edward M. Kennedy, Chairman, Comm. on Health, Edu., Labor and Pensions, U.S. Senate (July 26, 2007), at 6 (HHS statement supporting same proposition).

<sup>6</sup> “Looking Into the Future Biosimilar Landscape: A Case Study,” Presentation of Helen B. Hartman, Ph.D., Pfizer, at the FTC Follow-On Biologics Workshop, Slide 6, [http://www.ftc.gov/system/files/documents/public\\_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/hartman.pdf](http://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/hartman.pdf).

requests for comments, and citizen petitions filed by industry stakeholders. These filings emphasized the same points about patient safety and reliable postapproval pharmacovigilance methods that we raise in these comments.

Recently, FDA has acted to require distinguishable nonproprietary names for several biologics due to patient safety and pharmacovigilance concerns. For example, FDA required a unique nonproprietary name for Teva's filgrastim product in order to distinguish it from Neupogen® (filgrastim), a previously approved biologic sponsored by Amgen.<sup>7</sup> According to FDA:

FDA has concluded that a nonproprietary name for Teva's product that is distinct from Amgen's product will help to minimize medication errors by (1) preventing a patient from receiving a product different than what was intended to be prescribed and (2) reducing confusion among healthcare providers who may consider use of the same nonproprietary name to mean that the biological products are indistinguishable from a clinical standpoint. FDA also has concluded that unique nonproprietary names will facilitate postmarketing safety monitoring by providing a clear means of determining which "filgrastim" product is dispensed to patients. Due to the fact that health care providers may use nonproprietary names instead of proprietary names when prescribing and ordering products, and pharmacovigilance systems often do not require inclusion of proprietary names, the use of distinct proprietary names is insufficient to address these concerns.<sup>8</sup>

Although FDA noted that its naming decision for tbo-filgrastim did not indicate how the agency would regulate the nonproprietary names of biosimilars,<sup>9</sup> this analysis reveals that FDA considers the same concerns that PhRMA views as key—patient safety and reliable pharmacovigilance—as highly relevant to naming conventions for biologics.

Furthermore, distinguishable nonproprietary names will provide transparency and protect patient and physician choice of a particular treatment for an individual patient. Particularly in the treatment of complex, debilitating, or life-threatening diseases, physicians must be able to communicate clearly with patients about their treatments, and there must be methods available for reliably and quickly identifying the medicines that the physician has chosen. Distinguishable nonproprietary names for all biologics are an effective means for achieving this objective.

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<sup>7</sup> FDA, Memorandum to File from Biological Product Naming Working Group on BLA 125294 – [xxx]-filgrastim (Aug. 2, 2012), at 1.

<sup>8</sup> *Id.* at 1-2.

<sup>9</sup> *Id.* at 2.

### III. State Substitution Laws for Interchangeable Biosimilars

Contrary to claims at the workshop, State law—not the BPCIA—controls pharmacy substitution of biologics. As States amend their pharmacy substitution laws to address biosimilars, PhRMA believes that several principles should guide their efforts. First, State laws should preserve the physician-patient relationship and recognize that doctors and patients are in the best position to make treatment choices. Second, to protect patients, State laws should require an FDA determination of interchangeability as a prerequisite for substitution. Third, State laws should contain ministerial requirements to facilitate accurate and consistent recordkeeping and thus, support robust pharmacovigilance.

The BPCIA appropriately defers to States on substitution policy, recognizing their traditional primacy in regulating the practice of medicine and the practice of pharmacy. Despite a speaker's claims at the workshop, the BPCIA does not preempt State substitution laws or authorize FDA to control or mandate pharmacy substitution policy for biologics. Instead, the BPCIA provides that a biosimilar deemed interchangeable by FDA “may”—not “must”—be substituted for the reference product without the intervention of the prescriber.<sup>10</sup> Moreover, during legislative negotiations, one of the principal sponsors of the BPCIA made clear that the legislation was not meant to preempt State substitution laws.<sup>11</sup>

As an overarching principle, PhRMA believes that State laws should respect the physician-patient relationship and a physician's authority to make treatment decisions. State biosimilar substitution laws should provide for physician and patient notification regarding automatic substitution. The mere ministerial requirement of physician notification will pose minimal burdens and will not affect competition—in fact, the notification would likely occur after the pharmacist substitutes the biosimilar. As the determination to prescribe a particular medication for a specific patient depends on many factors and requires selection of a particular medication versus other treatment options—the essence of competition—notification *after* that decision cannot be construed to affect negatively competition.

Physician notification is important because of the central role that physicians play in pharmacovigilance. This requirement will facilitate treating patients, tracking of adverse events, and the accurate keeping of patient medical records. Even interchangeable biosimilars may be associated with different rare events than their reference products, and physicians need to know which biologic the patient received when assessing these events, to properly evaluate and treat the suffering patients. Notification also facilitates accurate recordkeeping about the administered product to inform a patient's treatment and to allow attribution of adverse events to the correct products. Furthermore, as Geoff Eich (Amgen) noted at the workshop, the physician notification requirement is the only substantive difference between the State biologics

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<sup>10</sup> PHSA § 351(i)(3).

<sup>11</sup> See *Senate Panel Passes Biogenerics Bill; Still Working on Changes*, FDA Week (June 29, 2007) (“Sen. Tom Coburn (R-OK) withdrew an amendment after Kennedy agreed to work with him on the measure before conference. The amendment aims to make sure states may let doctors preclude biosimilar substitutions when they prescribe brand biologics . . . Clinton said the bill does not force substitution so the amendment is not needed”).

substitution laws that we support and the FTC’s model substitution act for generic drugs.<sup>12</sup> In other words, the other provisions of the FTC’s model generic substitution law—including those calling for patient notification of the substitution and recordkeeping of the product dispensed—mirror those in the State biosimilar substitution laws we support. The additional requirement of physician notification, not contained in the FTC model act for generic drugs, is needed in the biologics context to protect patients as described.

State biosimilar substitution laws properly require an FDA determination of interchangeability as a prerequisite for substitution. During the State biosimilar substitution portion of the workshop, it was suggested that FDA’s robust approval standards will ensure that biosimilars are “virtually interchangeable,” even where FDA has not made an interchangeability determination. This concept of “virtual interchangeability” conflicts with the explicit statutory requirement for interchangeable biosimilars to satisfy additional criteria beyond biosimilarity; namely the applicant must show that the biosimilar “can be expected to produce the same clinical result as the reference product in any given patient” and presents no increased risks in terms of safety or diminished efficacy upon switching or alternating with the reference product.<sup>13</sup> The concept of “virtual interchangeability” also conflicts with FDA’s statements that interchangeability constitutes a higher standard than biosimilarity.<sup>14</sup>

#### **IV. Publication of Reference Guide**

PhRMA believes that a single FDA-maintained reference guide listing FDA-approved biologics and FDA’s determination of interchangeability, or lack thereof, for FDA-approved biosimilars to their reference products would be valuable. Such a reference guide, if properly constructed and updated in a timely manner, is one of several options that should be considered as FDA seeks ways to educate stakeholders on the scientific and regulatory relationship between a biosimilar or interchangeable biologic and its reference product and the lack of these relationships between different biosimilars and interchangeable biologics. As discussed at the workshop, a reference guide issued at the federal level would uniformly free State boards of pharmacy from the burdens of maintaining a similar list of interchangeable products by enabling them to rely solely on the FDA-issued list. PhRMA believes that a State board of pharmacy is not well-positioned to maintain an accurate and up-to-date reference guide.

#### **V. Specialty Drugs**

Several speakers emphasized the costs of specialty drugs as evidence that additional action is needed to foster competition from biosimilars. Although there is some uncertainty about market dynamics resulting from the entry of biosimilars, spending on specialty medicines, of which most definitions include biologics, must be placed in context.

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<sup>12</sup> FTC/FDA Model State Act, Appendix 2 to FTC, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985), at 219-220.

<sup>13</sup> PHSA § 351(k)(4).

<sup>14</sup> *See*, FDA, *Guidance for Industry on Biosimilars – Q & As Regarding Implementation of the BPCI Act of 2009* (Feb. 2012), at 3.

Specialty medicines are typically used by patients with severe or rare health conditions and treat some of the most costly and complex diseases and conditions for which there are currently few or no treatment options. For some of these conditions, without medication options, patients with unmanaged disease would contribute disproportionately to increased costs elsewhere in the health care system. Although the definition of “specialty medicines” used by health plans and pharmacy benefit managers (PBMs) varies substantially, most payers narrowly define specialty medicines exclusively based on cost. This creates a false impression about drug cost growth and fails to account for the significant value these medicines provide.<sup>15</sup>

In reality, specialty medicines represent a small portion of prescription drug and health spending. Specialty medicines are generally used by less than 5% of U.S. patients.<sup>16</sup> In Part D, only about 3.3% of all enrollees filled a prescription for at least one specialty medicine in 2011.<sup>17</sup> Specialty medicines are not a main driver of health costs, even for those patients most likely to use them. Among high-cost, severely ill patients, specialty medicines accounted for just 6.6% of their total health plan costs and less than one-third of their overall medication costs, according to a study of large commercial health plans.<sup>18</sup> Other medical services accounted for the remaining costs.

Discussing the cost of specialty medicines in isolation from other medical costs fails to measure adequately the enormous value medicines bring to patients and the health care system. Without the development of new medicines by innovator companies, neither the new treatments essential to progress against disease nor generics and biosimilars would exist. The growing use of generic drugs and the entry of biosimilars will generate savings reflective of the prescription drug lifecycle, which begins when innovator biopharmaceutical companies produce medical advances through pioneering scientific work and large-scale investments, leading over time to generics and biosimilars that patients can use at lower cost for many years.

## VI. EU Marketplace

Although several presenters emphasized pharmacovigilance and uptake statistics for biosimilars in Europe, these data do not apply directly to the U.S. marketplace. For example,

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<sup>15</sup> See Mitchell, “Who Pays for Specialty Medicines?” *Pharmaceutical Executive*, November 2012, <http://www.pharmexec.com/pharmexec/Article/Who-Pays-for-Specialty-Medicines/ArticleStandard/Article/detail/796497>; Pharmacy Benefit Management Institute (PBMI), “2012 Specialty Drug Benefit Report;” Prime Therapeutics, “Prime at a Glance: Company Overview,” February 2012, [http://www.primetherapeutics.com/pdf/Prime\\_at\\_a\\_Glance.pdf](http://www.primetherapeutics.com/pdf/Prime_at_a_Glance.pdf), and Prime Therapeutics, 2012 Drug Trend Insights, p. 33; Adams, “Specialty Drug Use and Cost Continue to Rise,” *Biotechnology Healthcare*, Fall 2010, p. 35.

<sup>16</sup> See Mitchell, “Who Pays for Specialty Medicines?” *Pharmaceutical Executive*, November 2012, <http://www.pharmexec.com/pharmexec/Article/Who-Pays-for-Specialty-Medicines/ArticleStandard/Article/detail/796497>; Pharmacy Benefit Management Institute (PBMI), “2012 Specialty Drug Benefit Report;” Prime Therapeutics, “Prime at a Glance: Company Overview,” February 2012, [http://www.primetherapeutics.com/pdf/Prime\\_at\\_a\\_Glance.pdf](http://www.primetherapeutics.com/pdf/Prime_at_a_Glance.pdf), and Prime Therapeutics, 2012 Drug Trend Insights, p. 33; Adams, “Specialty Drug Use and Cost Continue to Rise,” *Biotechnology Healthcare*, Fall 2010, p. 35.

<sup>17</sup> Diegues et al., “Specialty Tiers: Benefit Design Considerations for Medicare Part D,” *Milliman*, June 25, 2013.

<sup>18</sup> Willey et al., “Costs of Severely Ill Members and Specialty Medication Use in a Commercially Insured Population,” *Health Affairs*, May/June 2008.

European law requires biologics to bear unique product names,<sup>19</sup> whereas the United States has no such requirement and thus presents different pharmacovigilance issues. The European Union also has very different marketplace dynamics, particularly with respect to patient access and payment policies. Therefore, uptake and competition data from the EU (and the impact of nonproprietary names on them) cannot be readily extrapolated to the U.S. market.

## VII. Significance of USP Monographs and Role of the USP in Nonproprietary Naming of Biologics

In the workshop and other contexts,<sup>20</sup> USP has asserted that a biologic would be misbranded if the biologic complies with a USP monograph but does not bear the nonproprietary name specified in the official title of that monograph. For example, USP's workshop presentation stated: "[T]he Federal Food, Drug, and Cosmetic Act [(FDCA)] specifies that "[i]f there are already applicable USP standards ... when FDA approves a drug or biologic for marketing[,] the 'official title' in the USP monograph must be used as the official name for the drug substance and product."<sup>21</sup> USP's slides cited to sections 501 and 502 of the FDCA. Moreover, based on the executive summary of a recent World Health Organization (WHO) meeting, it appears that USP informed the WHO that "[a] monograph for filgrastim becomes official late 2013 and if tbo-filgratsim [*sic*] complies with the identity test for filgrastim, then essentially it is mis-branded."<sup>22</sup>

These claims fail to acknowledge the role of FDA in naming and reflect an over-reading of the relevant FDCA provisions. Section 501 of the FDCA provides that a drug (including a biologic) is adulterated if "it purports to be or is represented as a drug the name of which is recognized in [USP] and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium." This provision does not require the opposite—i.e., that a drug that meets the compendial standard be claimed to do so. Under section 502, a drug or biologic is misbranded if its label does not bear its "established name," if there is one. The statute defines "established name" as the FDA-designated official name or, if there is none, "and such drug . . . is an article recognized in an official compendium, then the official title thereof in such compendium." FDA has authority to determine whether a specific biologic (e.g., a biosimilar) is recognized in a particular compendial standard and therefore, whether the biologic must bear the USP official title as its established name. Moreover, FDA has clear authority to require biologics to bear official names that differ from the USP titles.<sup>23</sup>

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<sup>19</sup> Directive 2001/83, Articles 1(20), 54, 59.

<sup>20</sup> See, e.g., USP, USP Documentary Standards for Biologics & Biotechnology, <http://www.usp.org/usp-manufacturers/biologics-biotechnology/usp-documentary-standards-biologics-biotechnology>.

<sup>21</sup> Angela G. Long, "Introduction to Drug Naming," Follow-On Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition (Feb. 4, 2014), at 8; see also *id.* at 11 ("If USP has an applicable monograph (Identity), the drug/ biologic is deemed misbranded unless its label bears the 'official title' (naming) recognized in USP").

<sup>22</sup> WHO, 57th Consultation on International Nonproprietary Names for Pharmaceutical Substances (Oct. 22-24, 2013), at 8.

<sup>23</sup> FDCA § 508.

Legal issues aside, PhRMA believes that it is currently not scientifically possible to develop cogent and workable monographs for all biologics, given the complexity of biologics and their manufacturing processes.

**VIII. Conclusion**

PhRMA appreciates the FTC's efforts to solicit input about the regulation of biosimilars. We hope these comments will inform your consideration of how naming proposals and State legislation support competition in the marketplace for biologics, and most importantly, promote patient safety. We also urge the FTC to consider the costs of specialty drugs in context and to recognize that the EU experience with biosimilars is not directly relevant to the U.S. marketplace. Finally, we disagree with USP's assertions that a biologic would be misbranded if it complies with a USP monograph but does not bear the nonproprietary name specified in the official title of that monograph.

If you have any questions, please do not hesitate to contact us.

Respectfully submitted,

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