

March 1, 2014



Workshop on Follow-On Biologics: Project No. P131208

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

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

Dear Sir or Madam:

Mylan, Inc. (“Mylan”) is pleased to provide its comments in response to the Federal Trade Commission’s (“FTC”) request for comments in connection with its recent public workshop held on February 4, 2014, entitled *Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*. Mylan is the world’s third largest generic and specialty pharmaceutical company and the largest global generics company headquartered in the United States. Today, one out of every 11 prescriptions dispensed in the United States, brand or generic, is a Mylan product. Over the course of its 50 year history, Mylan has demonstrated an unwavering commitment to enhancing patient access to high-quality, affordable generics, which are equally as safe and efficacious as their brand counterparts. As part of that commitment, Mylan is taking a leading role in the development of biosimilars and interchangeable biologics for the U.S. marketplace and currently has five products in various stages of development. Mylan thus has a strong interest in ensuring that any legislative or regulatory policies regarding substitution, interchangeability or naming for biosimilars and interchangeable biological products are consistent with both patient safety and consumer access to affordable, high-quality medications.

Mylan opposes state laws that seek to impose barriers to legitimate substitution of interchangeable biological products. These state laws typically require physician and/or patient notification either before or within short timeframes after an interchangeable biological product is dispensed; onerous pharmacy recordkeeping requirements; and state-created lists of interchangeable biological products. Although these laws are defended on grounds of transparency and safety, their real goal is to increase the barriers to, and thus hamper, legitimate automatic substitution of biological products that have met the rigorous Food and Drug Administration (“FDA”) requirements to establish interchangeability. Mylan thus is pleased to see the FTC investigating these proposals, and the purported justifications for them, from the standpoint of competition and consumer access. Mylan believes that these state bills are, at bottom, highly anti-competitive and inconsistent with one of the main goals of Biologics Price Competition and Innovation Act (“BPCIA”), i.e., to increase competition among expensive biological products.

Brand companies also are seeking to have FDA and/or the World Health Organization (WHO) require distinguishable non-proprietary names for biosimilars and interchangeable biological products. Brand companies disingenuously argue that this is necessary to facilitate

pharmacovigilance and to inhibit improper substitution. Again, however, these proposals operate to hamper competition from and the *legitimate* substitution of interchangeable biological products, and do so without positively impacting their stated goals. Although the current pharmacovigilance system as a whole certainly could be improved, these improvements should not be limited to biologics or biosimilars but instead should be applied comprehensively to all drug and biological products. Moreover, there is no evidence that the use of distinguishable non-proprietary names for biosimilars would improve pharmacovigilance. On the contrary, because distinguishable names likely will engender additional confusion among physicians, pharmacists and patients, these naming proposals could have the perverse effect of hampering pharmacovigilance and exacerbating medication errors. The fact is that we already have experience with the use of the same non-proprietary name for biosimilars in both Europe and, on a limited basis, even in the U.S. (e.g., somatropin), and that experience demonstrates that the concerns raised by the brands are unsubstantiated and overblown.

I. Proposed State Barriers to Substitution of Interchangeable Biological Products Are Unnecessaruy and Anti-Competitive

Mylan opposes state legislative initiatives that seek to impose unnecessary barriers to the substitution of interchangeable biological products at the pharmacy level. In 2013, legislation seeking to restrict the substitution of interchangeable biological products was introduced in 19 states. These legislative proposals sought to add administrative burdens at the pharmacy level, such as requiring physician notification either before or after substitution and imposing onerous record-keeping requirements that are greater than generally required for substituting small molecule drugs. Mylan believes that these types of barriers to substitution will reduce competition and limit access to more affordable interchangeable biologics, contrary to the intent of the BPCIA.

With the enactment of the BPCIA in 2010, Congress authorized the approval of biosimilar and interchangeable biological products subject to regulation under the Public Health Service Act (“PHS Act”). Under the new law, the FDA is authorized to approve a “biosimilar” if: (1) the biological product is “highly similar” to a single reference product notwithstanding minor differences in clinically inactive components; and (2) there are no clinically meaningful differences between the two products in terms of safety, purity and potency.¹ Biosimilarity must be demonstrated by means of robust analytical studies and non-clinical and clinical testing, including an assessment of immunogenicity.² Consequently, although a biosimilar may not necessarily be interchangeable with a reference product, it nevertheless must be so similar to the reference product that the only differences are “minor” and without clinical relevance.

The BPCIA also authorized the approval of “interchangeable” biological products. Under the new law, a biological product will be considered “interchangeable” with a reference product if it “may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.”³ In other words, interchangeability reflects an FDA determination that two biological products can be substituted for one another at the pharmacy level without the knowledge or authorization of the prescribing physician, much like small molecule

¹ 42 U.S.C. § 262(i)(2).

² *Id.* § 262(k)(2)(A)(i)(I).

³ *Id.* § 262(i)(3).

generic drugs. In order to be approved as “interchangeable,” a biological product not only must be biosimilar to a reference product but also must be “expected to produce the same clinical results as the reference product in any given patient.”⁴ In addition, for biological products that are administered more than once, the risks associated with alternating or switching between products in terms of safety or diminished effectiveness must be no greater than the risk of using the reference product without such alternating or switching.⁵

Accordingly, as it stands today, United States law essentially creates three different categories of biologic products: (1) the reference or brand biologic; (2) the biosimilar; and (3) the interchangeable biological product. Interchangeable biologics are the conceptual equivalent of small molecule generics, which may be substituted for the brand product without the intervention of a health care provider who prescribes the brand product.

One way brands try to forestall competition is to create obstacles to the substitution of interchangeable biologics. Proposed legislation in various states aims to do just that through the requirement of notification of substitution. Notification requirements not only add layers of unnecessary bureaucracy to busy pharmacies, but also seek to raise questions in the minds of prescribers as to whether or not a particular biological product really is interchangeable with the reference product despite a specific FDA determination of interchangeability. Moreover, notification creates an incentive for prescribers to specify “Dispense As Written” or “DAW” in order to avoid receiving multiple calls from the pharmacy throughout the day notifying the prescriber about substitutions.

Notification of substitution is not a new concept. Brand manufacturers and their allies have attempted to thwart competition by creating barriers to substitution of small molecules since generics first came to market in the mid-1980s. This latest state legislative effort is simply another attempt to undermine competition and reduce access to more affordable medicine – this time to high-priced brand biologics. Indeed, the average daily cost of a brand name biologic is approximately 22 times greater than a traditional, small-molecule drug.⁶ Fortunately, state legislatures have generally rejected this type of legislation in the past. However, in one instance where such legislation was passed, the impact was significant and serves as a stern warning against the anti-competitive effects of notification requirements.

In 2007, Tennessee imposed a requirement for prescriber notification before a pharmacist could substitute generic anti-convulsants medications. By 2010, TENNCARE, the Tennessee agency that runs the state Medicaid program, reported that the notification requirement had cost the state’s general fund nearly \$5 million and had resulted in a 29.4 percent increase in brand dispensing of multi-source drugs in the product class. In other words, requiring prior notification to the prescribing physician had imposed real competitive barriers that not only interfered with appropriate generic substitution but also cost taxpayers millions of dollars to purchase brand products even though safe, effective and therapeutically equivalent generic products were available. Although many of the current state bills seek to impose *post*-dispensation notification, this is an irrelevant difference for purposes of competition, since pharmacies are likely to create

⁴ *Id.* § 262(k)(4)(A).

⁵ *Id.* § 262(k)(4)(B).

⁶ Hillary Krame, Why Biologics Remain Expensive, *Forbes* (2009).

policies that require notification *before* dispensing in order to minimize patient confusion and loss of expensive, biological stock.

Mylan believes that state notification requirements not only are anti-competitive but also unnecessary and inconsistent with the BPCIA. Under the statute, FDA is the proper authority to make a determination of interchangeability, and a finding of interchangeability indicates that the biological product “may be substituted for the reference product *without the intervention of the health care provider who prescribed the reference product.*”⁷ As noted above, a biological product cannot be approved as interchangeable by FDA unless the manufacturer demonstrates that the product is “highly similar” to the reference product notwithstanding minor differences in components that do not have any clinical activity, works the same way as the reference product (i.e., same mechanism of action), and “can be expected to produce the same clinical result as the reference product in any given patient.” Further, for biological products intended to be administered more than once to a patient, the manufacturer also must show that there is no additional risk from switching between the reference and the interchangeable product.

Congress entrusted FDA with the highly technical and scientific decision whether to designate a biological product as interchangeable to a reference product. This was an appropriate choice because FDA has the scientific expertise to make these decisions. Thus, there is no scientific or public health rationale for adopting additional barriers to substitution, particularly prescriber notification requirements, once FDA has made the decision that a biological product may be substituted for the reference product “without the intervention of the health care provider who prescribed the reference product.” Mylan strongly opposes any efforts to curtail competition to brand biologics for more affordable interchangeable biological products once FDA has approved the product and determined it to be interchangeable.

Mylan also believes that FDA should create a version of the Orange Book for biologics. At the very least, such a publication should provide information on whether biological products have been approved as biosimilars or as interchangeable biological products, much like the Orange Book’s current therapeutic equivalence designations. The FDA list would identify with precision the biologics determined by the Agency to be interchangeable with a reference product without the intervention of a physician, and thus would provide physicians and pharmacists an authoritative resource regarding the substitutability of biologics. Moreover, this federal list would obviate the need for separate state lists and ensure national uniformity.⁸

Congress recognized that creation of a competitive marketplace for biological products was a key to achieving savings for the health care system, and that substitution is critical to encouraging a truly competitive biologics market. Mylan believes that imposing barriers to substitution of biological products determined by FDA to be interchangeable could be a significant disincentive for at least some manufacturers to seek interchangeability status. Instead, they may choose to seek approval for their product as just another brand. In this case, they will likely need to hire a sales force and incur marketing costs to convince physicians to prescribe their product instead of the

⁷ 42 U.S.C. § 262(i)(3) (emphasis added).

⁸ Although it would be helpful to include patent listing and exclusivity information in an Orange Book for biologics, this may not be feasible as an initial step. It thus would be important to begin with information about interchangeability determinations and discuss the best way to include patent and exclusivity information in later iterations.

reference biologic or another biosimilar, which will decrease available cost savings to patients, insurers and state and federal governments. Indeed, it appears that many of the brand and biosimilar companies that are supporting these types of state barriers to substitution intend to rely upon sales and marketing rather than automatic substitution to drive sales. In that light, these state laws appear to be designed to protect the biosimilars market for detailing by erecting anti-competitive barriers to automatic substitution at the pharmacy level.

In sum, small-molecule generic drugs operate in an extremely competitive marketplace because they offer the same safety and effectiveness as the brand and can be automatically substituted at the pharmacy level without any barriers or interference. This in turn drives down prices and costs for patients and payors alike. State governments, insurers, patients and others will see the greatest benefit in costs if there is competition in the market from interchangeable biologics that can be substituted without the intervention of the prescriber, as Congress intended. Barriers to substitution, such as mandatory prescriber notification, will undermine competition and impede the goals established by Congress with enactment of the BPCIA.

II. Regulatory Proposals to Require Distinguishable Non-Proprietary Names for Biosimilar and Interchangeable Biological Products Are Unnecessary and Anti-Competitive

Mylan strongly opposes regulatory proposals to require distinguishable non-proprietary names for biosimilar and interchangeable biological products. These proposals are unnecessary from a public health and safety perspective and are highly anti-competitive. Instead, Mylan strongly supports a policy requiring the use of identical non-proprietary names to identify biosimilar and interchangeable biological products approved under Section 351(k) of the PHS Act, 42 U.S.C. § 262(k).

First, a “same name” policy appropriately reflects the fact that biosimilar and interchangeable biological products have been demonstrated to be “highly similar” to a reference product, with no clinically meaningful differences in terms of safety, purity, and potency. Because of the potential complexity of biological products and the current analytical technology, it may not yet be possible to fully characterize a biological product or demonstrate that one biological product is identical in all respects to another. For this reason, Congress adopted a “highly similar” standard for biosimilars and interchangeable biological products. This, however, does not mean that a biosimilar meeting the “highly similar” standard has a *different* active ingredient than the reference product or that it should be identified by a different non-proprietary name. On the contrary, it simply reflects the fact that biological products are much more complex than small-molecule drug products and may have minor, clinically irrelevant differences.

Accordingly, all products meeting the stringent “highly similar” standard should be identified with the same non-proprietary name as the reference product. This policy would appropriately reflect FDA’s scientific determination that biosimilars and interchangeable biologics incorporate only slight variations from the reference product and that these minor differences have no clinical significance. Using distinguishable non-proprietary names, on the other hand, could misleadingly suggest to physicians and pharmacists that there are significant and/or clinically relevant differences between a reference product and its biosimilar or interchangeable version

when, in fact, there are none.⁹ The baseline presumption thus should be that biosimilar, interchangeable, and reference products will share the same non-proprietary name.

Second, a “same name” policy also is consistent with FDA’s longstanding practice of applying identical non-proprietary names to drug and biological products that have been shown to be highly similar to each other but not necessarily chemically or physically identical. Perhaps the best example of this – and the one most analogous to biosimilars – is Omnitrope[®] (somatropin [rDNA] origin for injection). The active ingredient in Omnitrope is somatropin, a single-chain, 191-amino-acid, recombinant protein hormone. Because of the complexity of somatropin, the sponsor could not demonstrate that Omnitrope contains the “same” active ingredient as the reference product, Genotropin[®]. Instead, Omnitrope was approved based upon a showing that its somatropin active ingredient is “highly similar” to the somatropin in the reference product.¹⁰ Although Omnitrope is regulated as a drug under the FD&C Act, it is as complex as many biologics and, in fact, was approved using the “highly similar” standard that now applies to biosimilars under the PHS Act.

Even though Omnitrope was approved based upon the “highly similar” standard rather than the “sameness” standard applicable to Abbreviated New Drug Applications (“ANDAs”), and even though it is neither bioequivalent nor therapeutically equivalent to the reference product, Omnitrope nevertheless bears *the exact same non-proprietary name as the reference product, i.e., somatropin*. FDA has explained this situation as follows:

Although they may differ in some respects, all products with the established name *somatropin* share relevant, identifying characteristics of their active ingredients. Accordingly, each of the seven rhGH product lines approved by FDA has the international nonproprietary name *somatropin*.¹¹

In other words, the non-proprietary name *somatropin* is broad enough to include numerous variations of the complex protein hormone, including molecules that are “highly similar” to each other despite differing in some respects.

There are numerous other examples of complex peptide and protein products that share the same non-proprietary name even though they are not chemically or physically identical to one another. For example, all currently approved pancrelipase products use the same non-proprietary name (i.e., pancrelipase) even though, because of their complexity, FDA has questioned whether it is possible to demonstrate that the active ingredient in one product is the “same” as the active ingredient in another product from a different manufacturer.¹² Likewise, a generic menotropins

⁹ If clinically meaningful differences are later identified after approval, FDA could at that time require distinct non-proprietary names (as it did with botulinum toxin products). See 21 U.S.C. § 358.

¹⁰ FDA Response to Omnitrope Petition, Docket No. FDA-2004-P-0339, at 14 (May 30, 2006) (hereinafter “Omnitrope Petition Response”).

¹¹ Omnitrope Petition Response, p. 15, n. 35.

¹² FDA Guidance for Industry, Exocrine Pancreatic Insufficiency Drug Products – Submitting NDAs, at 2 (Apr. 2006) (hereinafter “Exocrine Decision”) (“Because of the complexity of pancreatic extract products, it is unlikely that currently available physicochemical and biological analytical tools would be able to demonstrate that the active

product shares the same non-proprietary name as the reference product even though it differs in glycosylation pattern. FDA determined that these differences “appear not to be clinically significant”¹³ and thus approved the generic product with the same non-proprietary name as the RLD, i.e., menotropins. This example indicates that complex peptide and protein products with different glycosylation patterns nevertheless can be considered to have the “same” active ingredient – and use the same non-proprietary name – provided the differences are not “clinically significant.” As noted above, this is basically the same standard applied to biosimilars, which may be approved with differences from the reference drug as long as those differences are minor and not “clinically meaningful.”¹⁴

The above examples (and others) indicate that FDA has established a long-standing practice of applying the same non-proprietary name to complex, biological drug products that are “highly similar” to each other but not necessarily chemically or physically identical. Mylan is not aware of any evidence that the historical use of the same non-proprietary name in this context – and particularly for multi-source products that may or may not be interchangeable – has had any adverse impact on pharmacovigilance or inadvertent product switching. Accordingly, FDA should continue to follow this practice for the highly analogous situation regarding the naming of biosimilars.

Although some have argued that recent naming decisions regarding biological products approved via full BLAs establish an FDA practice of requiring distinguishable non-proprietary names, these examples are inapposite and thus do not establish a policy with respect to biosimilars and interchangeable biological products. Brand companies typically point to three recent examples of naming decisions that purportedly establish an FDA naming policy applicable to biological products, including biosimilars. First, in 2009, FDA decided to add prefixes to the non-proprietary names of several botulinum toxin products to help reduce the potential for dosing errors. Second, in 2012, FDA approved a BLA for Teva’s Granix (tbo-filgrastim) and required a distinguishable non-proprietary name to differentiate it from Neupogen (filgrastim). Finally, in 2012, FDA approved a BLA for Sanofi’s Zaltrap (zivaflibercept) and likewise required a distinguishable non-proprietary name to differentiate it from Eylea (aflibercept). FDA justified these decisions as a way to reduce the potential for medication errors and enhance pharmacovigilance.

Even a cursory review of these “precedents” reveals that they are not applicable. For example, the decision to adopt distinguishable names for botulinum toxin products was prompted by specific new safety information regarding dosing discrepancies between the various products obtained by FDA after the products had been approved. Without a similar particularized and significant safety concern, there simply is no justification for applying a similar requirement for distinguishable non-proprietary names across-the-board to all biosimilar and interchangeable drug products.

ingredients in pancreatic extract products from two different manufacturers are the same.”). FDA treats all pancrelipase products as New Chemical Entities.

¹³ FDA Response to Menotropins Petition, Docket No. 92P-0487 (Legacy Docket), at 13 (June 17, 1997) (hereinafter “Menotropins Decision”).

¹⁴ See 42 U.S.C. § 262(i)(2).

Likewise, the Granix and Zaltrap examples are distinguishable because they involved full, standalone BLAs, not abbreviated applications. This means that they (1) did not rely upon any “reference product” for approval, and (2) were not subject to any official scientific finding of biosimilarity or interchangeability by FDA. Moreover, Zaltrap had significant differences from the previously approved drug (Eylea), including different indications and a different route of administration.¹⁵ These types of differences are not permissible in a biosimilar or interchangeable biological product.¹⁶ Given these distinguishing factors, the Granix and Zaltrap examples have little or no relevance to the naming of biosimilars, which, by statute, must be found by FDA to be “highly similar” to a reference product. Because the examples discussed above (e.g., somatropin) are much more analogous to the approval process for biosimilars, since they involved reference products and similarity or sameness findings, they provide the relevant precedent for biosimilar naming.

This point, in fact, is made crystal clear by FDA itself. In its Granix decision, FDA specifically cautioned that its decision to require a unique non-proprietary name in the context of a full BLA “is separate from any decision FDA may make in the future regarding the naming convention for biosimilar and interchangeable products under section 351(k) of the PHS Act.”¹⁷ FDA thus explained that it “[did] not anticipate that any decision on nomenclature for biosimilar and interchangeable products will conflict with FDA’s determination regarding the nonproprietary name for this product.”¹⁸ Read in context, FDA’s meaning is clear: the Granix/Zaltrap decisions cannot conflict with FDA’s ultimate biosimilars naming policy because the Granix/Zaltrap examples are distinguishable (for the reasons discussed above) and thus simply not relevant to the issue of biosimilar naming.

Third, a “same name” policy is fully consistent with (and in fact demanded by) the applicable statutory language and Congressional intent in enacting the BPCIA. By contrast, a policy requiring *distinct* non-proprietary names would conflict with the relevant statutory provisions. The BPCIA requires biosimilar and interchangeable products to have the same “strength” as the reference product.¹⁹ This “same strength” requirement makes sense only if biosimilar and interchangeable products bear the same non-proprietary name as the reference product, because strength always relates to a specific active ingredient.

In addition, the BPCIA includes a provision explaining how biosimilars will be treated for purposes of the pediatric assessment requirements under the FD&C Act (21 U.S.C. § 355c). According to that provision, a biosimilar that is not interchangeable with a reference product “shall be considered to have a new active ingredient under [21 U.S.C. § 355c].”²⁰ This clarification is

¹⁵ See Zaltrap Action Package, Memorandum from FDA Biological Product Naming Working Group, at 2 (July 17, 2012), available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/125418Orig1s000NameR.pdf.

¹⁶ A biosimilar product must have the same indication(s) and route(s) of administration as the reference product. 42 U.S.C. § 262(k)(2)(A)(i)(III), (IV).

¹⁷ See Granix Action Package, Memorandum from FDA Biological Product Naming Working Group, at 2 (Aug. 2, 2012), available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/125294Orig1s000NameR.pdf.

¹⁸ *Id.* FDA made a similar statement in requiring a prefix for Sanofi’s Zaltrap (ziv-aflibercept) in order to distinguish it from Eylea (aflibercept).

¹⁹ 42 U.S.C. § 262(k)(2)(A)(i)(IV).

²⁰ 21 U.S.C. § 355c(m)(1). Pursuant to this provision, a biosimilar would need to comply with applicable pediatric testing requirements.

required, however, only if Congress intended biosimilars to share the same non-proprietary name as the applicable reference product. If FDA requires biosimilars to have distinct non-proprietary names, this provision would become superfluous, since a product with a new non-proprietary name, by definition, contains a new active ingredient.²¹

Likewise, the fact that interchangeable biologics can be substituted for the reference product without the intervention of the prescribing physician²² leaves little doubt that interchangeable products must have the same non-proprietary name as the reference product. Congress was certainly familiar with the rules and processes governing substitution and would have known that the type of automatic substitution contemplated in the BPCIA would not be possible, or would be severely impaired, if interchangeable products were required to have distinct non-proprietary names. As FDA has explained, “[t]he concept of therapeutic equivalence . . . applies only to drug products containing the same active ingredients and does not encompass a comparison of different therapeutic agents used for the same condition.”²³

If interchangeable biologics must have the same non-proprietary name as the reference product, it follows that biosimilars likewise should be subject to the same naming convention. Indeed, it would be exceedingly odd – and highly confusing – to create a system in which biosimilars receive a distinguishing non-proprietary name upon initial approval and then, upon meeting the more stringent standards for interchangeability, change to a new non-proprietary name that is the same as the reference product.²⁴ Yet, given FDA’s guidance that interchangeability likely will require a two step process, this is exactly what would happen under the “distinguishable name” proposals.²⁵ However, it simply is not reasonable to assume that Congress would have created such an eccentric and confusing process for naming biologics approved via section 351(k), particularly without clear statutory language specifying this type of name migration. Accordingly, given the structure of the statute, the only reasonable interpretation is that both biosimilars and interchangeable biologics must bear the same non-proprietary name as the reference product.

Fourth, although Mylan agrees that robust pharmacovigilance is important for biosimilars and interchangeable biological products (just as it is for small molecule drugs), this can and should be accomplished without requiring distinguishable non-proprietary names. As discussed above, there are numerous instances of similar but non-identical products sharing the same non-

²¹ See *Milner v. Dept. of Navy*, 131 S. Ct. 1259, 1268 (2011); *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 335 (D.C. Cir. 1993) (applying “the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative”) (citation omitted); *FTC v. Manager, Retail Credit Co.*, 515 F.2d 988, 994 (D.C. Cir. 1975) (“The presumption against interpreting a statute in a way which renders it ineffective is hornbook law.”); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (interpreting “law” narrowly, in part, because a broad interpretation could include regulations, thereby rendering the express reference to “regulations” superfluous); *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 837 (1988) (rejecting interpretation of provision that made it redundant with another provision).

²² 42 U.S.C. § 262(i)(3).

²³ “FDA Draft Guidance for Industry: Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling, at 3 (Dec. 1998).

²⁴ It also would render both provisions of 21 U.S.C. § 355c(m) superfluous.

²⁵ *Guidance for Industry on Biosimilars: Q&A’s Regarding Implementation of the BPCI Act of 2009*, at 11 (Feb. 2012) (“At this time, it would be difficult as a scientific matter for a prospective biosimilar applicant to establish interchangeability in an original 351(k) application given the statutory standard for interchangeability and the sequential nature of that assessment.”).

proprietary name without any reported negative impact on pharmacovigilance. Moreover, because of the known limitations with the passive adverse event reporting system, requiring distinguishable non-proprietary names likely will do little to improve pharmacovigilance for biosimilars, contrary to the claim of proponents. For example, proponents often claim that distinguishable non-proprietary names are necessary because there is a high degree of inaccuracy when proprietary names are reported in adverse event reports. These proponents, however, fail to explain why a similar rate of errors would not be made in the reporting of non-proprietary names, especially those involving multiple prefixes or suffixes, which could be highly confusing. Unfortunately, a high margin of error is an unavoidable feature of the passive adverse event reporting system, which relies upon voluntary reporting by patients and physicians, and likely would be reflected in the reporting of non-proprietary names too.

This type of drastic policy change also could have other unintended consequences that negatively affect patient safety and access to affordable medications. For example, distinctive non-proprietary names could actually confound reporting by introducing the possibility of increased discrepancies between the reported proprietary name and non-proprietary name. If the proprietary and non-proprietary names do not match up, it may be even more difficult to trace the suspect product.

Likewise, the use of prefixes or suffixes to distinguish biosimilar and interchangeable products could cause significant confusion that impairs effective pharmacovigilance. In past cases where FDA has required distinguishable non-proprietary names for biologics, FDA has required that the prefix be meaningless. The problem with prefixes or suffixes that are meaningless, however, and especially for those that are both meaningless and long, is that they would not be particularly memorable and thus their use in effectively identifying products would be diminished. This diminished effectiveness could, in turn, lead to sub-optimal pharmacovigilance for biosimilars. Indeed, it could have the perverse effect of increasing misattributions of adverse events to the reference product, as reporters might tend to simply drop or forget a long and meaningless prefix or suffix.

Finally, Mylan is concerned that pharmacovigilance issues are being raised as a pretext for hampering competition and interfering with the authorized substitution of interchangeable biological products, contrary to the intent of the BPCIA. It is important to remember that optimal patient care encompasses not just patient safety once treatment has been received, but also requires patient access to safe and effective medicines as part of the treatment in the first place. As discussed previously, a major goal of the BPCIA and the establishment of an abbreviated regulatory pathway for biosimilars is increased patient access to important therapeutic medicines. The entrance of biosimilars on the market is expected to introduce price competition, helping to make the very high costs of current biologic treatments more affordable for patients.

The purported justifications for distinct non-proprietary names offered by proponents at the FTC workshop are highly inadequate, and adoption of their proposals likely would weaken – not strengthen – the current pharmacovigilance system for biosimilars. Although the use of the same non-proprietary name does not imply anything about bioequivalence or interchangeability, the use of distinguishing non-proprietary names would, under current laws and practices, completely preclude – or at least severely hamper – the legitimate substitution of two products

found to be interchangeable. Different names also may impede adoption of biosimilars by payers and physicians, thus limiting access to patients and the potential cost savings to the U.S. healthcare system, as was intended by Congress. Consequently, even if proposals to require distinct non-proprietary names are not intended primarily to interfere with legitimate substitution and product use in this way, this nevertheless may be the unintended effect. For the reasons set forth above, Mylan believes that an appropriate balance will not be achieved if distinguishable non-proprietary names are required for biosimilars and their reference products.

III. Conclusion

Mylan appreciates the opportunity to submit comments to the FTC in connection with this important public health issue. As discussed above, Mylan is concerned that the above-described proposals are highly anti-competitive and will impair the use of lower-cost, safe and effective, interchangeable biological products, contrary to the intent of Congress.

We appreciate your consideration of these comments. If you have any questions, please do not hesitate to contact the undersigned directly.

Sincerely,

Mylan Inc.