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May 7, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: FDA-2013-D-1543-0212:

Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability

Dear Sir/Madam:

Amgen is a global biotechnology and pharmaceutical products company based in Thousand Oaks, CA. We appreciate the U.S. Food and Drug Administration's ("FDA's") development and implementation of important policies for biological products, including biosimilars, and we are pleased to offer comments on the Draft Guidance for Industry, *Nonproprietary Naming of Biological Products: Update* ("Draft Guidance").[1] As a manufacturer of over a dozen FDA-licensed biological products, including two biosimilars, Amgen has an intimate understanding of and experience with the distinctive characteristics of biologics. It is from this vantage point that we provide comments on the Draft Guidance.

Sincerely,

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Senior Vice President, Global Regulatory Affairs and Safety
Amgen, Inc.

ENCLOSURE: Amgen comments on: **Nonproprietary Naming of Biological Products; Update; Draft Guidance for Industry; Availability**

[1] FDA, *Draft Guidance, Nonproprietary Naming of Biological Products: Update* (Mar. 2019).

I. Executive Summary

Amgen supports the policies outlined in the most recent Draft Guidance. Namely, we agree that inclusion of a distinguishable four-letter suffix in the nonproprietary name of each biological product, including an interchangeable biosimilar, upon approval will facilitate product-specific pharmacovigilance, promote accurate identification, and minimize inappropriate and inadvertent substitution of biological products. The suffix convention also will help promote manufacturer accountability and will help FDA to tailor remedial action to a particular product where appropriate, avoiding unwarranted class-wide recalls or product scares. Early data suggest that the suffix convention has already helped facilitate accurate adverse event reporting.

Amgen in particular supports FDA's plan to include distinguishable suffixes in the nonproprietary names of interchangeable biosimilars. These suffixes will advance the described safety objectives and also, when coupled with other measures (such as utilization of the Purple Book), help healthcare practitioners, pharmacists, and patients differentiate among products that are and are not subject to automatic pharmacy substitution under state law.

In our experience as a manufacturer of biological products having nonproprietary names with and without suffixes, we have observed that a suffix has not conferred a competitive disadvantage, nor has the lack of a suffix provided a competitive advantage. Further, retrospective application is unnecessary to achieve FDA's policy goals, as products can still be uniquely identified, and this action would impose significant burdens. Accordingly, Amgen supports FDA's plan to apply the distinguishable four-letter suffix naming convention to all biologics—originator biological products, related biological products, biosimilar biological products, and interchangeable biosimilars—prospectively, at the time of approval.

II. Comments

A. Distinguishable Suffixes Facilitate Accurate Identification of Biological Products and Enhance Effective Pharmacovigilance

An effective pharmacovigilance system for biological products requires accurate product identification. Unlike small molecule generic drugs and their reference drugs, originator biological products, related biological products, biosimilar biological products, and interchangeable biosimilars do not contain identical active pharmaceutical ingredients. For example, biosimilars and interchangeable biosimilars are "highly similar," but not identical, to their reference products in terms of active substance.[2] All drugs—biologics in particular due to their inherent complexity—carry product-specific risks not fully elucidated at the time of approval that warrant robust post-approval pharmacovigilance. Biologics also are more sensitive than small molecule products to handling conditions, and improper handling during the distribution chain could result in product-specific safety concerns. In addition, variability in presentation or delivery systems between reference products, biosimilar products, and interchangeable

[2] *See* PHSA § 351(i)(2) ("The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means (A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.").

biosimilars or related biological products may create additional product-specific use-risk errors that must be accounted for in pharmacovigilance programs.

An effective pharmacovigilance system in a growing multi-source biologics marketplace requires product-specific traceability, which requires the ability to distinguish different biological products in pharmacovigilance reports. Without this ability, attribution of adverse events to the wrong biological product or unintentional pooling of adverse event data for distinct products can occur. Further, the inability to accurately attribute adverse events to the involved product(s) may lead to ineffective remedial action or improper imputation of a product-specific issue to an entire class of biological products. Unwarranted class-wide remedial action can lead to recalls or shortages that are not in the interests of patients or can prompt a "product scare," where patients and prescribers avoid an entire class of products due to concern about the drugs' collective safety. These product-class recalls, product scares, and drug shortages could negatively affect the entire biologics market, including the market for biosimilars. The inability to attribute a specific adverse event to a reference product or biosimilar product could prompt negative perceptions about biosimilars more generally. FDA's suffix convention, in combination with additional measures to improve traceability, will help minimize risk of these outcomes by helping to enable product-specific pharmacovigilance. This will promote targeted regulatory action, help ensure that patients get the medicine their doctors intended, and help avoid drug shortages and product scares.

The ongoing angiotensin II receptor blocker ("ARB") recalls involving valsartan, losartan, and irbesartan shows these concerns are not theoretical. Hundreds of lots of these drugs have been recalled in the United States over the last several months,[3] and FDA announced in January that "valsartan products are in shortage, and we know that other types of products may fall into shortage soon."[4] The allegedly contaminated products have been difficult to identify because, although they are sold by different manufacturers (multi-sourced), multiple products share the same nonproprietary names (i.e., valsartan, losartan, and irbesartan). Pharmacies have struggled with the recall because many pharmacies do not keep the lot numbers of medications after dispensing.[5] Some patients have reacted by requesting changes to their prescriptions,[6] apparently fearing use of the entire class of products or that the recall of specific lots of products will not be effective.

As the biological product market expands and more biosimilar products and eventually interchangeable biosimilars enter the market, accurate identification of prescribed and dispensed biological products will become increasingly more important to facilitate an effective pharmacovigilance system. Amgen agrees that distinguishable nonproprietary names will play an important role in achieving this objective. Indeed, as FDA is aware, a drug product's proprietary name and manufacturer are not consistently

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[3] *See* FDA, *FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan*, WWW.FDA.GOV available at https://www.fda.gov/drugs/drugsafety/ucm613916.htm (last visited Apr. 1, 2019).

[4] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues*, WWW.FDA.GOV (Jan. 25, 2019), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629796.htm.

[5] *See* Jacqueline Howard, *Blood pressure medication recall expands again to include losartan*, CNN.COM (Mar. 4, 2019), available at https://www.cnn.com/2019/03/01/health/losartan-recall-bn/index.html (last visited Apr. 1, 2019).

[6] *Id*.

identified in many spontaneous adverse event reports. And even where they are, evidence from the small molecule context—where a generic drug and reference drug share a nonproprietary name because they have the same active ingredient—shows that the reported proprietary name and manufacturer often are erroneous. As then-Commissioner Gottlieb and Center for Drug Evaluation and Research ("CDER") Director Woodcock have stated, adverse event reports in the FDA Adverse Event Reporting System ("FAERS")

> often refer to the brand name product and manufacturer (rather than to the specific generic products and corresponding manufacturers) as the "providing manufacturers," and those reports can far exceed the brand products' percentage of prescriptions dispensed when compared with generic products.
>
> But this is not surprising. This type of discrepancy has been noted before in [adverse event] reporting, and likely represents health care professionals' familiarity with and use of the brand name. This mismatch suggests the identification of the manufacturer in these reports is unreliable.[7]

Thus, adverse event reports in the small molecule context, where the suffix convention does not apply, often do not permit correct attribution of adverse events to the involved products.

In contrast, available data suggest that distinguishable suffixes can play an important role in promoting patient safety. Biological products are being identified by their nonproprietary names (with suffixes) in FDA's pharmacovigilance systems. For example, a search of the FAERS public dashboard shows that over two years (2017-2018), 531 spontaneous adverse event reports were submitted to FDA using *only* the nonproprietary name for infliximab products, and the shares of such reports with distinguishable suffixes aligned with the market shares of the corresponding products at the time of the reports. Specifically, twenty-one out of 531 reports (approximately four percent) utilized the -dyyb suffix, and three out of 351 reports (less than 0.6 percent) utilized the -abda suffix. The remaining adverse event reports used the nonproprietary name with no suffix, consistent with the nonproprietary name of the reference product and consistent with its market share.[8] At the time, the market share of infliximab-dyyb was approximately five percent, and the market share of infliximab-abda was approximately 0.3 percent.[9] These data show that suffixes can be effective at distinguishing between biological products when such products are identified only by their nonproprietary names.

In contrast, in the European Union ("EU"), biologics and biosimilars share international nonproprietary names. In 2010, the EU passed legislation calling for use of brand names and batch numbers in

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[7] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., and Director of FDA's Center for Drug Evaluation and Research Janet Woodcock, MD., on the FDA's continuing efforts to maintain its strong oversight of generic drug quality issues domestically and abroad*, WWW.FDA.GOV (Feb. 22, 2019), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631838.htm.

[8] These results were obtained from a search of the FDA FAERS Database Public Dashboard. Last accessed September 10, 2018.

[9] Data obtained by Amgen from IQVIA Drug Distribution Database, 2018.

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pharmacovigilance reporting, and the law went into effect in 2012.[10] In 2017, however, seven years after the legislation was passed and five years after the legislation was implemented, nearly twenty-one percent of adverse event reports for infliximab lacked a brand name identifier, and this number was substantially higher in 2018.[11] Inclusion of batch numbers was even rarer. For ten classes of biologics for which biosimilars or related biological products have been approved in Europe, batch traceability was possible for less than twenty-one percent of adverse event reports from 2011 to 2016.[12] These data suggest that even a law calling for inclusion of a brand name or batch identifier in adverse event reports is insufficient to enable consistent attribution of adverse events to specific biological products.[13]

Similarly, experience from Australia shows that non-specific identification of biological products in adverse event reports can result in misattribution of those adverse events. For example, during 2012-2016, sixty-two percent of Australian adverse event reports for filgrastim products were reported using only the shared nonproprietary name ("filgrastim"). Over ninety percent of these reports were attributed to Amgen's originator product NEUPOGEN® (filgrastim), even though the market share for that product averaged only thirty-nine percent during the same period.[14] This type of misattribution can delay identification of product-specific risks, especially when the involved product has a large market share.[15] For example, it is estimated that misattribution of only five to ten percent of spontaneous adverse event reports for products with a high (ninety-five percent) market share can approximately double the time and number of cases required to detect product-specific risks if the risk has a weak association with the product of interest.[16] During the additional time needed to identify the correct suspect product, patients will be exposed to the (unidentified) risk.

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[10] The European Parliament and the Council of the European Union. Directive 2010/84/EU of the European parliament and the council of 15 December 2010 amending, as regards pharmacovigilance, directive 2001/83/EC on the community code relating to medicinal products for human use. 2010 Dec. Under the law, at Article 102(e), Member States are required to "ensure ... that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product, in accordance with Article 1(20), and the batch number." Article 1(20) of Directive 2010/84/EU defines the "Name of the medicinal product" as "[t]he name given to a medicinal product, which may be either an invented name or a common or scientific name, *together with a trade mark or the name of the manufacturer*; the invented name shall not be liable to confusion with the common name" (emphasis added).

[11] T. Felix, et al., Current state of pharmacovigilance in the European Union: improvements are needed. *Expert Opin Drug Saf*, 2019. Epub ahead of print.

[12] *Id*.

[13] N.S. Vermeer et al., The effect of exposure misclassification in spontaneous ADR reports on the time to detection of product-specific risks for biologicals: a simulation study. *Pharmacoepidemiol. Drug Saf.* 25, 297-306 (2016).

[14] Amgen submission to Australian Therapeutic Goods Administration on nonproprietary naming. Available at https://www.tga.gov.au/sites/default/files/submissions-received-nomenclature-of-biological-medicines-aapl.pdf. Last accessed April 8, 2019.

[15] N.S. Vermeer et al., The effect of exposure misclassification in spontaneous ADR reports on the time to detection of product-specific risks for biologicals: a simulation study. *Pharmacoepidemiol. Drug Saf.* 25, 297-306 (2016).

[16] *Id*.

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As the availability of originator, related, biosimilar, and interchangeable biosimilar biological products increases, product-specific pharmacovigilance will become increasingly important. The available evidence suggests that distinguishable suffixes are starting to work. Amgen believes such suffixes are a practical mechanism to achieve clear product identification, promote effective product-specific pharmacovigilance, and retain access to needed medicines in the event of a product-specific issue.

B. Distinguishable Suffixes Will Help Facilitate Appropriate Substitution of Biological Products

Amgen agrees that a distinguishable suffix in the nonproprietary name of a biological product will help minimize inadvertent and inappropriate substitution of biological products. As noted above, a reference product and a biosimilar do not contain identical active pharmaceutical ingredients, and, in the absence of an interchangeability determination, they are not substitutable for one another at the pharmacy without prescriber intervention (per US state pharmacy laws). Therefore, a pharmacist must be able to identify the exact biological product that has been prescribed by the physician. Distinguishable suffixes, along with utilization of the Purple Book, will help with this identification.

Distinguishable suffixes will also facilitate appropriate pharmacy substitution. FDA may designate a biosimilar as "interchangeable" with the reference product if the statutory standard is met, and this designation reflects FDA's conclusion that the interchangeable biosimilar may be substituted for the reference product without the intervention of the prescriber.[17] State laws that address biologic substitution permit substitution of a biosimilar for the prescribed reference product only if FDA has designated the biosimilar as interchangeable with that reference product.[18] Therefore, pharmacists must be able to distinguish between biosimilars that have been designated as interchangeable biosimilars and those that have not in order to make appropriate substitutions.

Where multiple products are approved as either a biosimilar or an interchangeable biosimilar with a single reference product, distinguishable suffixes also will facilitate continuity of information between the prescriber and the pharmacy. Supporting this concept, a survey conducted by the Alliance for Safe Biologic Medicines ("ASBM") in 2015 found that sixty-six percent of US prescribers and sixty-eight percent of US pharmacists surveyed agreed that distinguishable nonproprietary names would be desirable.[19]

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[17] *See* PHSA § 351(i)(3).

[18] *See, e.g.*, N.J. STAT. ANN. § 24:6K-1 (defining "interchangeable" to mean "'interchangeable' as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. § 262(i)) and indicated as interchangeable by the federal Food and Drug Administration in the 'Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations,' sometimes referred to as the 'Purple Book'").

[19] Alliance for Safe Biologic Medicines, *Survey - US Prescribers and Biosimilars Naming* (Oct. 2015) & *Survey - Biosimilars Naming and Labeling, A study of U.S. Pharmacists* (Oct. 2015), available at https://safebiologics.org/surveys/ (last visited Apr. 24, 2019).

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C. *Distinguishable Suffixes for Interchangeable Biosimilars Will Facilitate Consistent Product-Specific Traceability*

Amgen agrees with FDA that distinguishable suffixes are necessary to achieve adequate pharmacovigilance for interchangeable biosimilars. As the Draft Guidance states, "[a] unique suffix will facilitate manufacturer-specific pharmacovigilance by providing a means of determining which biological product is dispensed to patients when other means to track this information are not readily accessible or available."[20] Such product-specific traceability will become even more important as pharmacy substitution with interchangeable biosimilars takes place.

For several reasons, other approaches to nonproprietary naming of interchangeable biosimilars—shared suffixes with the reference product or shared nonproprietary names with no suffixes—would hinder pharmacovigilance efforts. First, either alternative approach would undermine the usefulness of a distinguishable suffix in facilitating product-specific traceability of biological products, particularly in the setting where FDA has approved multiple biosimilars as interchangeable with a single reference product. Second, either alternative approach would require nonproprietary name changes for products first approved as biosimilar and later deemed interchangeable. They also would require name changes if reclassification of an interchangeable biosimilar to a non-interchangeable biosimilar becomes necessary as a matter of public health.[21] As the Draft Guidance correctly notes, nonproprietary name "changes could be burdensome on sponsors, FDA, and the health care system...."[22] In addition, such changes could also interfere with the continuity of pharmacovigilance systems. Applying a policy of distinguishable nonproprietary names for interchangeable biosimilars avoids the need to change the name of any biological product at any point in the lifecycle of that product.

D. *Suffixes Do Not Confer a Competitive Disadvantage, and Retrospective Application of the Suffix Policy is Not Necessary*

Amgen firmly believes that a suffix, or lack thereof, does not provide a competitive advantage or disadvantage. In our previous comments to FDA and the Federal Trade Commission ("FTC"), Amgen analyzed the relationship between nonproprietary naming and uptake in certain countries where regulators have licensed particular biosimilar products with distinguishable nonproprietary names.[23] Multiple and varying market factors affect biosimilar uptake, and our analyses found no compelling evidence that distinguishable nonproprietary names have a significant impact on market penetration.

The same conclusion may be drawn from comparisons of market uptake of biosimilars *with* suffixes in the US and market uptake of those same biosimilars *without* suffixes in the EU. For example, the biosimilar Zarxio® (filgrastim-sndz) carries a distinguishable suffix in the US but does not carry such suffix

[20] Draft Guidance at 5–6.

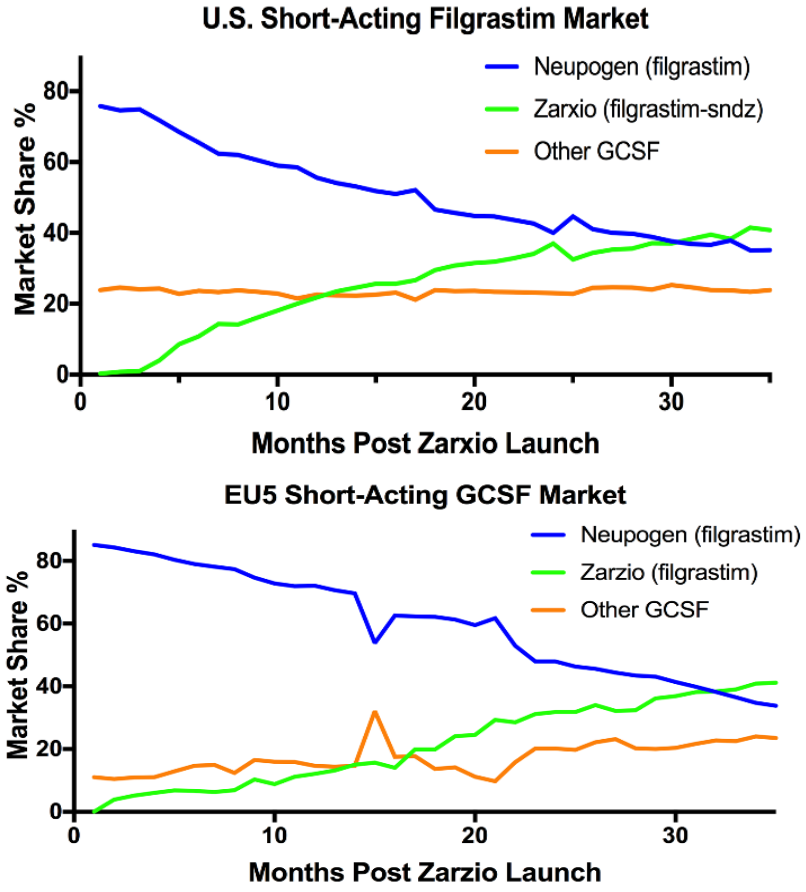
[21] As noted in prior comments, Amgen recommends that FDA establish a transparent mechanism for reclassifying a designation from interchangeable to biosimilar where necessary and subject to appropriate procedures. *See* Amgen Comments, Re: FDA's Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments, FDA-2018-N-2689 (Sept. 21, 2018), at 24–25.

[22] Draft Guidance at 6. *See also* Amgen Presentation at FDA Listening Meeting on Considerations in the Implementation of FDA's Nonproprietary Naming Policy (Sept. 28, 2017).

[23] *See* Amgen Comments, Re: FDA-2013-D-1543: FDA Draft Guidance and Proposed Rule on biosimilar naming (Oct. 27, 2015); Amgen Comments to FTC, Re: Workshop on Follow-On Biologics: Project No. P131208 (Mar. 1, 2014).

in the EU (Zarzio (filgrastim)). Nonetheless, in both jurisdictions, the filgrastim biosimilar experienced very similar uptake and now commands the majority market share for short-acting granulocyte-colony stimulating factors ("GCSFs") (See Figure 1). Thus, the data support that the presence of a suffix does not confer a competitive disadvantage, nor does the absence of a suffix confer a competitive advantage.

Figure 1. Market Share of Short-Acting GCSFs in the First 35 Months Post-Biosimilar Launch[24]



Furthermore, we agree with FDA that prospective application of the suffix convention to all biologics at the time of approval, whether "licensed under 351(a) or 351(k) of the [Public Health Service] Act[,] should encourage routine use of FDA-designated suffixes … and should avoid inaccurate perceptions of biological products based on their licensure pathway."[25] The application of suffixes to the nonproprietary names of new originator and related biological products conveys that all biological products, including originators and biosimilars alike, are on equal footing. As more originator and related biological products are licensed with distinguishable suffixes, the proportion of biological products without suffixes will diminish. We agree with then-Commissioner Gottlieb that "patients and

[24] Market share calculated from units sold. Data obtained by Amgen from IQVIA, National Sales Perspectives/MIDAS, <2010-2018>.

[25] Draft Guidance at 4.

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providers increasingly will understand that the suffixes reflect a consistent naming convention and are not an indicator of product quality."[26]

Moreover, we agree with Dr. Woodcock that practitioners are "not worried about the name of the product," but rather whether it's "going to deliver," and whether they can "trust the system to be vigilant if some unexpected problem arises."[27] As discussed above, a suffix convention that promotes accurate identification of a biological product is key to promoting an effective pharmacovigilance system that allows this vigilance and that therefore promotes confidence in biosimilars and originator biological products alike—confidence that is key to a competitive biologics market. To the extent there are misperceptions about the purpose or meaning of suffixes, Amgen firmly believes that these misperceptions can be addressed through health care provider and patient education.

For these reasons and to avoid imposing undue burden on the doctors, patients, and others in the healthcare delivery system, Amgen supports FDA's proposal not to apply the suffix convention retrospectively to the nonproprietary names of previously-licensed products. Amgen agrees with FDA that retrospective application is not necessary to achieve the aims of FDA's policy, in part because biological products that were licensed without suffixes in their proper names will still "have nonproprietary names that are distinct from each other"[28] and from other biological products that are licensed with suffixes.[29]

As Dr. Woodcock stated, however, retrospective application of the suffix convention would have been a "tremendous burden,"[30] especially given the short 90-day transition period anticipated under FDA's proposed rule to re-name six already-marketed products that were approved without suffixes.[31] Renaming would have entailed revising packaging, labeling, and promotional materials to reflect the suffix addition, as well as managing exceptionally complicated operational logistics while product with *and* without the suffix was on the market at the same time.[32] As Amgen has commented previously,

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[26] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's steps on naming of biological medicines to balance competition and safety for patients receiving these products*, WWW.FDA.GOV (Mar. 7, 2019), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632870.htm.

[27] Michael Cipriano, *Woodcock: Concerns About US FDA's Biosimilars Suffix Policy Detached From Reality*, PINK SHEET (Mar. 20, 2019).

[28] Draft Guidance at 5.

[29] *See* Michael Cipriano, *supra* note 27 ("As far as pharmacovigilance for the older biologics, the CDER director said FDA will know to attribute an adverse event report to an innovator product because it will not have a suffix.").

[30] *Id.* (quoting CDER Director Janet Woodcock). Amgen estimated that retrospective implementation could cost sponsors $12-13 million, even if sponsors were given a five-year window period. *See* Amgen Presentation, *supra* note 22 at 23.

[31] *See* FDA, *Proposed Rule, Designation of Official Names and Proper Names for Certain Biological Products*, 80 Fed. Reg. 52224, 52229 (Aug. 28, 2015) ("FDA proposes that any final rule that may be issued based on this proposal become effective 90 days after the date of its publication in the Federal Register."). *See also* Amgen Presentation, *supra* note 22, at 2 ("Burden on manufacturers could be minimal if implemented over sufficient timelines ... 5-year phased application to approved products [is] likely to lessen burden on manufacturers and supply chain[.]").

[32] *See* Amgen Presentation, *supra* note 22, at 5.

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retrospective application could be feasible given a sufficiently long transition period.[33] Due to the short transition period anticipated under the proposed rule, however, we agree that the better approach is to not apply the naming policy retrospectively. We agree that "the crucial public health goals of the naming policy [can] still be accomplished by applying the naming convention to newly licensed biological products, while avoiding the negative consequences raised by extending the naming convention to previously licensed products."[34] To ensure clarity of the policy reflected in the Draft Guidance, Amgen recommends that FDA formally withdraw the proposed rule.

III. Conclusion

Amgen believes that distinguishable suffixes in the nonproprietary name of biological products are a useful tool for both originator biological products, related biological products, biosimilar biological products, and interchangeable biosimilars. They promote manufacturer accountability, facilitate effective pharmacovigilance efforts, enhance patient safety, facilitate continued patient access to needed medicines, and promote appropriate pharmacy substitution. As a biotechnology pioneer with originator biological products as well as biosimilar biological products with suffixes, Amgen is confident that suffixes do not confer a competitive disadvantage. We also believe that retrospective application of the suffix policy is not necessary to achieve the policy's public health objectives. Thus, Amgen supports the Draft Guidance policy that proposes continued prospective application of a distinguishable suffix in the nonproprietary name of each newly approved biological product, including an interchangeable biosimilar.

[33] *See* Amgen Comments re: FDA Draft Guidance and Proposed Rule on biosimilar naming, FDA-2013-D-1543 (Oct. 27, 2015) ("If [retrospective application] is executed with inadequate lead time and a failure to mitigate stakeholder concerns, patient care, clinical trials, and confidence in biosimilars may suffer."); Amgen Comments re: FDA Proposed Rule on Biosimilars Naming, FDA-2015-N-0648 (Nov. 12, 2015) ("As Amgen has stated in our comments to the draft guidance on this issue, we appreciate FDA's willingness to work with manufacture[r]s to implement the policy and believe that FDA should avoid setting a rigid timeline.") (internal citations omitted); Amgen Comments re: FDA's Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments, FDA-2018-N-2689 (Sept. 21, 2018) ("[I]t is our position that the concerns about the costs of retrospective implementation to manufacturers can be managed, assuming that implementation is done over a reasonable timeline and not on an accelerated basis.").

[34] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's steps on naming of biological medicines to balance competition and safety for patients receiving these products*, WWW.FDA.GOV (Mar. 7, 2019), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632870.htm.