



**American Pharmacists Association**<sup>®</sup>  
Improving medication use. Advancing patient care.

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[Submitted electronically to <http://ftcpublic.commentworks.com/ftc/biologicsworkshop>]

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

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

Dear Sir/Madam:

APhA is pleased to submit these comments regarding the impact of recent state legislative activities and regulatory naming proposals on competition for follow-on biologics (“biosimilars”). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

APhA considers FDA the appropriate authority for determining the interchangeability of biosimilars. The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) provides FDA the authority to approve biosimilars and determine interchangeability. APhA is confident that FDA will employ rigorous standards to ensure that approved interchangeable biosimilars will produce the same clinical result in patients with no increased risk. Consistent with BPCIA, biosimilars deemed interchangeable by FDA may be substituted without the prescriber’s intervention. This is the process used for generic substitution of small molecule drugs, and APhA believes that the process for biosimilar substitution should be consistent.

**I. State Biosimilars Activity**

A number of states have recently considered legislative proposals addressing biosimilar substitution requirements, many of which include a prescriber notification element. These prescriber notification requirements are notably inconsistent with the laws applicable to generic substitution practices for small molecule drugs.

APhA believes these laws are premature and could impede consumer acceptance of biosimilars, which could lead to increased costs for patients and the health care system. Advocates for state proposals that require patient or prescriber notification prior to substitution argue these new requirements are necessary for patient safety. However, as FDA is responsible for the determination of the risks associated with biosimilar interchangeability, these laws may create the impression that biosimilars are somehow “dangerous” or present greater risk to patients than the innovator biologics. Thus, APhA believes that state laws with special notification requirements will ultimately harm consumers by delaying prescription fills through additional administrative requirements, including calls to prescribers, and by scaring patients away from lower-cost biosimilars. Furthermore, if states pass laws that create barriers to the prescribing of biosimilars, pharmaceutical companies will be less incentivized to develop and release those products, which may decrease both price competition and therapeutic options for patients.

However, APhA does support state laws that further responsible biosimilar substitution practices. State substitution laws for interchangeable biosimilars should be consistent with state laws for the generic substitution of small molecule drugs. To that end, we would encourage policymakers updating their laws to look to the recently-enacted Florida law that recognizes and allows for the substitution of interchangeable biosimilars, but does not impose any special prescriber notification requirements.

To further facilitate substitution practices for interchangeable biosimilars, APhA hopes that FDA will produce a publication (akin to the Orange Book) delineating the substitutability of approved biosimilars. Ideally, such a publication would include all approved biosimilars and would identify biosimilars deemed interchangeable with each innovator biologic and separately identify those biosimilars that have not been deemed interchangeable with any innovator biologic. This book could function as an authoritative reference for pharmacists and the familiarity of its format would lend it to easy integration into existing practices.

## **II. Biosimilar Naming**

Since enactment of Hatch-Waxman, prescribers and patients have generally come to accept that generic versions of innovator small molecule prescription drugs are substitutable and safe. With respect to naming, using the same nonproprietary name for a brand and generic product immediately alerts a prescriber that the brand drug is comparable to the generic. In this way, nonproprietary names serve as a kind of shorthand for prescribers. Thus, it is critical that interchangeable biosimilar products maintain the same nonproprietary name as their reference biologic counterparts and not use suffixes or prefixes. Using unique individual nonproprietary names (INNs) for biosimilars and biologics could confuse both prescribers and patients and convince them that the two drugs are not substitutable. Moreover, unique INNs could potentially result in general confusion relative to the appropriate use, safety, and efficacy of biologic products and could result in therapeutic duplication that would be detrimental to patients’ health.

Using the same nonproprietary name for both brand and generic products reinforces to prescribers and patients that the generic product is comparable to the brand, which ultimately promotes fair competition between innovator and generic products. Given that pharmacists only substitute a generic for a prescribed brand in accordance with FDA’s determinations as set forth in the Orange Book (and with prescriber consent to substitution), there is no associated patient safety risk with the brand and generic product having the same nonproprietary name. This model

has historically worked well for small molecule prescription drugs. Accordingly, we believe there is no sound public safety reason to deviate from the established naming conventions for biologic and biosimilar products.

In addition to creating confusion for prescribers and patients, the use of unique names for biosimilar products would create challenges within pharmacy management and payor systems. The current industry norm for product classification within these systems is the use of the same nonproprietary name for brand and generic versions of small molecule drugs—pharmacy and payor systems link them together based their shared core chemical components. Applying unique names to each biosimilar invites confusion within these systems, as has proven to be the case with the non-traditional nomenclature recently applied to ziv-aflibercept, ado-trastuzumab emtansine (Kadcyla®) and tbo-filgrastim. Notably, some electronic healthcare record systems were dropping the prefixes, which created challenges within pharmacy management and payor systems.

### **III. Unique INNs are Not Necessary for Adverse Drug Event Reporting**

APhA believes that unique INNs are not necessary for the accurate reporting of adverse drugs events (“ADEs”). All information needed to complete ADE reports is available to prescribers on patient’s prescription labels (state laws require dispensed prescriptions to be labeled with product name and manufacturer) or by contacting a patient’s pharmacy to obtain information about specific products dispensed to the patient. Pharmacy dispensing records are designed around the National Drug Codes (“NDC”) and provide all information necessary for accurate ADE reporting. If improved ADE reporting is desired, APhA suggests considering targeted educational campaigns for healthcare providers focused on correct use of the ADE reporting process.

Thank you for the opportunity to provide information on this important issue. If you have any questions or require additional information, please contact Jillanne Schulte, JD, Director of Regulatory Affairs, at [jschulte@aphanet.org](mailto:jschulte@aphanet.org) or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BPharm, MBA, ScD (Hon), FAPhA  
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs