

VIA ELECTRONIC SUBMISSION:

<https://ftcpUBLIC.commentworks.com/ftc/biologicsworkshop>

February 26, 2014

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

To Whom It May Concern:

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

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the Federal Trade Commission (FTC) regarding the impact of recent state legislative activities and regulatory naming proposals on competition for follow-on biologics (also known as “biosimilars”).

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS’ 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

Upon enacting the Biologics Price Competition and Innovation (“BCPI”) Act of 2009, Congress set a high bar for FDA to approve biosimilars and to determine interchangeability. Given FDA’s expertise with biologic products, chain pharmacy is confident that the agency will employ rigorous standards to ensure that any approved interchangeable biosimilar can be expected to produce the same clinical result in any given patient, who will experience no greater risk from alternating or switching between the two products than if the patient were to continue to use the innovator biologic product. Consistent with the intent of federal law, biosimilars deemed interchangeable by FDA will be suitable for substitution without the prescriber’s intervention. Accordingly, chain pharmacy supports policies that accommodate the substitution of interchangeable biosimilars consistent with generic substitution practices for small molecule drugs.

State Biosimilars Legislative Proposals and Laws

Recently, there has been a proliferation of state legislative proposals addressing substitution requirements for biosimilar drugs that include prescriber notification requirements for substitution of interchangeable biosimilars. These prescriber notification requirements are notably inconsistent with the laws applicable to generic substitution practices for small molecule drugs.

Ostensibly, the goals of these proposals and laws are both to update state generic substitution laws to recognize and accommodate the substitution of interchangeable biosimilars, and to provide additional notification to prescribers when interchangeable biosimilars are substituted for “safety purposes.” Chain pharmacy has serious concerns with the addition of the special notification requirements that ultimately create barriers to substitution of biosimilar products. Considering that the biologic product manufacturers advocating for the special notification requirements stand to benefit financially from enactment of statutory barriers to substitution for biosimilars, we believe that the special notification requirements are designed to ultimately give some biologic drug manufacturers a competitive advantage over others.

Proposals creating special notification requirements for substitution of interchangeable biosimilars will make substitution of these products more cumbersome and therefore less likely. Moreover, these proposals unjustly perpetuate the notion that biosimilar products warrant special treatment as compared to traditional, small molecule drugs for which prescribers do not receive notification when generic substitution occurs; this ultimately serves to undermine prescriber and consumer confidence in biosimilar products.

We are also concerned that the prescriber notification requirements in these proposals would create otherwise unnecessary distractions from the important communications already initiated by pharmacists when there are pressing healthcare issues to address. For example, pharmacists commonly reach out to prescribers regarding potential drug interactions, patient allergies to medications, and formulary issues. It is important to maintain focus on patient care issues that need resolution, and not to inundate prescribers with irrelevant information.

NACDS supports updating state generic substitution laws to accommodate 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 looking to update 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.

State policymakers should avoid enacting a patchwork of state substitution laws that include varying barriers to substitution of interchangeable biosimilars, as this

may give a competitive advantage to innovator biologic products in the market and would make it less appealing for manufacturers of biosimilar products to go through the added steps necessary to prove interchangeability of a biosimilar to FDA. With less incentive for manufacturers to meet FDA's standards for interchangeability, there are likely to be fewer interchangeable biosimilar products on the market.

To further facilitate substitution practices for interchangeable biosimilars, we are hopeful 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 both biosimilar products that have been designated as interchangeable with the innovator biologic and therefore can be substituted for the innovator product, as well as identify approved biosimilar products that have not been deemed interchangeable by FDA. A publication such as this would serve as an authoritative reference for pharmacists to follow. Further, the Orange Book format is one that is familiar to pharmacists and state policymakers, and would therefore be easy to incorporate into current practices.

Naming of Biosimilars

Since enactment of Hatch-Waxman, physicians and patients have generally come to accept that generic versions of innovator small molecule prescription drugs are substitutable and safe. With respect to naming, having the same nonproprietary name for both the brand and generic product denotes to the prescriber that the generic product is comparable to the brand. It is critically important that interchangeable biosimilar products maintain the same name as their reference biologic counterparts and not use suffixes. The use of unique individual nonproprietary names (INNs) could give the impression that because a biosimilar product does not have the same name as the innovator biologic, the two are not substitutable. Moreover, unique INNs could potentially result in general confusion relative to the appropriate use, safety and efficacy of biologic products, as well as therapeutic duplication that would be detrimental to patients' health.

Notably, other highly regulated markets, such as Europe, have approved biosimilars with the name that matches that of their reference product because the active ingredient is the same. We believe this naming approach should be adopted in the United States as well.

Using the same INN names 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 delineated in the Orange Book (and where the prescriber has indicated substitution is permitted on the prescription,) 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 prescriptions drugs. Accordingly, there is no sound public safety reason to deviate from the established naming conventions for biologic and biosimilar products.

In addition to undermining prescriber confidence and 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 INN for brand and generic versions of small molecule drugs. Having the same INN for all products with the same chemical ingredient is a core principal in identifying products that should be associated with one another, and is also how different pharmacy and payor systems are able to link together to enable decision making by both clinical and administrative users. 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 the pharmacy management and payor systems.

Unique Individual Nonproprietary Names for Biosimilar Products and Special Notification Requirements that Impede Substitution of Interchangeable Biosimilars Are Not Necessary for Adverse Drug Event Reporting Purposes

Proponents of special notification requirements for substitution of interchangeable biosimilars and proponents of unique INNs for biosimilar products suggest that these are necessary to provide prescribers with information for the purpose of reporting adverse drug events. However, the information needed to complete adverse drug event reports is already available to prescribers who, under current practices, can either obtain this information from patients' prescription labels (state laws require dispensed prescriptions to be labeled with product name and manufacturer), or alternatively, contact pharmacies to obtain information about specific products dispensed to patients. When requested by prescribers, pharmacists can and do provide information to aid prescribers reporting adverse drug events.

In fact, pharmacies maintain robust and extensive dispensing records that can, through the national drug code ("NDC,") identify for each prescription dispensed the specific manufacturer, product, and even information about the specific dosage form, strength and packaging of the drug. Pharmacies do not use the INN name for this purpose. We are concerned that adopting use of the INN to track which particular biologic product a patient is taking may interfere with current pharmacy safety alert systems and complicate the collection of global safety information.

Notably, the current system for adverse drug events reporting can accommodate reporting of adverse events with *any* prescription drug product, including biologic

and biosimilar products. If there are shortfalls with the current adverse drug event reporting systems, we need to address those without undermining prescriber confidence in biosimilar medications that will otherwise result from unique INNs and from burdensome and confusing notification requirements that distract prescribers from more important communications. A more targeted and effective approach would be educational campaigns for healthcare providers that explain the adverse event reporting process and inform how to fully complete adverse event reporting forms to ensure that adverse events can be appropriately categorized and evaluated.

Thank you for considering our comments on this critically important issue. Please do not hesitate to contact me at 703-837-4183 or knicholson@nacds.org to discuss any of these matters further.

Best Regards,

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