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March 1, 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 Chairwoman Ramirez and Commissioners:

CVS Caremark appreciates the opportunity to contribute our perspectives and experience to the Federal Trade Commission (FTC) regarding the issues raised in Federal Register notice entitled *Follow-On Biologics and the Impact of Recent Legislative and Regulatory Naming Proposals on Competition* (78 Fed. Reg. 68840, Nov. 15, 2013), in the wake of our participation as panelists at the Follow-On Biologics Workshop held on Tuesday February 4, 2014. CVS Caremark is comprised of more than 7,400 CVS/pharmacy retail stores and employs more than 24,000 pharmacists. We are a leading specialty and mail service pharmacy provider and our pharmacy benefits manager (PBM) is the second largest in the nation. Our 800 MinuteClinic locations employ more than 1,500 combined nurse practitioners and physician assistants, who provide convenient access to routine health care services. CVS Caremark is also a leading provider of Medicaid prescription drugs and health care services.

Our extensive experience in managing the prescription, delivery, and patient use of pharmaceuticals gives us a unique perspective on the potential impact of various legislative and regulatory proposals on patient choice, access, and consumption of biologics. CVS Caremark believes that biosimilars and interchangeable biologics will provide specialty pharmacies with invaluable opportunities to apply our current prescription-management tools, as well as to help moderate the cost of specialty products over time. This will make access safer and more affordable for patients, while simultaneously helping to create a competitive marketplace for biologics in the US.

We offer our reactions and recommendations as the FTC seeks to further explore its approach to competition issues facing the rollout of the biosimilars and interchangeable biologics marketplace in the United States (US).

CVS Caremark Opposes Efforts to Require Biosimilars to Have Unique Non-proprietary Names

Biologics have distinguishable names; these are the brand or proprietary names that are already reviewed for clarity and recognition by the FDA. Some stakeholders want to see biosimilars given non-proprietary names that have a unique suffix or prefix for each product approved. This would provide what they define as an additional product-specific field to simplify adverse event tracking and other

post-market safety purposes. CVS Caremark contends that such proposals confuse the role of the non-proprietary name (which describes the active ingredient) with the brand name (which describes the product). Meanwhile, the value of being able to collectively assess all medicines containing the same active ingredient through sharing the same non-proprietary name would be lost. Ample precedent shows that products sharing non-proprietary names do not create safety concerns, nor create confusion in our ability to track their use, given that we have multiple biologics on the US market today that share such non-proprietary names and have done so for decades:

- Medicinal products with the same active ingredient have always shared the same International Non-proprietary Name (INN) issued by the World Health Organization (WHO) based solely on their containing the same active ingredient. These products have the same INN worldwide, even though their approvals are regulated separately by the multiple regulatory authorities around the world. These products include biologics as well as drugs. This system has been in place for over 60 years, and is administered by the WHO expressly to help inform health care providers in their day to day practice of medicine.
- In the US, there are multiple biologic products on the market today with the same non-proprietary names (called the United States Adopted Name, USAN, which generally matches the INN) even though they are made by different sponsors and have never been analytically or functionally compared with one another.
- The same INN also applies to both generic and brand drugs, as well as to biologics that have gone through multiple manufacturing changes over the course of the drug's lifetime (including in the US—using the “highly similar” analytical standard proposed for biosimilars). Each product keeps the non-proprietary name it was given on the day of its original approval throughout its entire lifetime.
- Biosimilars approved in Europe, as well as elsewhere, have the same non-proprietary name as their reference with no evidence of safety problems, even though they have been extensively used, collectively accumulating hundreds of millions of days of patient exposure. All monitoring of biosimilars in Europe is the same as for originator products—the lack of observed difference is not based on a lack of research.

The Biologics Price Competition and Innovations Act (BPCIA) notably did not include any statutory language regarding the naming of approved biosimilar products, instead leaving it up to the FDA. Biosimilars will have brand names (unlike small molecule generic drugs), making them virtually identical to other biologics available in the US market today. Fundamentally, biosimilars and interchangeable biologics are biologics and all the systems in place today can be applied to them.

Because of the expectation that the non-proprietary name is the name of the active ingredient, state laws are currently set up to only allow substitution for those products that share such non-proprietary names. If resolution of the non-proprietary naming issue requires biosimilars to have a different non-proprietary name (such as a distinct prefix/suffix to the non-proprietary name of the reference) states will likely not allow the substitution of a brand product with a biosimilar—even when it explicitly cites it as its reference product, and even when the FDA has designated a biosimilar as interchangeable with its reference. The different proprietary name will be used to prevent substitution by suggesting that the active ingredient in the two medicines is different. Compounding this with additional notifications between the pharmacist and the prescriber will deter substitution further. In short, unique non-proprietary names will make for a less competitive biologic marketplace, and will create the potential for unnecessary confusion among healthcare providers and patients. Those biosimilars not yet

designated as interchangeable will become de facto new biologics in the market and have to be marketed as such, with the expected consequences of higher prices.

The FDA, Not the State, is the Appropriate Entity to Make Science-Based Decisions Regarding Interchangeability

It is important to ensure that biosimilars and interchangeable biologics, like all new therapies, are determined to be safe and effective by the FDA. Only the FDA sees the primary data on which the approval decisions for any medicines are based. Therefore, it must be the FDA that makes that decision. CVS Caremark believes that the agency is taking prudent steps to ensure that the approval pathway works for all parties, and that all biologics are treated consistently and held to the same regulatory standards of safety, purity, and potency. We remain concerned that the implementation process is taking too long, and it is unclear to us why other highly regulated markets have multiple biosimilars in safe use and none are yet available in the US. Nonetheless, we believe that the agency is the best positioned and only regulatory body with the scientific expertise to make determinations for the US.

Substitution Legislation in States Is Premature and Misguided

CVS Caremark understands that the BPCIA authorizes the automatic substitution of interchangeable biologics at point of sale. Efforts at the state level to treat (with respect to substitution) interchangeable biologics differently from how small-molecule generic products are treated will thwart competition. CVS Caremark encourages states considering such substitution laws to consult with the FTC prior to evaluating such legislation.

The FTC should also adopt a policy opposing anti-competitive state substitution laws that add additional burdens on pharmacists and others in the health care system, or that in any way suggest that biosimilars and interchangeable biologics are (in any manner) less effective than their reference products. For instance, the nature of some recent state legislation under consideration currently proposes to require that a pharmacist record the name and manufacturer of the product dispensed in an interoperable health records system shared with the prescribing physician within 10 days—or, when an interoperable system is not available, communicate to the prescribing practitioner the name and manufacturer of the dispensed biologic product. Such reporting is burdensome, creates unnecessary communications between pharmacies and prescriber offices, and will provide no added benefit to the patient.

Standardized language could be very helpful to the extent that it could be proposed by the FTC. We recognize that state laws with respect to generic small molecule drug substitution vary, but consistency will help ensure similar expectations, as well as more dependable access to biologics, biosimilars, and interchangeable biologics by patients in the future.

Pharmacies Will Track Biosimilars and Interchangeable Biologics in the Same High-Quality Manner as They Track All Dispensed Products Today

Current pharmacy best practices call for the tracking of which product is dispensed to which patient, and ensuring that all applicable product and manufacturer information on the prescription label is appropriately noted in the patient record. This will continue to be the case if and when biosimilars and interchangeable biologics become available in the US market. In the event of a recall of a biosimilar or interchangeable biologic, pharmacies will have the necessary information to be able to track the products, reaching out to patients just as they do for branded biologics today.

We note that this level of quality system in place for pharmacies and specialty medical facilities must also apply to all other parts of the supply chain. CVS Caremark remains confident that the automated systems in place today contain sufficient redundancy to ensure that complete records are kept. Any proposal to add or change data elements must be subject to a thorough risk analysis to assess its ability to add to current quality control systems.

Arbitrarily suggesting new data elements, or negating old ones (such as the non-proprietary name), will not create a safer system. More likely, it will be destructive and confusing to the integrity of the systems implemented daily for millions of patients by CVS Caremark. No system can compensate for the failure to keep complete and accurate records, and in most of the anecdotal instances we have heard cited, this would appear to be the source of error.

Conclusion

CVS Caremark appreciates the opportunity to comment on these important issues. We support efforts to remove barriers and facilitate the approval of biosimilars in order to increase accessibility to life-saving medications by making them more affordable for American patients. The US small molecule marketplace is highly competitive, and we need to begin to develop such competition for biologics too. For these reasons, CVS Caremark opposes activities by individual states to establish standards that do not recognize FDA decisions on biosimilars and interchangeable biologics.

Further, we oppose efforts to change the established non-proprietary naming systems for biologics already being implemented through the USAN Committee and aligned with WHO's INNs, in a manner that would make both biosimilars and interchangeable biologics less able to compete. In particular, pharmacists should be able to substitute biosimilars designated as interchangeable by the FDA in the same manner as generic drugs.

We appreciate the Commission's thoughtful and collaborative approach to evaluating these issues, and are available at your convenience if you would like to discuss anything further.

Sincerely,

Larry Burton
Senior Vice President
Government Affairs