

## BRIEF OVERVIEW OF FEDERAL TRADE COMMISSION FOLLOW-ON BIOLOGICS WORKSHOP – FEBRUARY 4, 2014

On February 4<sup>th</sup>, the Federal Trade Commission held a Follow-On Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition. The Workshop was designed to focus on:

- The potential impact of state regulations affecting competition
- How regulations, if necessary, might be structured to facilitate competition while still protecting patient health and safety
- How naming may affect competition
- The experience of other countries with follow-in biologic competition

The record will remain open for filing public comments until March 1, 2014. Online comments may be filed at: <https://ftcpublic.commentworks.com/ftc/biologicsworkshop>. Comments may also be mailed to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, Washington, DC 20580.

The Workshop format included individual speakers and also a panel discussion. Speakers and panel discussion participants included representatives from Harvard Medical School, Independent Consultants, AARP, PCMA, Amgen, Express Scripts, Momenta, Mylan, Sandoz, Hospira, CVS Caremark, National Alliance of State Pharmacy Associations (NASPA), USP, Pfizer, AbbVie, Inc., Aetna Specialty and Home Delivery Pharmacy. The presentations are available on the FTC website under the events tab and a transcript will also be available.

A brief overview of comments made by speakers is as follows:

### **FDA Approval Process**

- Follow the science: interchangeable biologics possible for some products not all –FDA has expertise available to make decisions..
- Although FDA was not on the program, one presentation described the FDA's process: FDA will not waive an element if the reviewers are uncertain that the product will have clinical activity that is highly similar to the US-licensed reference product. FDA has experienced reviewers with deep knowledge of protein products (track record), and there will be multiple levels of supervision and oversight. FDA will only approve a biosimilar that can *reliably be expected* to perform similarly to a US-licensed reference product.
- Adverse event reporting is going to be very important for this new class of drugs.

## State Regulation of Biosimilars

- Blanket state anti-substitution biosimilar laws highly problematic for products judged interchangeable
- As to the regulation by states of these products, AARP stated that it was unclear why state regulation was necessary given that FDA has yet to approve a biosimilar. AARP stated that if FDA can be trusted to approve and regulate biologics, we can trust them to approve and regulate biosimilars. Further, once FDA has approved a biosimilar drug as interchangeable with the original reference biologic, no valid reason exists for a different process for substituting interchangeable biosimilar products with reference biologic counterparts than with traditional generic substitution for their brand-name counterparts. AARP believes that if enacted, state legislation would reduce substitution and subsequent competition, increasing health care costs. They testified that 8 of the 10 highest expenditures for Medicare Part B drugs in 2010 were biologics. The costs associated with biologics are not sustainable for patients or payers. Many patients will be unable to afford biologics if competition does not provide some level of price relief and medical advances are meaningless if no one can afford to use them.
- PCMA noted that the FDA is the only U.S. regulatory body with the scientific expertise to determine interchangeability. If the FDA approves a biosimilar as interchangeable, the interchangeable biosimilar should be substitutable as is the case with generics for branded drug products. State legislation that places onerous requirements on the substitution of interchangeable biosimilars is premature and may conflict with the national standards the FDA is currently developing. Since the FDA is currently in the process of creating a pathway for the approval of biosimilars and determining interchangeability, state legislation on this issue is extremely premature. There are NO biosimilars in the United States marketplace today that have been approved under section 351(k) of the Public Health Service Act (42 U.S.C. § 262). There is NO patient safety issue because the interchange of biologic products cannot occur without prescriber approval. There is concern that premature legislation will create confusion in state substitution laws. Such legislation attempts to undermine public confidence in biosimilar
- The supporters of state legislation restricting biosimilar substitution stated that the notification requirements for the prescriber were necessary for the prescriber to have a complete patient medical record.
- Physician notification is a barrier to access and why once FDA approved as interchangeable biosimilars should these drugs be treated differently than traditional generic products.

## Naming

- Experience has shown that naming conventions are important for traceability. Adverse events were being attributed to the brand name product when the patient was actually taking the generic. Naming does matter.
- According to USP their role in naming is grounded in the law and the United States does not follow the World Health Organization's International Nonproprietary Names (INN) because they have no role in United States law.
- The cost of biologics is the "elephant" in the room. Patients will find it harder to pay for these medications and that will impact not just the prescription drug benefit but will also impact the overall medical benefit. The cost of biologics has been growing at a rate of about 15% a year.

Questions that the FTC is interested in receiving input are as follows:

1. How would particular provisions in new state substitution laws (or similar legislative proposals) likely affect:
  - Competition between biosimilars and reference biologics?
  - Competition between interchangeable and reference biologics?
  - Investment in biosimilars and interchangeables?
2. If particular provisions may have anticompetitive effects, what justifications support the need for those provisions?
3. Would it be useful for the FDA to create a new publication, comparable to the Orange Book, that provided an authoritative listing of FDA-approved biosimilars and interchangeables and their reference biologics?
4. How would unique or distinguishable USANs or non-proprietary names for biosimilars and interchangeable biologic medicines either reduce or increase confusion?
5. How would unique or distinguishable USANs or non-proprietary names likely affect
  - Competition between biosimilars and reference biologics?
  - Competition between interchangeables and reference biologics?
  - Investment in biosimilars and interchangeables?
6. If certain naming conventions could increase confusion or have anticompetitive effects, what justifications support the need to use unique or distinguishable USANs or non-proprietary names for biosimilars and interchangeables?
7. What is the best way to assure accurate and complete adverse event reporting? How could the current adverse event reporting system be improved? Should an adverse event reporting system be integrated with the new track and trace reporting system?