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

February 28, 2014

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 Madame Secretary:

The Academy of Managed Care Pharmacy (AMCP) is pleased to submit comments in response to questions posed in the November 15, 2013 *Federal Register* notice: *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition.*

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

Questions regarding State FOB Legislative Proposals and Laws

1. How would new state substitution laws passed in 2013, or similar proposals pending in other states, affect competition expected to develop between biosimilar or interchangeable biologics and reference biologics? In the context of state substitution laws, what is the likely competitive impact of a biologic product being designated "interchangeable?"

   AMCP has consistently opposed state follow-on biologics (FOB) legislation that would place unnecessary burdens on the substitution of biosimilars determined to be interchangeable with reference biologic products by the U.S. Food and Drug Administration (FDA). We believe that state FOB legislation is premature, as the FDA has not yet finalized their guidelines for approving biosimilars and determining their interchangeability with reference products. Until those guidelines are finalized, states cannot know if additional steps are warranted prior to substitution of an interchangeable product or dispensing of a biosimilar. Furthermore, the FDA has not yet approved any biosimilars; in fact, it has only received several investigational new drug applications but no actual applications for approval to date.

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Most state legislation introduced to date would discourage substitution which only benefits those innovator biologic companies' products, which typically are more expensive than FOBs resulting in increased medication costs to patients and payers and thereby threatening patient access to more affordable treatments. In fact, an FDA spokesperson has stated that "efforts to undermine trust in these products are worrisome and represent a disservice to patients who could benefit from these lower cost treatments."

Moreover state FOB legislation does not recognize the potential value that biosimilars offer to patients and payers by enhancing access to safe and lower cost medications.

AMCP supports:

- the FDA's pathway as the mechanism to assure that safe drugs are permitted in the marketplace,
- prescribers' ability in conjunction with determinations made by plan pharmacy and therapeutics committees to select appropriate medications for patients with the ability to prohibit substitution,
- the ability of a pharmacist to rely on the FDA's determination of interchangeability,
- the patient's ability to have the opportunity to use biosimilars without the additional legislative and regulatory requirements not applicable to other prescription selections, and
- the ability of employers, health plans and other payers to provide cost savings to their members by making available FDA approved biosimilar and interchangeable drugs.

The likely competitive impact of a biologic product being designated "interchangeable" is that it will be highly competitive with the biologic especially when affordability is the deciding factor.

During the Follow-on Biologics Workshop, a presenter stated that FOB laws are necessary so that prescribers through notification will have a complete medical record and also that prescription bottle labeling is important so that prescribers can trace the biosimilar by manufacturer in order to track adverse events. However, since the legislation is only directed at biosimilars; it begs the question as to the justification to notify prescribers and track adverse events for only one class of drugs -- biosimilars. Currently prescribers do not receive notification on any other drug substitution and the patient record does not contain information about every drug substitution. Those records are maintained by each pharmacy and in most cases patients use multiple pharmacies and prescribers so the idea that a prescriber needs a complete medical record when a biosimilar is dispensed is not consistent with current record keeping practices. However, AMCP has long advocated with other pharmacy organizations for pharmacists' access to the full EHRs with the complete medical record. This is what the goal of the health care industry should be and not simply focusing on accessing EHRs for one type of medication.

2. What are the compliance costs associated with new state law requirements? How are those costs likely to affect completion from biosimilar and interchangeable biologics?

Since there are no biosimilars or interchangeable biologics currently being dispensed, we do not have an estimate of the compliance costs. However, we can identify the main area where there

will be a cost: pharmacists' time. This state FOB legislation will increase the amount of time that a pharmacist has to spend on each prescription in order to comply with the additional patient and prescriber notification requirements. In addition some state proposals require very detailed labeling on the prescription bottles which will also require additional pharmacist time.

3. What are the rationales behind new state proposals and laws for regulating FOB substitution? Which provisions are most important? Are some provisions redundant or otherwise unnecessary?

   Unfortunately, the only rationale that we can identify, given the premature restrictive regulations, is that those entities offering more costly biologic drugs are trying to prevent competition by seeking enactment of these proposals. Organizations that represent patients, pharmacists and employers do not support these proposals. The prevention of competition also has the effect of potentially increasing medication costs to patients and payers and thereby threatens patient access to more affordable treatments.

   AMCP believes states should follow the FDA's determination of interchangeability with regards to granting substitution authority to pharmacists. If the state follows the FDA's determination then there will not be redundancy in state laws. When the states pass laws that do not recognize the FDA's role in this process and in fact, ignore that role, then the inherent redundancies will have a direct negative impact on competition in the marketplace.

4. Could an FDA publication concerning biologics and FOBs, comparable to the Orange Book, provide an authoritative listing of FOBs that are biosimilar to or interchangeable with reference biologics? Would such a publication facilitate substitution? Would such a publication need to be limited to interchangeable FOBs or should it include both biosimilar and interchangeable FOBs?

   AMCP believes that this is an idea that deserves consideration and comment by stakeholders. It could serve as a valuable tool to provide uniformity and a benchmark for this emerging area. Given the variety of state approaches already in this area, we do believe that providing a "guide" is an appropriate response in order to limit the proliferation of inconsistent state by state requirements.

5. Does the potential for many different state laws regulating FOBs affect the prospects for the development of FOBs? Does the answer differ between biosimilar versus interchangeable biologic products?

   AMCP believes that biosimilars and interchangeable biologic products are the future of prescription drugs, i.e., the next generation. We do not believe that the different state laws will stop their development but they can and will slow the delivery of these valuable and affordable drugs to patients.

6. Would it be helpful to develop a model state substitution biosimilar law? If so, what provisions should the law include? Should state laws coordinate their guidance with provisions in the BPCIA and guidance from FDA?

   At this time, AMCP does not support a model state substitution biosimilar law for the same reason that we do not support state FOB legislation because it would be premature.

Questions related to the Naming of FOBs

In November of 2013, AMCP shared our concerns with the Food and Drug Administration's (FDA) removal of its 2006 policy on biosimilars naming from its website. AMCP believes that the intent of the Biologic Price Competition and Innovation Act of 2010 (BPCIA) is to ensure patient access to affordable biosimilars would be advanced if a single International Nonproprietary Name (INN) is assigned to interchangeable biosimilars. AMCP was concerned that FDA's recent removal of its 2006 policy for biosimilars naming may be an indication that FDA plans to change its policy in order to seek clarification.

AMCP supports the adoption of a uniform INN for biologic products deemed by the FDA to be interchangeable, and believes that this direction is the most reasonable course of action to ensure patient access to safe and affordable biosimilars. The World Health Organization (WHO) has supported the INN classification system to establish generic names by active ingredients, not specific products. The FDA's 2006 statement also supported the WHO approach of using consistent INNs for products with the same active ingredient deemed interchangeable and FDA noted this approach is necessary for ensuring proper pharmacovigilance of biologics.

AMCP believes that nothing has changed in the development of biologic products that would warrant a change in the naming approach and furthermore, FDA is not under any statutory authority to implement a different naming approach. BPCIA does not include provisions for biosimilar naming, and in fact, Congress rejected an amendment that would have required unique INNs.

Finally, the adoption of a single INN for interchangeable biosimilars with the same active ingredient would be consistent with generic naming requirements for small molecule agents that allow pharmacists and other practitioners to substitute products with the same active ingredient deemed to be bioequivalent to the brand name product. Generic substitution of interchangeable products has led to decreases in pharmaceutical prices for consumers while ensuring greater access, a trend that could be continued if the same approach is adopted for biosimilars.

Also in November 2013, AMCP shared its concerns with the World Health Organization (WHO) about its Executive Summary published by the 56th International Nonproprietary Naming (INN) Consultation that includes a proposed naming convention to include word identifiers or a two-part name for biosimilars. AMCP was concerned that this nomenclature would create confusion in identifying two products with the same active biologic components and also result in the inability of prescribers, pharmacists, and other health care providers to identify products that are considered interchangeable, safe biologic alternatives. AMCP urged the WHO to consider our concerns when they consider those issues at their 57th INN Consultation in April 2014.

A standard INN would allow electronic health record systems (EHRs) and pharmacy systems to recognize biologics that are grouped in a therapeutic class. A consistent nomenclature for interchangeable products will help prescribers and pharmacists identify and select products identified by the Food and Drug Administration as interchangeable. Then, national drug codes (NDCs) or other package-specific identifiers, such as lot numbers and manufacturer names may be used to identify products that have been dispensed to patients. While the use of unique INNs may seem to be a solution to identifying specific products in the marketplace, simply adding a suffix or two-part naming convention to a product does not ensure full traceability of specific packages.

Some concern has been raised about the use of NDCs when billing for specialty medications. AMCP and others in the industry believe that the growth of integrated medical and pharmacy specialty drug benefit has led to more medical claims including NDC-level detail. AMCP is currently considering the formation of a data consortium to monitor adverse drug events associated with biologic agents. Preliminary information gained from an expert panel that included health plans, representatives from existing data consortiums, pharmacy benefit management companies, pharmacies, pharmaceutical companies, and government representatives believe that NDC-level data will be available for surveillance monitoring.

In the absence of NDC data, AMCP supports the immediate adoption of product-specific J codes when infusion drugs are approved. A study[1] demonstrates that where an NDC is not available, algorithms are available to accurately identify the specialty product. These algorithms may be used in active surveillance products. These algorithms can accurately identify newly approved biologics administered parenterally prior to the assignment of specific drug costs with sensitivity and specificity of 94% to 100% respectively.

Thank you for your consideration of our comments on Follow-on Biologics. AMCP believes that the FTC should study the effects of the proliferation of state legislation as it relates to competition. Patients need to have access to safe and affordable medications. AMCP agrees that biosimilar competition should be encouraged and not subject to restrictive requirements that do not apply to any other category of drugs approved by the FDA. If you have questions regarding AMCP comments or require further information, please contact me at (703) 683-8416 x645 or erosato@amcp.org.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

[1] Curtis, Xie, Chen R, Chen L, Kilgore, Lewis, Yun, Zhang, Wright and Delzell, Identifying newly approved medications in Medicare claims data: a case study using tocilizumab (Pharmacoepidemiology and Drug Safety, 2013) 22;1214-1221