January 28, 2014

The Honorable Jonathan David Leibowit
Chairman, Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Chairman, Leibowit:

I am writing in comment to the Federal Trade Commission on the issue of Naming Conventions Concerning Follow-on Biologics, so-called biosimilar products.

As a member of the public health community, a practicing pharmacist and a patient advocate I am pleased that FTC is holding hearings and considering its position regarding the potential impact naming conventions for biosimilars may have on consumer disclosure, access and the evolving regulation of commercialization of complex biologic products. Biosimilars will be of long-term value to patients only if regulations are in place to prevent commercial abuses, facilitate access to products of consistent and traceable quality, can be safely used in varied critically ill patients as well as products that are affordable.

Patients across the US and in every other country in the world will be best served if distinguishable names are required for all biologics and their biosimilar follow on compounds. Providing clarity of information with distinguishable names or codes that are transparently traceable back to the point of bio-manufacture and ending at the point of dispensing/administration to the consumer is essential to keeping a secure process that insures patient safety. As history shows, the integrity of drug and biologic supply and the ability to properly manage clinical care require clear unique product identification. Such unique naming/coding also continues FTC's long and valued tradition of advocating for full and transparent disclosure of product information for the consumer

Commercialization of biologically similar therapeutic agents is a very new and unvalidated branch of commercial biomedical science. Because of its potential market valuation it will quickly become the focus of globalized pharmaceutical markets. It is essential then that regulatory processes be put in place to insure that as the science and market access to such products progress the rights of patients to full disclosure of precisely what they are receiving is a core regulatory safeguard. Equally important are a regulatory processes and climate that will optimize patient safety and critically asses the true therapeutic bioequivalence of molecular variants of products. Such underpinnings are needed to insure safety and good clinical care as the understanding of this science matures. Unique nomenclature or coding of biosimilar products is core to such regulation and manufacturer accountability. The importance of providing for specific and precise product identification is of heightened importance with biosimilar products and their presumed biotherapeutic equivalents because of the large proportion of immunocompromised, frail and vulnerable populations with complex and life-threatening medical conditions that are most likely to receive these products.

As has been seen over and over again with drugs and biologics, unanticipated adverse and salutary effects of newly commercialized products introduced into a global market frequently take up to five years to become noticed. At this point, without the benefit of precise post-marketing surveillance, real-world experience and broadly monitored product exposure in varied populations, the assertion that small molecular differences between biosimilar products are inconsequential is simply not yet proven. In the truest sense of the word, the assertion of biotherapeutic equivalency by some in support of non-unique product designations is by any convention a scientific hypothesis that needs to be validated.

Requiring unique names or identifier codes for biosimilars at the outset of the global market explosion in this area will provide essential, broad based, real-life clinical experience to use in determining if the hypothesis of biotherapeutic equivalency for biosimilars is correct or not correct. Protecting the integrity of the scientific process for this evolving area of commercial biomedical science is essential to meeting the goals of facilitating new market entrants and building a trustworthy and competitive market. *If distinct nomenclature or identifier codes are not required for biosimilars as they are introduced by various commercial entities valuable and possibly life-saving information will be lost forever*. If untraceable biosimilars become the norm and should the hypothesis of biotherapeutic equivalency not prove to be correct it would likely cause significant morbidity and mortality and thus irreparably damage this market and consumer and practitioner confidence in this class of products. Once new untraceable products are introduced to the world's population it would be practically impossible to go back and reproduce the pedigrees and the needed scientific examination of efficacy and safety. I would urge that the time tested precept of scientific hypothesis generation and proof be applied to this important infant branch of biologic. If regulators do not provide at the outset for nomenclature or identifier codes that can differentiate biosimilar products at the outset, and until the hypothesis outlined above is adequately tested, it puts the public and correct science at risk.

Respectfully:
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and
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