April 15, 2012

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Commissioner Hamburg:

I am writing on behalf of the Alliance for Patient Access (AfPA), a national network of over 400 physicians dedicated to ensuring the highest quality of care for our patients. The AfPA appreciates the U.S. input from physician groups such as ours.

Health policy issues including: comparative effectiveness, therapeutic substitution, prescriptive authority, evidence-based medicine, and health access disparities.

In 2011, AfPA launched the National Physicians Biologics Working Group, which is a home for physicians interested in policy issues relating to access to biologic therapies.

As physicians, we see the influence of biologic products firsthand. In many areas of medicine including oncology, neurology, and endocrinology, biologics have provided life-changing improvements in health outcomes. In some cases, biologics are the only effective treatment left for our patients. It is because of our unique role in providing concern to us.

While the United States has had nearly three decades to perfect the pathway for the approval of generic versions of traditional pharmaceuticals, the regulatory framework for the approval of biosimilars is still in its nascent stage and several challenges remain. An important challenge centers on the highly sensitive nature of biologics. Because many biologics are proteins, they are significantly larger than a traditional pharmaceutical and are often exceptionally sensitive to heat and light in addition to being denatured by agitation. The active product that a patient receives is often a complex three-dimensional protein structure and even the slightest differences in the manufacturing process can induce unexpected adverse events or significant differences in efficacy and dosing.

RE: Docket Number FDA-2011-D-0605 -- Considerations in Demonstrating Biosimilarity to a Reference Product

Docket Number FDA-2011-D-0602 -- Considerations in Demonstrating Biosimilarity to a Reference Protein Product


Determining the dosing, efficacy, and safety of biologics and biosimilars is an entirely different undertaking when compared to the usual procedures comparing traditional, small molecule, pharmaceuticals. To ensure patient safety, we join with many others in advocating that the FDA include the following elements in forthcoming regulations:

· Clinical testing should be mandatory for each biosimilar product, even if it contains the same biologically active component(s) as a product that is already on the market;

· Each step of the manufacturing process must be monitored with a robust tracking system that includes unique nonproprietary names and lot numbers. A comprehensive labeling system must be implemented to allow the precise tracking of an individual dose of a biologic product to the specific manufacturer;

· Interchangeability determinations should only be made after a biosimilar product has been fully investigated in pre-market clinical trials and then been utilized in the US post-market in a sufficient number of patients over a long enough period to reflect its performance in typical clinical practice.

Because of the diversity of biologic products being considered for this pathway, interchangeability standards and determinations must be very narrowly defined for each specific class of therapeutics; and

· Most important to the AfPA, the physician-patient relationship and decision making process must be preserved. Insurers or other third parties must not be empowered to dictate what therapies physicians can prescribe and patients can access. Only physicians, not insurers or other third parties, have the medical education and understanding of these powerful therapies.

With these principles included in the new FDA regulations, the AfPA supports the development of a biosimilars pathway that balances patient safety, affordability, and physician-patient autonomy.

Thank you for the opportunity to provide our recommendations on the draft biosimilar guidance documents. Please do not hesitate to contact the AfPA with any questions.

Sincerely,

David Charles, M.D.
Alliance for Patient Access