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September 26, 2013

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

I am writing you today on behalf of the Global Healthy Living Foundation (GHLF) and the more than 56,000 members we represent to express our urgency in the need for unique non-proprietary names for all licensed biological products and in particular, biosimilar versions of reference products.

Biologics are complex molecules whose production is subjected to many steps (all of which are proprietary) and cannot be replicated for diminished cost by generic manufacturers. Biosimilars are not generic medicines, and do not have to meet the same standards of equivalence that generic products do. Because biosimilars are similar to, but not the same as, their biologic reference product, it is essential that each biosimilar product have a distinguishable name so that patients and doctors can easily differentiate between medicines.

As patient advocates, it is the GHLF's duty to ensure that patients and physicians are in charge of the drugs prescribed, that patient safety is the top priority in the health care process and that medical decisions remain between a doctor and his or her patient. We believe this can best be accomplished through assignment of distinguishable non-proprietary names that stay the same for the life of the product. Accurate medical product identification and distinction is a critical component to the safety of a public health system. Robust record-keeping and tracking will increase our ability to attribute adverse events to the correct product. From the time an adverse event is reported, the clock begins ticking. The sooner the problematic source can be identified, the lower the negative impact will be on unknowing patients and physicians.

As a prescribing physician who manages a wide spectrum of autoimmune disorders and in view of the many quality control elements whose sacrifice potentially threatens patient safety, I endorse a system of distinguishable names for biologic medicines. I commend the FDA for their long history of dedication to patient safety and thank you for your consideration of my perspective.

Sincerely,

Jonathan Krant, MD, FACP
Chief Medical Officer, Global Healthy Living Foundation
Section Chief of Rheumatology, Adirondack Health