



Global Healthy Living Foundation  
515 North Midland Avenue  
Upper Nyack, New York 10960 USA  
+1 845 348 0400  
+1 845 348 0210 fax  
[www.ghlf.org](http://www.ghlf.org)

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Donald S. Clark  
Office of the Secretary  
Federal Trade Commission  
600 Pennsylvania Ave.  
Room H-113, Annex X  
Washington, DC 20580

RE: Workshop on Follow-On Biologics: Project No. P131208

Dear Secretary Clark,

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 FTC for their efforts in organizing a workshop to explore competition issues involving biologic medicines and follow-on biologics. I understand the issue facing the FTC; with expanding demand for good-quality healthcare, comes the challenge of controlling healthcare expenditure. Biosimilars are forecasted to increase access to much needed biologic medicines and reduce costs. However, this promise must not deter from the responsibility we have to patients to remain diligent in ensuring

the safe and regulated introduction of biosimilars into the market.

Sincerely,

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

