Draft Guidances Relating to the Development of Biosimilar Products
Part 15 Public Hearing

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FDA White Oak Campus
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Silver Spring, Maryland 20993

by

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Disclosure:
I have no disclosures to make regarding my travel here today. The GHLF accepts grants and charitable contributions from many pharmaceutical companies as well as government, private foundations and individuals.

Good morning. On behalf of the Global Healthy Living Foundation, I want to thank this committee for allowing me to speak. GHLF is a 501(c)(3) patient advocacy group that works to improve access to care for people with chronic disease, often focusing on those least likely to advocate for themselves. We represent more than 55,000 members in our CreakyJoints arthritis organization. Approximately 70 percent have Rheumatoid Arthritis and many take biologics. Other groups we have created and nurture are CreakyBones for osteoporosis and RedPatch for psoriasis. Of course, many patients in these groups take biologics, too.

My name is Alexey Salamakha, the national program manager for the Global Healthy Living Foundation. I am speaking for these patients as well as our President and co-founder Seth Ginsberg who was diagnosed with arthritis 17 years ago when he was 13. Seth regrets not being able to deliver our remarks personally.

Dr. Behrman and members of the panel:

In sports there is a winner and a loser. Infrequently there is a tie.

We know in medicine there can be all three at the same time. The cliché, a level playing field, comes from sports because fairness is the foundation that protects players, and ensures a credible outcome that each team respects – win, lose or tie.

In medicine we can't always have clear winners or clear losers. Sometimes medications work and sometimes they don't. But we need to strive for the level playing field so patients are protected and all parties respect the process.

The Global Healthy Living Foundation is asking the committee to build a level playing field for biosimilars so that all parties – physicians, patients, caregivers, insurers, pharmaceutical companies, regulators, and advocacy groups like ours – will respect the process.

We believe the committee's current guidance can become the foundation for the level playing field our constituencies require, and we thank the committee for this important beginning. Everyone is here today to help guide the process, and *we* would like to do this in the following categories:

1. The biosimilars definition
2. Clinical testing issues
3. The physician/patient relationship
4. Interchangeability and substitution
5. Pharmacovigilance and naming

Because biosimiliars are comprised of living unique and complex structures, they are not easily replicated. Small changes in the creation of biosimilars have the potential to help or hurt a patient. They are not identical copies of the innovator drug, and we want to ensure that the populations we serve understand this. Therefore a comprehensive definition is necessary.

Because of the inherent difference between the innovator drug and the biosimilar, we believe clinical trials are critical. There are no short-cuts to safety or efficacy that might be otherwise appropriate with traditional small-molecule drugs. We support testing and post-approval monitoring.

Physician organizations and the innovator companies themselves recognize there is an increased risk of infection with biologics. It is the physician who is charged with mitigating this risk by monitoring treatment and knowing patient history. Despite the fact that biologics are well tolerated and safe, the physician is the person most qualified to make the right medical decision, not a third party that will make that decision based on economics that translate into profit. Medical decisions are not arbitrary, and neither are those that promise a greater return to the payer. As a society we have to decide whether we want physician-based or profit-based care. The Global Healthy Living Foundation recommends physician-based care which prevents payer-initiated automatic substitution and interchangeability.

Our last request asks the committee to allow all constituencies to readily tell the difference between biosimilars and the original biologics. We have spoken with several people on both sides of the biosimilars issue and we have not heard a substantive reason for abandoning unique biosimilar names and distinctive labels so physicians can make informed decisions, and regulatory bodies can track any quality or safety issues. Our community deserves to know what drug it is taking and that all drugs have successfully passed safety and efficacy trials.

We believe a clear definition, stringent testing, preserving the physician/patient relationship, eliminating substitution and interchangeability, and a naming system that provides a clear audit trail, is imperative if the committee is to continue to build on its foundation of providing a level, and healthy playing field for all parties.

When the analogy of a level playing field is applied to sports, it means all parties have an equal chance to pursue victory. When profit intrudes to the benefit of one team, it is illegal and it's called game-fixing.
When the level playing field analogy is applied to medicine, it means all parties enjoy the support of the fair rules of government and society so the patient and physician can pursue an individualized, productive health and improved quality-of-life strategy.

We respectfully request that the committee consider our point of view, and although I am standing in for Mr. Ginsberg today, I can either answer questions you may have or refer them to him so he can respond directly.

Thank you again for allowing us to speak on this important issue.

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