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FDA PUBLIC HEARING STATEMENT

Approval Pathway for Biosimilar and Interchangeable Biological Products

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 the quality of life for people with chronic disease, often focusing on those least likely to advocate for themselves. We focus on several disease states and the people who live with these diseases, including more than 42,000 members of CreakyJoints.org, CreakyBones.org, and RedPatch.org, our arthritis, osteoporosis and psoriasis patient advocacy groups respectively.

My name is Seth Ginsberg, and I am a co-founder of the GHLF and its communities. I was diagnosed with Spondyloarthritis at 13. By age 15, I was a national spokesperson for the Arthritis Foundation. At 18, when I went away to college – 200 miles from home and in pain – I quickly realized there was a need for a positive, supportive community – experts and other patients alike – with whom to share strength and experience. The virtual community we called “CreakyJoints” was the result of this realization. In the past 11 years, we have incorporated additional conditions, and advocated for patients within the private health insurance, Medicaid and Medicare communities, in order to help ensure access to care.

It is in this outreach context that I am speaking here today -- representing our members, nearly 70 percent who take, or are considering taking biologics. This subgroup is mostly female, ranging in age from their mid 20s to their 70s.

But the word “represent” does not properly define the relationship between GHLF and our members. It is a cold word that falls short in describing our commitment or our activities, and in order to make my eight minutes here today as effective as possible, I need to explain this commitment and why biosimilars are so important to us.

Imagine yourselves, for a minute, at a circus, looking up to the top of the tent at a high-wire performer. When we watch her make her way across that wire we are doing more than watching. We are feeling her every move. And when she slips, and then regains her balance, we gasp in empathy. And when she reaches the other side, we applaud and exhale. If she falls, we fall with her, and become silent as people

gather around to help her. And we hope she will get up and take a bow. We, in the audience, emotionally participate in her walk across the wire. We are walking with her.

Frans De Waal, the famous primatologist and author, recounts in his latest book, “The Age of Empathy”, this feeling we have watching high wire acts. He uses the German word *Einfühlung* to describe it – which translates as “feeling into”.

At the Global Healthy Living Foundation, we have *Einfühlung* because many of the 42,000 of us are on the high wire ourselves, living with the disease, putting our faith and hope in a biologic. We and our families gasp when it doesn’t work, and applaud and exhale when it does.

But not everyone involved in the delivery of our healthcare has *Einfühlung*. For example, payers do not have it. They cannot have it, because they don’t live with the disease. They live with the business of the disease, and that doesn’t even bring them into the *Einfühlung* tent. We’re not sure they even want to be there, because *Einfühlung* – feeling into – is a luxury too dear for today’s shareholder-run business model they have adopted. If they did have *Einfühlung*, they would brook no deviation from the proven process and the established product that makes up the biologics market today. They would welcome new biologics, and as the American College of Rheumatology clearly states, they would respect the differences and allow physicians to prescribe the biologic they think will work best for their patient. They would not make patients fail on one biologic first before moving to the one preferred by their physician, or switch biologics solely for economic reasons in order to achieve cost savings. Now if you think I’m digressing, I am not, because these policies – fail first, drug switching, and, in certain circumstances, the use of biosimilars – are all based on good economics, not great medicine. And in this case especially, as the author Jim Collins said, “Good is the enemy of great.”

Having said all this, we are **not** against biosimilars. We want maximum choice for our members and biosimilars can help reach this goal. That maximum choice, however, has to meet their expectations in five key areas and we are not sure biosimilar proponents are ready to meet our members’ expectations. The key areas are:

1. Pre-marketing clinical data that ensures biosimilars are safe and effective.
2. Even if it looks like the reference biologic, it may not act like the reference biologic and, as the scientists say, “determinations of comparability” cannot be made for products that are not comparable. This is why we need clinical trial experience. We cannot extrapolate indications across biosimilars.
3. Biosimilars cannot be considered as interchangeable with the biologics they attempt to copy. They are not identical, generic versions of biologics. That’s why nobody calls them generics.
4. There must be post-marketing clinical and safety studies.
5. There must be a way for patients, physicians and government agencies to clearly differentiate between biosimilars and the original biologics, and to track the molecules to their origin by manufacturer and batch. We do it with eggs. We must do it with biosimilars.

Again, paraphrasing from the scientific community, biologics are not produced through strict adherence to a defined chemical process, but through a complex process that involves living cells and organisms.



There is much that can go wrong if we ignore or underestimate the unique and complicated path biosimilar producers must navigate.

But, as I understand it, if biosimilars went through this process, the cost involved, some say, would make them as expensive as the branded biologics they seek to mimic. And with no cost advantage, their relevance as a treatment protocol is in question by those in the business of the disease. So, in order to keep these costs down, in order to make the business case for biosimilars, the process of making, identifying and prescribing them deviates from the rigid science and learned art that determines how original biologics are brought to market, and this deviation is responsible for their success. Nomenclature which allows tracking to a specific manufacturer could be lost, and patient and physician understanding of exactly what drug is being used, and from whom, also could be lost.

We think this loss is unacceptable and represents a step backward for science, for physicians, and for us patients. We do not know how much this step backward will cost in patient care and confidence in our health care system, and its ability to deliver safe and effective treatment protocols. But cost, in these terms, isn't the issue with biosimilars, savings are. And contrary to what some people hearing me speak today might think, I need to say again, we are not against biosimilars or saving money in healthcare.

We are against using biosimilars as the vehicle for making money by disregarding the standards and practices that have created the biologics miracle. I know, I just used the word miracle in front of a panel of scientists. Maybe not the best choice of words, but remember *Einfühlung* – feeling into. Remember the high wire performer. Remember our constituency. Biologics to us are the miracle that has allowed our members to go back to work, to stop the progression of their disease, to allow the word remission to creep into the autoimmune lexicon. Biologics have taken away pain, and have allowed a grandmother, a great grandmother, and a mother to hold their children close and make the world a little better, a little safer and a little more welcome

We are not willing to welcome a new protocol that does not hold these promises as a priority.

Thank you for allowing me to speak on behalf of our members.

