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**FDA PUBLIC HEARING STATEMENT**  
Arthritis Advisory Committee on BLA 125370, belimumab  
*by*  
Seth Ginsberg  
President, Global Healthy Living Foundation  
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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. We have not accepted any contributions from Human Genome Sciences or Glaxo Smith Kline, the companies associated with belimumab.*

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 42,000 members.

My name is Seth Ginsberg. I was diagnosed with Spondyloarthritis at 13. At 15, I was a national spokesperson for arthritis. Eleven years ago, at 18, I co-founded GHLF

Today I am representing our members who have Lupus Nephritis, their families, caregivers and healthcare workers, and those who will be diagnosed with this disease in the future.

John Maynard Keynes, a name not often invoked at FDA hearings, said, during the Great Depression – when many people were decrying capitalism – that capitalism was the best system ever devised to achieve a civilized economic society. But he recognized it had two major faults: “its failure to provide for full employment and its arbitrary and inequitable distribution of wealth and incomes. Until these were corrected, he argued, capitalism would be highly unstable, and vulnerable to economic booms that would often be followed by catastrophic collapses.

Applying Keynes’ structured economic logic to our drug approval process, we know it is the best system ever devised to achieve a healthy society. But it has two major faults: Its inability to reduce the highly complex nature of today’s drugs and their interaction with others to achieve a simple “yes” or “no” regarding approval, and its inability to approve a drug that will deliver positive results in all patients. Until these are corrected, medicine will be vulnerable to celebrations of science followed by the devastation of failure.

Today we are asked to work within the confines the best but imperfect system that will decide the fate of belimumab, the first new drug for Lupus in decades. A drug that patients and physicians want.

At GHLF, we recommend that when science serves up its best, we look into the eyes and hearts of patients to see if the best is good enough, and in the case of belimumab, we think it is.

Today, Rheumatologists and their patients live with the destruction Lupus causes to families, employers, patients, and society. And this drug, if approved, offers another opportunity for all of us to benefit from the best system ever devised to achieve a healthy society.

Thank you for allowing me to speak on behalf of our members. We urge the committee to approve belimumab.

