FDA PUBLIC MEETING STATEMENT, OPINION AND RECOMMENDATION

Arthritis Advisory Committee Public Meeting

The committee will discuss biologics license application (BLA) 761024, for ABP 501, a proposed biosimilar to AbbVie Inc.'s HUMIRA (adalimumab), submitted by Amgen, Inc.

Speaker:
Seth Ginsberg
President and Co-Founder
CreakyJoints, the arthritis organization of the
Global Healthy Living Foundation

July 12, 2016

Disclosure:
I have no disclosures to make regarding my travel here today.

On behalf of the non-profit Global Healthy Living Foundation and its arthritis organization, CreakyJoints, I want to thank the FDA for its commitment to listening to a diverse set of stakeholders.

We are not scientists or doctors. We are patients.

My name is Seth Ginsberg, co-founder of CreakyJoints and the Global Healthy Living Foundation. I was diagnosed with Spondyloarthritis at 13.

For patients, biosimilars represent hope as well as fear. Hope for expanded treatment options through a broader formulary; fear of being switched from a drug that works to one they don't know, and not participating in the promised cost reductions.

Nevertheless, at CreakyJoints we are optimistic about biosimilars and look forward to seeing them in our therapeutic space where, through ArthritisPower, our PCORI-sponsored work as a Patient Powered Research Network, we can track patient-reported outcomes.

In order to achieve the promise originally intended by the BPCIA in 2010, we are addressing patient and physician *confidence*. We believe the FDA and biosimilar manufacturers can support this effort by examining their supply chain and support services, creating unique naming and clear labeling, as well as interchangeability policy decisions that prevent payer-level switching for non-medical reasons.

For this particular BLA, we believe the applicant has shown exemplary effort to increase patient and physian confidence. First, they have provided clinical studies that prove safety and efficacy for two indications, rheumatoid arthritis and plaque psoriasis, surpassing the FDA requirement of just one. Second, the applicant created an assay with an extraordinarily high level of sensitivity to gauge the biosimilarity of their molecule to the reference product. In the future, we suggest

more weight be given by members of this committee to the sensitivity of the assays created by applicants.

Although it is a controversial topic among the patient community, we support FDA's position to allow extrapolation. We understand that you can't have biosimilars without having extrapolation. It is needed in order to reduce cost and allow biosimilars to reach many patients. Once this expanded access and savings is achieved, our hope is that more healthcare dollars will be allocated to innovative therapies. However, we respectfully oppose extrapolation when the mechanism of action for the extrapolated indication is not clearly understood or the drug is considered scientifically or therapeutically outdated.

Science is only part of biosimilar success. Use and satisfaction is where success also will ultimately be measured.

We thank the FDA for emphasizing the value of the patient perspective through public meetings, and we continue to mobilize our patient community to create a better life for those who will benefit from biosimilars.