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November 2, 2021

Dr. Janet Woodcock, Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave  
Silver Springs, MD 20993

**RE: FDA Decisions on New Safety Warnings and JAK Inhibitors**

Dear Acting Director Woodcock,

The Global Healthy Living Foundation (GHLF) is concerned with the recent FDA MedWatch communication on September 1, 2021 regarding new warnings for patients taking Janus kinase (JAK) inhibitors to treat chronic inflammatory conditions. We received the press release from FDA but, unfortunately, no additional information for our research and communications teams to review, process and relay onward to patients. We are seeking more clarity from FDA on safety warnings for these medication(s) so that we may continually and effectively communicate this vitally important information to the millions of patients living with diseases that are part of our community.

GHLF is a 501(c)(3) patient group that works to improve the quality of life for people with chronic disease. We represent millions of chronically ill people across the country and around the world, including hundreds of thousands of U.S. chronic inflammatory disease patients with rheumatoid arthritis, psoriasis and IBD. GHLF is also one of the original PCORI-funded PCORnet patient-powered research networks established in 2014. The ArthritisPower registry actively conducts patient-centered research with more than 34,000 arthritis patients on topics that include medication side effects, and patient perspectives and experiences with these adverse events. In addition, our digital arthritis community, CreakyJoints.org, serves more than 1 million patients a month through its English and Spanish websites, and averages 19 million impressions a month on social media in 2021.

We understand that the FDA faces incredible pressure to ensure that patients and the public are fully aware of all risks of all medications. We appreciate your commitment to making sure products are safe and information about safety is communicated clearly, consistently and quickly to the public. Our concern is that broad press release communication without additional data results in confusion, disruption and access issues for patients. We are hopeful that following discussions with patient groups like ours, and provider groups such as the American College of Rheumatology, practicing physicians and individual patients, the FDA will clarify safety warnings for these medications, incorporating as much data from as many sources as possible to then provide specific or targeted warnings for individualized at-risk patients.

We are eager to engage with the FDA in discussions regarding risk/benefit data collection and patient communication, for JAKs as well as for other classes of medication for our patient communities, and we thank FDA again for its continued emphasis on safety.

Respectfully submitted,

A handwritten signature in black ink that reads "Steven Newmark".

Steven Newmark, JD  
Director of Policy and Chief Legal Officer