# Congress of the United States
## Washington, DC 20515

February 14, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Stephen M. Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Secretary Azar and Commissioner Hahn:

We write to request the Food and Drug Administration (FDA) hold public workshops on the development of Valley Fever diagnostics, drugs, and biologics in order to inform development of a guidance for industry document to help with approval of these and related products.

As you likely know, Coccidioidomycosis, also known as Valley Fever, is caused by inhaling the spores of a fungus found in the soil in the American Southwest and Pacific Northwest, with reported cases on the rise recently in California and Arizona. This fungal disease typically presents flu-like symptoms, but can spread to other parts of the body and become life-threatening. While the scientific community has made important advances in recent years, treatments are limited and there is currently no FDA-approved cure or vaccine.

That is why we introduced the Finding Orphan-Disease Remedies with Antifungal Research and Development (FORWARD) Act of 2019 (H.R. 2858), which focuses on fungal disease research, the development of new antifungal therapies, and vaccine development. Section 4 of this bill would direct the FDA to hold public workshops and initiate the guidance for industry process on development of antifungal therapies and vaccines for Valley Fever. We were pleased to see in FDA's October 9, 2019 correspondence regarding the Tropical Disease Priority Review Voucher Program that the FDA is planning on holding a public workshop on the development of therapies to treat Valley Fever, including a discussion on trial designs, endpoints, and patient populations.

We understand that FDA guidance for industry documents convey the FDA's current thinking on a topic and contain non-binding recommendations on the best practices for getting drugs and therapies approved by the FDA. It is our belief that increased collaboration through public workshops, as well as the FDA issuing a guidance for industry document, will be an important step to facilitate the development of novel therapies and a vaccine for Valley Fever. Accordingly, we fully support these public workshops and look forward to them being scheduled as soon as possible. Furthermore, we hope that FDA uses these workshops to inform and ultimately initiate a guidance for industry process with respect to Valley Fever diagnostics, drugs, and biologics. Please keep us informed on when the FDA Valley Fever workshops are scheduled.

Thank you for your attention to this important matter.

Sincerely,

KEVIN McCARTHY
House Republican Leader

DAVID SCHWEIKERT
Member of Congress