Congress of the United States
Washington, DC 20515

March 6, 2024

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write to encourage the U.S. Food and Drug Administration (FDA) to reconsider expediently the addition of coccidioidomycosis, also known as Valley Fever, to the current list of tropical diseases that qualify for a Priority Review Voucher ("PRV")[1]as directed in House Report 117-392.

Valley Fever is an infectious disease caused by the fungus *Coccidioides*. The fungal infection can be severe or deadly, with approximately 200 deaths occurring each year.[2] It is endemic to discrete areas of the American southwest.[3] Given that the vast majority of infections occur in only certain parts of Arizona and California, particularly the south San Joaquin Valley, the disease is particularly concerning to our constituents.[4] Nationally, however, Valley Fever is considered a rare disease. In 2019, the most recent year for which the Centers for Disease Control and Prevention (CDC) has published data, there were 20,003 reported cases of Valley Fever.[5] As is often the case for rare diseases, there have not been sufficient market incentives to encourage recent development of products for the treatment or prevention of Valley Fever. Moreover, the off-label use of certain antifungals to combat the disease is associated with significant adverse effects.[6]

From our understanding, the FDA should be able to qualify Valley Fever as part of the Tropical Disease PRV program due to it being an "infectious disease for which there is no significant market in developed nations and [it] disproportionately affect[ing] poor and marginalized populations."[7] In 2015, the FDA issued an order explaining the factors used to designate diseases for the list. It is our understanding the Valley Fever prevalence in the United States is below the threshold set by the FDA for this program, which indicates a lack of a significant market to support the development of treatments and a vaccine, and

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[1] https://www.federalregister.gov/documents/2020/07/15/2020-15255/notice-of-decision-not-to-designate-coccidioidomycosis-as-an-addition-to-the-current-list-of
[2] https://www.cdc.gov/fungal/diseases/coccidioidomycosis/definition.html; https://www.cdc.gov/fungal/diseases/coccidioidomycosis/statistics.html
[3] https://www.cdc.gov/fungal/diseases/coccidioidomycosis/maps.html
[4] https://www.modbee.com/opinion/article279837719.html
[5] https://www.cdc.gov/fungal/diseases/coccidioidomycosis/statistics.html
[6] FDA Drug Safety Communication: FDA limits usage of Nizoral (ketoconazole) oral tablets due to potentially fatal liver injury and risk of drug interactions and adrenal gland problems | FDA
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332027/

disproportionately impacts marginalized populations according to data collected by the CDC and other public health organizations.

In light of the current standard of care, there is a critical need for improved products. We believe that an incentive in the form of a priority review voucher would provide necessary interest and investment. Accordingly, we request that the FDA review any and all new information related to Valley Fever and make a new determination on adding this disease to the PRV program, consistent with congressional direction, so we can stamp out this public health threat.

Sincerely,

John Duarte
Member of Congress

David Schweikert
Member of Congress

David Valadao
Member of Congress

Jim Costa
Member of Congress

Michelle Steel
Member of Congress

Juan Ciscomani
Member of Congress