

Congress of the United States
Washington, DC 20515

July 26, 2019

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

The Honorable Norman Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Secretary Azar and Acting Commissioner Sharpless:

We write today to ask you to consider reviewing the inclusion of Coccidioidomycosis on the list of infectious diseases eligible under the Food and Drug Administration's Tropical Disease Priority Review Voucher (PRV) Program.

Coccidioidomycosis, often referred to as Valley Fever, is an infection caused by inhaling the spores of a fungus commonly found in the soil of the American Southwest and more recently in the Pacific Northwest, but also Central and South America, including Argentina, Bolivia, Brazil, Colombia, Guatemala, Mexico, Paraguay, and Venezuela.¹ While the scientific community has made important advances in Valley Fever research in recent years, much remains to be understood about this disease, including the fact that rapid diagnostics and treatments are limited and there is still no cure or vaccine.

Under Section 524(a)(3)(S) of the Federal Food, Drug, and Cosmetic Act, the Health and Human Services Secretary has the authority to expand the list of diseases in the Tropical Disease PRV Program to include, "any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations." Further, the Food and Drug Administration (FDA) issued a final order in 2015 (80 FR 50559) titled, "Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act," clarifying the various factors taken into consideration for adding infectious diseases to the list.

No Significant Market

In order to determine "no significant market," the FDA takes the following factors into consideration: 1) occurrence of the disease in developed nations; and, 2) existence of a sizeable indirect market for the tropical disease drug. As stated in the order, "If the prevalence of a disease in developed countries is less than 0.1 percent of the population of those countries, it is unlikely that ordinary market forces will offer a sufficient incentive to drive the development of new preventions or treatments." According to the Centers for Disease Control and Prevention (CDC), from 1998 through 2016, there have been roughly 170,000 reported cases of Valley Fever in the United States. Based on the CDC's reports, Valley Fever has a 0.05 percent incidence rate in the U.S. throughout the 19 years it has been reported—highlighting the

¹ <https://www.ncbi.nlm.nih.gov/pubmed/17395731>; <https://www.ncbi.nlm.nih.gov/pubmed/23824371>

insufficient market dynamic for development of new diagnostics, vaccines, and treatments for this disease. The FDA has indicated that it acknowledges a developed nation by referencing the World Bank's list of "high income economies." By that standard, the U.S. is the only developed nation in which Valley Fever is endemic and has a corresponding very low incidence rate.

As you know, drug development is a complicated, time-consuming, and capital-intensive process. This undertaking only becomes that much more difficult when a disease afflicts a smaller population of individuals. That is in addition to the FDA's own position articulated in the aforementioned regulation that, "If a disease's prevalence is high in populations who cannot afford treatment and low in populations that can, there likely will be little market incentive for drug companies to create new treatments."

Disproportionately Affects Poor and Marginalized Populations

Additionally, the FDA final order considers various factors to judge whether a disease "disproportionately affects poor and marginalized populations," including the: 1) proportion of global disability-adjusted life years for the disease that is attributable to developing countries; 2) relative burden of the disease in the most impoverished populations within the countries in which it is found; 3) relative burden of the disease in infants, children or other marginalized segments of the populations; and, 4) designation by the World Health Organization (WHO) as a neglected tropical disease.

According to a 2016 CDC Morbidity and Mortality Weekly Report, those at increased risk for the severe form of this disease include persons of African or Filipino descent, pregnant women, adults in older age groups, and persons with weakened immune systems.² Similarly, a report by the California Department of Public Health indicated that African Americans and Hispanics in California have higher rates of hospitalization compared with whites, while African Americans and Filipinos appear to be at higher risk for disseminated disease.³ Further, because Valley Fever is often connected with exposure to dust, in countries in Central and South America, the disease typically attacks persons in rural areas where *per capita* income can be low.

While Valley Fever is endemic to certain regions in the Americas, there is limited data and information on the prevalence of this disease in developing countries located in endemic areas. However, the WHO recently acknowledged the neglected nature of certain fungal diseases by adding to their neglected tropical disease list in 2017 "Mycetoma, Chromoblastomycosis, and other deep mycoses."

Conclusion

For the aforementioned reasons, we respectfully ask you to review Coccidioidomycosis for inclusion on the list of infectious diseases under the Tropical Disease Priority Review Voucher Program. Given the extremely low prevalence in developed nations and resulting lack of a feasible market, combined with the disease disproportionately impacting poor and marginalized populations—including pregnant women, children, and minorities—we believe

² https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a4.htm?s_cid=mm6631a4_w

³ <https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/VFRaceEthnicity.pdf>

Valley Fever merits inclusion on this list based on criteria set forth in statute and regulation so that vouchers can help expedite the development of treatments and preventions of this terrible infectious disease, both here at home and in developing countries in Central and South America. If you have any questions, please do not hesitate to reach out to us.

Thank you for your attention to this important matter.

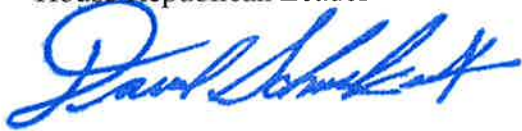
Sincerely,



KEVIN McCARTHY
House Republican Leader



MARTHA MCSALLY
United States Senator



DAVID SCHWEIKERT
Member of Congress



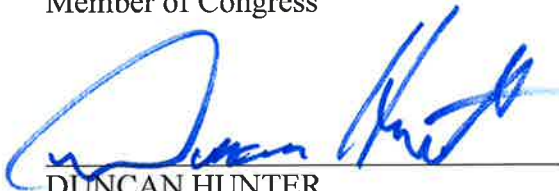
JOHN CORNYN
United States Senator



DEVIN NUNES
Member of Congress



KEN CALVERT
Member of Congress



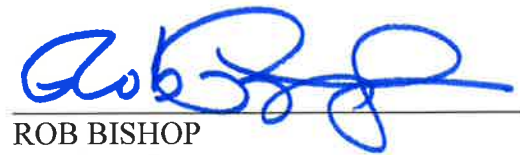
DUNCAN HUNTER
Member of Congress



DOUG LAMALFA
Member of Congress



PAUL COOK
Member of Congress



ROB BISHOP
Member of Congress



TOM McCLINTOCK
Member of Congress