

UC Office of the President

U.S. Department of Health and Human Services (HHS)

Title

UC Comments on FDA Final Order regarding Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Acton [FDA-2008-N-0567-0055]

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OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA Final Order regarding Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Acton [[FDA-2008-N-0567-0055](#)]

To Whom It May Concern:

I write on behalf of the University of California (UC) system with regard to the Final Order on Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Acton published on August 28, 2018.

The UC system has more than 800 research centers, institutes, laboratories, and programs that span ten campuses, six medical schools, a Division of Agriculture and Natural Resources, and three affiliated U.S. Department of Energy national laboratories. UC has established an unparalleled reputation for research and innovation that contributes to the state and nation through discoveries and new technologies that improve health, quality of life, and public safety.

The UC system appreciates FDA's effort to expand the list of tropical diseases as part of the Priority Review Voucher (PRV) Program and supports the addition of Lassa fever, chikungunya virus disease, rabies, and cryptococcal meningitis announced in this Final Order. However, we believe that coccidioidomycosis should also be included on the list.

In addition to the specific comment provided below, UC strongly supports the remarks submitted by UCSF on February 20, 2020 and the University of Arizona on December 3, 2019.

Include Coccidioidomycosis on the List of Infectious Diseases Eligible under the PRV Program

UC urges the FDA to include coccidioidomycosis to the list of infectious diseases eligible under the 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 Western regions of the U.S, as well as Central and South America, including Argentina, Bolivia, Brazil, Colombia, Guatemala, Mexico, Paraguay, and Venezuela. Although 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.

To address unmet needs for prevention, treatments, and cures, the FDA has sought to incentivize the development of orphan products through its Tropical Disease PRV Program. 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 based on the following criteria: 1) "there is no significant market in developed nations" and 2) the infectious disease "disproportionately affects poor and marginalized populations." Coccidioidomycosis meets both of these criteria.

In order to determine "no significant market," the FDA considers the following factors: 1) occurrence of the disease in developed nations; and, 2) the 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 insufficient market dynamic for the development of new diagnostics, vaccines, and treatments for this disease. New evidence suggests that, by 2100, climate change will more than double the areas in the US affected by Valley Fever and increase by 50% the persons who will become sick.¹

In terms of FDA's second criteria for inclusion within the Tropical Disease PRV Program, Valley Fever is particularly aggressive among African Americans and Filipinos communities. Although anyone living or traveling in the Southwestern US may be exposed to coccidioidomycosis, subsets of the population are at an increased risk for the severe form of this disease, including persons of African or Filipino descent, pregnant women, adults 60 years or older, and persons with weakened immune systems.² African Americans and Hispanics in California have higher rates of hospitalization compared with whites; African Americans and Filipinos face a higher risk for disseminated disease.³ Lower-income persons who work the soil in Central and South America also appear to be at risk for infection.

For these reasons, UC respectfully urges the FDA to include coccidioidomycosis in the Tropical Disease PRV Program, which would expand opportunities to make important advances in the prevention, treatment, and cure of Valley Fever.

Sincerely,



Lourdes G. DeMattos
Acting Executive Director
Research Policy Analysis & Coordination

¹ <https://agupubs.onlinelibrary.wiley.com/doi/epdf/10.1029/2019GH000209>

² <https://www.cdc.gov/fungal/diseases/coccidioidomycosis/risk-prevention.html>

³ <https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/CocciEpiSummary2018.pdf>