

United States Senate  
WASHINGTON, DC 20510

June 28, 2023

The Honorable Thomas J. Vilsack  
Secretary of Agriculture  
U.S. Department of Agriculture  
1400 Independence Ave., S.W.  
Washington, DC 20250

Secretary Vilsack:

We write to request an update on the canine Valley fever vaccine application (*Coccidioides Posadasii* Vaccine, Avirulent Live Culture, Code 1431.R0 (unlicensed)) from Anivive Lifesciences, Inc. currently under review by the U.S. Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS). As United States senators representing Arizona, where Valley fever is endemic, we know an approved vaccine would be able to address serious canine health issues. We also believe it holds serious potential for further development for human fungal prevention. We urge the USDA for a timely decision and stand ready to support this public health effort.

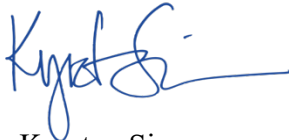
Valley fever (coccidioidomycosis) is a fungal infection endemic to the southwestern United States contracted by breathing in fungal spores. Found in dry soil, Valley fever is a significant health concern for both human and canine health in Arizona. Dogs are very susceptible to Valley fever and experts at the University of Arizona's Valley Fever Center for Excellence estimate that the infection costs Arizona dog owners at least \$60 million per year for diagnosis, treatment, and follow-up care. In humans, this disease disproportionately affects people with weakened immune systems with rates typically highest among people age 60 and older. The number of Valley fever cases reported to the Centers for Disease Control and Prevention (CDC) likely underestimates the true number of cases: tens of thousands more illnesses likely occur and may be misdiagnosed because many patients are not tested for Valley fever, and visitors or newer residents to the state may not be as familiar with its symptoms.

More than 65% of all human cases in the United States occur in Arizona. According to the University of Arizona, our state's Valley fever economic burden totals \$736 million, with \$671 million in direct costs and \$65 million in indirect costs. Direct costs include health expenses such like hospitalization, diagnosis and treatment, and follow-up care. Indirect costs include short-term work loss and lost earnings. Additionally, tribal and rural populations, and outdoor workers face higher risks for both the infection and complications. The Arizona Department of Health Services reports that Valley fever remained one of the most commonly reported infectious diseases in Arizona during the pandemic.

Many of the treatments available are decades old, and no preventative fungal vaccine currently exists for humans or for dogs. As the endemic region of Valley fever is projected to grow to nearly half of the United States within a few decades, our offices have been following the Anivive Lifesciences application for a canine Valley fever vaccine with great interest. If successful, the vaccine could be further developed and potentially approved for use in human health in collaboration with the relevant federal agencies (the Food and Drug Administration, the National Institutes of Health, as well as the CDC).

We urge the USDA to provide all due consideration to this important vaccine application, which we feel could be an important tool in combatting Valley fever in both animal and eventually human health. In accordance with all existing agency rules, regulations, and ethical guidelines, we respectfully ask that you give this vaccine application full and fair consideration as you make important approval decisions.

Sincerely,



Kyrsten Sinema  
U.S. Senator



Mark Kelly  
U.S. Senator