

Congress of the United States

Washington, DC 20515

August 29, 2023

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

Dear Commissioner Califf,

We write to express our concerns with the recent outbreak of Tuberculosis (TB) in bone graft material that has led to serious health complications and deaths in our state and around the country.

In July 2023, a physician with Michigan Medicine contacted us regarding a TB infection transmitted from a ViBone Allograft to his patient. This patient experienced severe health complications after being one of 36 patients who received infected bone matrix materials that were implanted in patients across the country. Regrettably, on August 10, 2023, the patient passed away due to the TB infection. No patient should suffer such devastating health outcomes from a transplant product.


This is not the first TB contamination incident with the company, Azyio Biologics, located in Silver Spring, Maryland. In 2021, a similar outbreak occurred where TB was transmitted via bone graft. The contamination of the infected donor product was placed in up to 100 patients and eight patients lost their lives. Our patients should rely on the integrity of their products, as they are used to improve their health and wellbeing.


We have long supported investments into medical research that have produced life changing therapies, products, and pharmaceuticals for patients across the country. While Azyio took proactive testing precautions after the 2021 incident, these precautions were not sufficient to prevent an outbreak two years later. Under the Public Health Service Act, the FDA has authority to determine the parameters of tested communicable diseases, which already includes Hepatitis, Syphilis, and Human Immunodeficiency Virus (HIV). As TB incidence is lower compared to the aforementioned diseases, the prevalence and devastating impacts of these outbreaks calls for prompt action from the FDA.

The American Association of Tissue Banks (AATB) is the top accreditor of bone and tissue transplant banks. On August 7, 2023, AATB released Bulletin 23-6, "Requirements and Recommendations for Reducing Risk of Mycobacterium tuberculosis Transmission." The bulletin outlines donor ineligibility criteria including TB exposure, infection, travel history, and age. We urge the FDA to consider these recommendations and promptly issue guidance or regulations based on sound science to protect patients and increase accountability for human tissue transplant products.

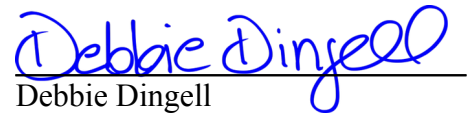
We appreciate FDA scientists, researchers, and medical professionals' dedication to ensure the health and safety of our communities. Thank you for your attention to this important matter. We look forward to your response and welcome any opportunity to work together to prevent future outbreaks.

Sincerely,


Debbie Stabenow
United States Senator


Gary C. Peters
United States Senator


John R. Moolenaar
Member of Congress


Debbie Dingell
Member of Congress