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August 17, 2023

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

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention
395 E Street, S.W.
Washington, D.C. 20024

Dear Commissioner Califf and Director Cohen,

This letter is to express my serious concerns regarding a recent outbreak of tuberculosis (TB) linked to the implantation of contaminated bone graft material.

The Centers for Disease Control and Prevention (CDC) has reported it is working to respond to tuberculosis cases appearing to be linked to bone graft material supplied by Aziyo Biologics.[1] Shipments of the bone matrix material were sent to thirteen facilities in seven states, including my home state of Michigan, between February 27 and June 20 of this year. It has been reported a total of 36 patients underwent surgical or dental procedures using products from the contaminated lot.

Regrettably, I have now learned a Michigan patient had recently undergone a surgical procedure and received Aziyo Biologic's bone repair product, called ViBone Moldable, from the contaminated lot. After spending a month being treated for a severe post-surgical TB infection in an intensive care unit in Washtenaw County, the patient recently died. The patient had no other possible way of contracting tuberculosis, and the primary site of infection was the site of the ViBone Moldable insertion.

The CDC has identified several other patients who have contracted TB from the same lot of the product that was harvested from the TB-infected donor, and it has been reported that all patients are being treated for TB.[2]

While Aziyo Biologics has issued a voluntary recall of its bone matrix products, I remain seriously concerned about the company's troubling history. This new outbreak follows a similar outbreak in 2021 that is also linked to contaminated products from Aziyo Biologics. According to a review published in the National Library of Medicine, bone tissue was procured from a

[1] https://www.cdc.gov/hai/outbreaks/TB-bone-allograft.html
[2] https://www.washingtonpost.com/health/2023/08/04/tb-outbreak-tuberculosis-bone-graft/

tissue donor who had unrecognized signs consistent with tuberculosis.[3] Units of the bone graft product were implanted into 113 recipients in 18 states between March 1 and April 2, 2021. Of those 113 patients, at least 87 patients developed TB, and eight died after receiving the contaminated bone matrix material.[4]

It is unacceptable another outbreak of this kind to occur at all—let alone another outbreak from the same company—due to TB-contaminated materials. According to the FDA, "new requirements to determine donor eligibility, which also went into effect on May 25, 2005, include important steps to ensure that donors do not harbor infections that could be transmitted to recipients."[5] Unfortunately, despite these requirements, it is clear not enough is being done to regulate bone tissue implantation.

It is my understanding bone tissue donors are not required to be tested for TB or TB risk factors. Some allege that testing for TB is not currently conducted because infection is rare in bone grafts.[6] Given there have been two outbreaks of TB-infected bone grafts since 2021 that have resulted in unnecessary human deaths, it is critical changes are made to ensure safeguards are in place to mitigate dangerous and preventable outbreaks.

As we work to better understand this outbreak and identify ways to improve the regulation of human tissue, please provide responses to the following questions:

1. How are FDA and CDC monitoring and addressing the current TB outbreak linked to tainted bone tissue materials? How are FDA and CDC working with Aziyo Biologics on the ongoing investigation?
2. Have FDA and CDC identified the total number of patients who received product from the contaminated lot? If so, please provide a full accounting of impacted patients. Additionally, how many of these patients have since developed TB infections?
3. Following this most recent outbreak, have all patients been notified, evaluated, and treated?
4. Have all unused products from the recalled lot been sequestered and safely disposed?
5. Can CDC confirm that genetic sequencing from the patients who received Aziyo Biologic's bone grafts indicate the bacteria came from the same donor source?
6. How does the FDA determine tissue donor eligibility, and is reviewing TB-related risk factors taken into consideration during this assessment?
7. What are the FDA's current testing requirements for human tissue products, and what infections do they test for?
8. What has FDA done since the 2021 TB outbreak to prevent implantation of contaminated bone tissue?
9. Does the FDA have plans to update its bone tissue testing requirements to mandate testing for tuberculosis in tissue products?

[3] https://pubmed.ncbi.nlm.nih.gov/35934016/
[4] https://arstechnica.com/health/2023/07/not-again-bone-grafts-linked-to-another-deadly-bizarre-tb-outbreak/
[5] https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-and-tissue-product-questions-and-answers#:~:text=FDA%20regulates%20human%20cells%20or,)%2C%20Parts%201270%20and%201271
[6] https://www.washingtonpost.com/health/2021/06/18/tb-bone-product/

10. Does the FDA require new authorities or resources to prevent similar outbreaks in the future?

Thank you for your attention to this alarming matter. No family should have to grieve the loss of a loved one due to a preventable death. I look forward to working with you to strengthen the regulation of human tissue implantation to ensure these outbreaks do not continue. We must ensure that our laws and regulations are strong enough to prevent this from happening again.

Sincerely,

Debbie Dingell
Member of Congress