



June 6, 2024

Azza AbuDagga, MHA, PhD
Health Services Researcher
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009

Dear Dr. AbuDagga:

Thank you for your letter dated April 30, 2024, to Food and Drug Administration (FDA) Commissioner Robert M. Califf, MD, and Centers for Disease Control and Prevention (CDC) Director Mandy K. Cohen, MD, MPH, concerning the CDC advisory on counterfeit or mishandled botulinum toxin injections. I am responding on behalf of Dr. Cohen.

Botulism is typically described as producing symmetric neurologic deficits, and the pathophysiological mechanism of the disease (i.e., circulatory distribution of the toxin to neuromuscular junctions) is consistent with this description¹. While some data suggest that clinical variations in symptoms may occur, the CDC Health Alert Network (HAN) Health Advisory² focuses on the most common clinical presentation of botulism to provide clear, actionable guidance to healthcare providers. When evaluating patients for botulism, healthcare professionals should remain vigilant and consider the full spectrum of possible presentations.

The CDC HAN Health Advisory states that negative results do not rule out botulism as levels of toxin in serum may be below the limit of detection of laboratory tests. Importantly, critical initial treatment and management decisions for patients with suspected botulism are made based on clinical findings and are not dependent on laboratory test results. Laboratory testing is performed to confirm cases in which there is clinical suspicion of botulism. In the event a physician consultation supports botulism, where botulinum toxin effects have spread beyond the injection site, CDC guidance instructs healthcare providers to request and administer antitoxin as soon as possible. Due to the severity of botulism symptoms, laboratory confirmation is not required to pursue treatment. If physicians are unable to reach their state [public health department](#), the CDC clinical botulism service is available 24/7 for consultation at 770-488-7100. CDC releases the antitoxin to all states other than California, Alaska, and Colorado. These three states facilitate their own consultation service and antitoxin release.

Botulinum toxin works by blocking the release of acetylcholine at neuromuscular junctions, leading to localized muscle paralysis. When administered in cosmetic procedures, such as

¹ Rao AK, Sobel J, Chatham-Stephens K, et al. Clinical guidelines for diagnosis and treatment of botulism, 2021. *MMWR Recomm Rep.* 2021;70(2):1-30.

² Centers for Disease Control and Prevention. Adverse effects linked to counterfeit or mishandled botulinum toxin injections. April 23, 2024. <https://emergency.cdc.gov/han/2024/han00507.asp>

wrinkle reduction, manufacturers and the FDA determine prescribed doses of licensed preparations to be used to achieve desired effects without causing systemic toxicity. The localized administration of a relatively small amount of toxin greatly reduces the likelihood of systemic absorption and subsequent systemic effects, including life-threatening botulism. However, vigilance and adherence to best practices in injection techniques and patient monitoring are essential to ensure patient safety in all botulinum toxin procedures.

CDC's botulism case surveillance system³ receives reports of both confirmed and probable cases of botulism. While these data can contribute to monitoring the safety of FDA-approved botulinum toxin products, the FDA and drug manufacturers maintain systems designed to collect data on adverse events associated with the use of these products.

The FDA is reviewing the citizen petition from Public Citizen that is referenced in your letter. Once FDA has made a decision, FDA will respond to Public Citizen and post the response in the designated agency docket for the petition (available on www.regulations.gov in Docket No. FDA-2023-P-5471). in Docket No. FDA-2023-P-5471).

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel B. Jernigan". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Daniel Jernigan, MD, MPH
Director, National Center for Emerging and
Zoonotic Infectious Diseases
CDC

³ Centers for Disease Control and Prevention. National Botulism Surveillance. [National Botulism Surveillance | Botulism | CDC](#)