

Louisiana Health Alert Message 25-4: Severe Illnesses Linked to Injection of Botox Products from Unlicensed Sources

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Severe Illnesses Linked to Injection of Botox Products from Unlicensed Sources

The Louisiana Department of Health (LDH) is issuing this health advisory to alert clinicians about risks of counterfeit or mishandled botulinum toxin injections, particularly from unlicensed sources and in non-medical settings.

During September 2025, LDH received **two unrelated reports of severe illness** following botulinum toxin injections among Louisiana residents. One patient received injections of an unlicensed botulinum toxin product **purchased online**, and one patient received injections from an individual with unknown licensure in a **non-medical setting**. These patients began experiencing botulism-like symptoms a few days following the injections, and **both experienced severe illness requiring hospitalization**.

Background

<u>Botulism</u> is a rare and sometimes fatal illness caused by botulinum toxin. Initial botulism <u>symptoms</u> include **double or blurred vision**, **drooping eyelids**, **slurred speech**, **difficulty swallowing**, **and difficulty breathing**. These symptoms can be followed by a descending, symmetric **muscle weakness** that progresses over hours to days. **A suspected case of botulism is a clinical and public health emergency**. Treating patients with botulism antitoxin early in the course of disease can prevent the progression of paralysis and consequent complications.

Botulinum toxin products can be safe and effective for cosmetic and medical applications when obtained from authorized suppliers of products approved by the U.S. Food and Drug Administration (FDA) and administered by licensed and trained providers. Healthcare providers and the public should be aware of the **serious risks associated with injection of non-FDA-approved products**. Unlicensed products may be misbranded, adulterated, counterfeit, contaminated, improperly stored and transported, ineffective, or unsafe. <u>Unsafe</u> injection practices could increase the risk of harm, even when using FDA-approved products.

Recommendations for Healthcare Professionals

Diagnosis, consultation, and treatment

• Consider the possibility of adverse effects from botulinum toxin injection, including for cosmetic reasons, when patients present with signs and symptoms consistent with botulism near the injection site

- Be aware of symptom overlap between the presentation of localized adverse effects from injection of botulinum toxin and the early symptoms of botulism. To help distinguish early botulism symptoms from localized adverse effects:
 - Assess for symmetry of cranial nerve palsies; symmetric cranial nerve palsies are expected with botulism.
 - Assess for progression of cranial nerve palsies, possibly followed by a descending symmetric flaccid paralysis. These should raise suspicion for botulism.
- If botulism is suspected, call LDH's Infectious Disease Epidemiology Clinician 24/7 Hotline at 800-256-2748.
- If public health clinical consultation supports botulism, request antitoxin and begin treatment as soon as available. Do not wait for laboratory confirmation to begin treatment.
 - Antitoxin binds only to circulating toxin in the bloodstream. Careful consideration of dose, injection site, symptom presentation, and timing can help determine the need for antitoxin. Importantly, antitoxin does not:
 - Reverse paralysis or other already present clinical features like ptosis or dysphagia;
 - Affect toxin that is already bound to nerve terminals; or
 - Affect or halt the diffusion of toxin from the injected muscle to a nearby muscle.
- Ask the patient about their history of botulinum toxin injection. If the patient reports receiving injections, do the following:
 - Try to get information about the source and strength of the botulinum toxin products, the administration method (e.g., self-injection or injection by a licensed, trained provider), the administration site, and if others were injected with the same product.
 - Make note of details that might indicate the patient received injections with botulinum toxin products from unlicensed sources, including whether the patient:
 - Purchased and/or administered the product:
 - Received injections outside a medical setting (e.g., home);
 - Received injections with a group (e.g., during a "Botox party");
 - Has a changing story; or
 - Is unable or unwilling to share information about the product.
 - Gathering details, pictures, or samples from the patient will help protect other people from unapproved, counterfeit, contaminated, or ineffective products.

Clinician reporting

- Report suspected botulism immediately to LDH's Infectious Disease Epidemiology Clinician 24/7 Hotline at 800-256-2748.
- Report adverse events related to the use of any medications, including unverified botulinum toxin products, to <u>FDA's MedWatch Safety Information and Adverse Event Reporting Program</u>.

Counseling patients

• Counsel patients who report using or being interested in using botulinum toxin about risks for potential adverse effects.

 Advise patients to receive injections only from licensed providers who are trained in proper administration of FDA-approved botulinum toxin products and practicing in accordance with state and local requirements.

Recommendations for Laboratories

- Diagnostic testing for suspected botulism may be done through CDC.
 - Laboratory confirmation of botulism is done by demonstrating the presence of botulinum toxin in serum through either mouse bioassay or mass spectrometry.
 - For further guidance on submitting clinical specimens for testing, contact LDH's Infectious Disease Epidemiology Clinician 24/7 Hotline at 800-256-2748.

For More Information

- Harmful Reactions Linked to Counterfeit "Botox" or Mishandled Botulinum Toxin Injections | CDC
- Counterfeit Version of Botox Found in Multiple States | FDA
- Notes from the Field: Illnesses After Administration of Presumed Counterfeit Botulinum
 <u>Toxin in</u>
- Nonmedical Settings Tennessee and New York City, March 2024
- Information for Health Professionals on Botulism | CDC
- Preventing Botulism | CDC

References

- 1. Rao AK, Sobel J, Chatham-Stephens K, Luquez C. Clinical Guidelines for Diagnosis and Treatment of Botulism, 2021. MMWR Recomm Rep. 2021;70(No. RR-2):1–30.
- 2. Rao AK, Lin NH, Jackson KA, Mody RK, Griffin PM. Clinical Characteristics and Ancillary Test Results Among Patients With Botulism United States, 2002–2015. Clin Infect Dis. 2018;66(suppl_1):S4–S10.