SKIN

IN-DEPTH REVIEW

Counterfeit Botulinum Toxin and Cosmetic Iatrogenic Botulism: Emerging Threats that Require Regulatory Reform

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ABSTRACT

Background: There has been a concerning increase in reported cases of cosmetic iatrogenic botulism (CIB) linked to botulinum neurotoxin type A (BoNTA) injections performed by unlicensed or untrained individuals or involving counterfeit BoNTA products administered in non-healthcare settings.
Methods: A search was conducted across PubMed, Google Scholar, and Cochrane databases from their inception to identify reports in English regarding CIB linked to procedures carried out by unlicensed or untrained individuals or involving counterfeit BoNTA products. Reviews, letters, and commentaries were excluded. Additionally, online searches were performed to locate reports from Federal and State Boards and Medical Societies.
Results: Ten reports of such occurrences were identified, six in the United States and four globally, involving a total of 303 participants. Four of these reports included health advisories issued by the Centers for Disease Control and Prevention (CDC) and State Boards. All but two reports specified the patient's gender, with a predominance of female patients. Symptoms of botulism typically began within three days of procedure–the most common initial symptoms were blurred vision and ptosis. Approximately half of the patients required hospitalization. When administered, botulism antitoxin proved immediately effective, leading to shorter hospital stays and no fatalities.
Discussion: The regulatory gaps that may contribute to unsafe practices in this area are highlighted. There is an urgent need for unified national regulations in the United States, along with global standards, to clearly define who is authorized to perform these procedures and under what conditions they can do so. Furthermore, it is essential to enhance enforcement measures and increase public awareness to protect patients and uphold the highest safety standards.

INTRODUCTION

Botulinum neurotoxin (BoNT) has become an integral component of both medical and cosmetic practice. Iatrogenic botulism (IB), a serious poisoning caused by the neurotoxin, has occurred when BoNT is absorbed systemically from superficial injections at large doses.[1,2] In botulism, the toxin affects

peripheral cholinergic nerve terminals and causes symptoms such as muscle weakness, double vision, drooping eyelids, voice changes, urinary incontinence, and breathing difficulties. However, IB following injections for cosmetic purposes (cosmetic iatrogenic botulism; CIB) can also occur[3] The systemic symptoms of IB are characteristic, regardless of whether injections were for medical or cosmetic purposes. There has been a concerning rise in reported cases of CIB linked to cosmetic procedures performed by unlicensed individuals or involving counterfeit BoNT type A (BoNTA) products administered in non-healthcare settings.[3,4] Here, we explore the underlying causes of these emerging cases, highlight the regulatory gaps that may contribute to unsafe practices, and discuss the urgent need for stricter oversight and public awareness to prevent further incidents.

METHODS

A search was conducted across PubMed, Google Scholar, and Cochrane databases from their inception to identify reports in English regarding CIB linked to procedures carried out by unlicensed or untrained individuals or involving counterfeit BoNTA products. Reviews, letters, and commentaries were excluded from this search. Additionally, online searches were performed to locate reports from Federal and State Boards and Medical Societies.

RESULTS

Key Findings

Ten reports documented cases of CIB related to counterfeit BoNTA administered in non-healthcare settings or by unlicensed or untrained individuals, involving a total of 303 participants, as summarized in **Table 1**.[3-12] There were six reports in the United States[3-8] and four reports globally.[9-12] Four of these reports included health advisories issued by the Centers for Disease Control and Prevention (CDC) and State Boards.[3,4,6,8] All but two reports specified the patient's gender, which was predominantly female.[4-14]

First author, reference	Year	Country	Patients	Comments
United States				
Chertow[3]	2006	USA	4	First laboratory-proved CIB cases; highly concentrated, unlicensed BoNTA; may have received doses 2857 times the estimated human lethal dose by injection; antitoxin given, recovery after protracted hospitalization
CDC[4]	2022	USA; several states	22 F	Counterfeit toxin or mishandled BoNTA injections; unlicensed or untrained individuals or in non-healthcare settings; 20 pts treated for cosmetic purposes; 11 pts hospitalized and 6 received antitoxin
Thomas[5]	2024	USA; Tennessee and New York City	7 F	Confirmed or suspected unlicensed injectors; counterfeit toxin in Tennessee cases; four pts hospitalized, two required ICU care

Illinois DPH[6]	2024	Illinois	2	Possibly counterfeit BoNTA; nurse operating outside her licensed scope of practice
Dawson[7]	2024	Florida	1 F	Counterfeit toxin; unlicensed aesthetician
Massachusetts DPH[8]	2025	Massachusetts	10	Typical botulism symptoms; injections by unknown individual at a non-healthcare facility
Worldwide				
Chen[9]	2021	China	31 F	Retrospective five-year record review; legitimacy of BoNTA preparation not confirmed; antitoxin administered to 10 pts with mild botulism
Qiu[10]	2025	China	158 F, 3 M	Retrospective ten-year record review; counterfeit, unlicensed, or unknown toxin; unlicensed providers in non-healthcare settings; nearly 50% required hospitalization; antitoxin administered to 93.75% of hospitalized pts and 70.37% of outpatient cases
Euroactiv[11]	2025	Bulgaria	27 F	Injections at non-healthcare settings by unlicensed individuals; unavailability of antitoxin in some hospitals
BBC[12]	2025	UK	38 F	Unlicensed BoNTA products

The latent period was hours to days after exposure.[10] Most patients began to exhibit mild-to-moderate symptoms of botulism within 3 days following BoNTA injection. In the largest cohort to date, blurred vision and ptosis were the predominant initial symptoms (88.20%), followed by dizziness (73.91%), fatigue (67.70%), dysphagia (58.39%), and dysarthria (54.65%).[10] Symptoms were classified into mild, moderate, and severe based on the presence of bilateral flaccid paralysis (such as diplopia, ptosis, headache, limb weakness), bulbar palsy signs (such as dysphagia, dizziness, fatigue), and respiratory difficulty, respectively. Approximately half of the patients required hospitalization.[4,5,10] BoNT detection was rarely positive because of limitations in detection methods, the timing of patient presentation, and the influence of treatment interventions.[5,10] Interventions must be tailored to patients' varying levels of botulism severity, focusing on stabilizing airway, respiratory, and circulatory functions, particularly in moderate to severe cases. When administered, botulism antitoxin proved effective, leading to shorter hospital stays and no fatalities.[3,4,9,10]

The CDC Reports

In 2006, Chertow et al. reported four cases of botulism after receiving injections of an unlicensed BoNTA preparation. Some patients had serum toxin levels up to 43 times the estimated human lethal dose.[3] This was the first report of laboratory-proven CIB. In 2024, the CDC reported 22 women across 11 US states who developed systemic symptoms such as ptosis, dysphagia, blurred vision, and generalized weakness following BoNTA injections administered by unlicensed individuals using products not approved by the United States Food and Drug

Administration (FDA).[4] Eleven patients required hospitalization, and six were treated with antitoxin. Although none met the CDC's definition for confirmed botulism,[13] the rapid symptom onset (median three days) and clinical features were consistent with IB.

Outbreaks State by State: A Growing Concern

In 2024, seven women aged 26 to 55 developed symptoms consistent with systemic absorption of BoNT, including ptosis, dry mouth, dysphagia, shortness of breath, and weakness.[5] These cases were reported by the New York City (NYC) Department of Health and Mental Hygiene (three patients) and the Tennessee Department of Health (four patients; one resident of Kentucky). All had received cosmetic BoNTA injections in non-healthcare settings 2–20 days before symptom onset. Four patients were hospitalized, two required ICU care, but none needed intubation. Confirmed or suspected unlicensed individuals were the injectors; the FDA confirmed the product used in Tennessee case was counterfeit. The NYC patients had no links to each other or the Tennessee cases. Two NYC patients reported either paying below the U.S. wholesale price or sourcing the product overseas. No botulinum antitoxin was deemed necessary for any of the patients.

In April 2024, two individuals in LaSalle County, Illinois, developed botulism-like symptoms after receiving cosmetic BoNTA injections from a nurse operating outside her licensed scope of practice.[6] The Illinois Department of Public Health (DPH), in collaboration with the CDC and FDA, issued a public health alert urging clinicians to screen patients presenting with neuromuscular symptoms for recent cosmetic procedures and reinforcing the legal requirement that only appropriately licensed medical professionals use FDA-approved BoNT products. Still in 2024, a patient developed botulism symptoms after receiving BoNTA injections at home from an unlicensed aesthetician in Miami, Florida.[7] The patient showed significant improvement within the first day of receiving botulism antitoxin and by 96 hours there was complete recovery. The mechanism of IB might have involved overdose or inadvertent intravascular injection. In June 2025, the Massachusetts DPH issued an urgent alert after ten suspected cases of botulism were linked to cosmetic BoNTA injections at an unaccredited spa in Milton.[8] Patients presented with classic signs of botulism. The DPH emphasized the need for early diagnosis and strongly advised that only licensed professionals in accredited settings administer such treatments.

Beyond Borders: A Global Warning Signal

In China, a retrospective review spanning five years identified 31 female patients diagnosed with CIB.[9] Most patients were unaware of the dosage and BoNTA brand administered, raising concerns regarding the authenticity of the product used. Clinical symptoms developed within 48 hours in most cases, with nearly half experiencing symptom onset within 24 hours. Presentations included both neuromuscular and nonspecific symptoms. Botulism severity was classified as mild in 17 patients, moderate in nine, and severe in five due to dyspnea. Ten patients with mild botulism who received antitoxin therapy had shorter hospitalization than patients who were not administered antitoxin. Some patients experienced symptom relief even when treated more than 72 hours after onset, suggesting potential benefits beyond early neutralization.

A single-centre retrospective cohort study in China identified 161 cases of CIB, nearly 50% of which required hospitalization.[10] Most cases were linked to injections of counterfeit, unlicensed, or unknown BoNT products from unlicensed providers in non-healthcare settings. Symptoms typically began within three days of procedure. Antitoxin therapy was administered to 93.75% of hospitalized patients and 70.37% of outpatient cases. Most patients began to show improvement within 24 to 72 h after receiving antitoxin. Symptom resolution occurred on average of 25 days post-treatment. This outbreak represents the largest cohort of CIB globally, highlighting the dangers of counterfeit BoNT. It underscores the urgent need for stricter surveillance and enhanced clinical preparedness, including the availability of antitoxin and supportive measures.

Bulgaria faced a public health alarm in early 2025 when at least 27 women developed botulism symptoms following BoNTA injections administered by unlicensed individuals in unregulated settings.[11] Symptoms ranged from ptosis and visual disturbances to systemic fatigue, with several hospitalizations reported. Investigations revealed the use of unauthorized or counterfeit products, prompting legal action and calls from Bulgarian medical authorities for stricter oversight and enforcement.

In England, 38 suspected cases of botulism linked to counterfeit BoNTA injections administered by unregulated providers were recently reported.[12] In response, health authorities issued urgent warnings, emphasizing the importance of seeking treatment only from licensed professionals using approved products.

DISCUSSION

The Legal Blind Spot: Who is Holding the Syringe?

A recent multi-enter survey conducted in Brazil found that nearly 13% of aesthetic procedures performed in clinical practice had been conducted by nonmedical personnel.[14] This practice often resulted in complications, with 17% of these incidents leading to permanent damage. The authors underscore an escalating international concern: injectable cosmetic treatments performed by unqualified practitioners not only present with cosmetic risks, but also pose serious health threats necessitating urgent regulatory intervention and public education.

In the United States, the regulation of BoNTA administration in cosmetic settings is primarily governed at the state level. The critical issue of who can administer these injectables is left to individual state medical boards. Most states restrict the administration of BoNT to licensed medical professionals, including physicians, nurse practitioners, and physician assistants, and require that these treatments be delivered directly or under some form of physician supervision (**Table 2**).[15,16] Non-medical staff, such as aestheticians and cosmetologists, are typically prohibited from performing BoNTA injections. However, weak and inconsistent enforcement has allowed unlicensed or undertrained personnel to administer injections, often in non-healthcare facilities or settings lacking sufficient medical oversight. This has led to a risky gray area where medical spas function on the borderline of legality, putting patients at greater risk for encountering counterfeit products and experiencing adverse outcomes.[16,17] There is still considerable ambiguity in many countries regarding what

State	Professionals authorized to inject BoNTA
Alabama	LP
Alaska	LP primarily; aesthetic nurse with physician supervision
Arizona	LP primarily; LPN with physician supervision
Arkansas	LP primarily; APRN, RN if the procedure is part of a physician's treatment plan
California	LP, dentist primarily; PA, NP, RN with physician supervision
Colorado	LP, NP, PA; RN and aesthetician with physician supervision
Connecticut	Licensed healthcare provider within his/her scope of practice
Delaware	LP, LPN, NP, RN
Florida	LP primarily; NP, PA under physician supervision
Georgia	LP, dentist
Hawaii	LP, PA
Idaho	LP
Illinois	LP, PA, NP, RN
Indiana	LP, NP
Iowa	LP primarily; other licensed professionals under physician supervision
Kansas	Medical professional holding an MD, DO, DDS, DMD, or NP license; nurse with physician supervision
Kentucky	LP primarily; licensed esthetician under immediate supervision by physician
Luisiana	LP, LPN, PA, NP, RN
Maine	LP, PA, nurse
Maryland	LP
Massachusetts	Licensed medical professional such as LP, dentist, LPN, NP, PA, RN
Michigan	LP primarily; other professionals under physician supervision
Minnesota	LP
Mississippi	LP primarily; PA, RN, NP, or electrologist with physician supervision
Missouri	Medical practitioner who holds an MD, DO, DDS, DMD, or NP license; RN with physician supervision
Montana	LP
Nebrasca	LP
Nevada	LP, dentist, podiatrist, APRN, PA, RN
New Hampshire	LP, PA, NP, RN
New Jersey	LP
New Mexico	LP, dentist, PA, NP, RN
New York	Professional with a valid state license and higher education training
North Carolina	LP, PA, NP, RN
North Dakota	LP
Ohio	LP, PA, NP, RN
Oklahoma	LP primarily; APRN, PA, RN with physician supervision
Oregon	Licensed medical professional
Pennsylvania	Professional with a valid state license and higher education training
Rhode Island	LP, PA, NP, RN
South Carolina	LP
South Dakota	LP primarily; APRN, PA, RN under physician supervision
Tennessee	Qualified healthcare or allied healthcare professional
Texas	Licensed medical professional; some professionals only under physician supervision
Utah	LP
Vermont	Licensed medical professional
Virginia	LP, PA
Washington	LP
West Virginia	LP, APRN, PA
Wisconsin	LP, NP
Wyoming	LP, PA, NP

constitutes sufficient physician supervision on BoNTA injections performed by nonphysician injectors.

State laws regarding the delegation of medical tasks can be categorized into two conceptual frameworks: the dictator model and the deference model.[18] In the dictator model, which is followed by states like California, the law specifies which licensed professionals—typically, registered nurses, physician assistants, or advanced practice registered nurses—are allowed to perform tasks such as administering BoNT injections. In states like Alabama and Maryland, BoNT may only be administered by licensed physicians while in others, like New York and Pennsylvania, by highly trained professionals who possess a valid state license and have completed appropriate training from an accredited higher education institution.[15] However, several states, like Oregon, Wyoming and Texas only require a medical professional's license without any additional qualifications. On the other hand, the deference model allows the supervising physician discretion to assess the competence of those they delegate tasks to, and they carry both the legal and ethical implications of that decision. This model introduces variability in practice and potential risk.[16] Improper delegation of tasks can constitute unauthorized practice of medicine.

What Drives the Rising Cosmetic Use of BoNTA by Nonphysician Injectors?

The practice of aesthetic procedures such as BoNTA by non-physician providers has grown globally. This is often driven by misleading media advertisements, particularly targeting young individuals.[19,20] The expansion in the scope of practice for non-physician healthcare providers can be viewed from different perspectives. Many healthcare provider councils share a common goal of expanding their practices to create more job opportunities and increase income for their associates.[21,22] At the same time, healthcare managers are increasingly focused on reducing costs, making the inclusion of non-physician roles an attractive option.[23] Furthermore, the industry may benefit from an increase in the number of professionals who can purchase its products. However, a recent study revealed that most cosmetic procedures performed by non-physicians occur in non-clinical environments, raising concerns about inadequate supervision and lack of regulatory standards.[24] Such conditions may compromise patient safety. The study also noted that burns and skin discoloration were the most commonly reported complications in these cases.

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Why Counterfeit Botox Is More Than Just a Cosmetic Concern?

Beer and Rothschild warned in 2014 against the use of unapproved BoNT products sourced from foreign or unlicensed suppliers, highlighting the potential harm to both patients and practitioners.[25] Over time, these concerns have proven valid, as the use of counterfeit or misbranded BoNT has led to increased patient risk and legal consequences for healthcare providers. In Brazil, insufficient regulatory controls have facilitated the widespread misuse and distribution of counterfeit BoNTA, including by untrained individuals operating in salons.[14] Since 2022, authorities have uncovered falsified products that were stored unrefrigerated and marketed under recognized brand names. While a major criminal ring dismantled in 2024, new counterfeit BoNTA batches reemerged in 2025.

The FDA's Office of Criminal Investigations (OCI) and the Department of Justice (DOJ)

have aggressively pursued both illegal distributors and practitioners using such products.[26] A landmark case involved Bridget "Gigi" Goddard, a California MedSpa owner, who pleaded guilty to injecting clients with unapproved Botox purchased online from Canada. Similarly, multiple other cases have led to federal charges and potential prison terms. Congress has responded by increasing penalties for such offenses under the Food, Drug and Cosmetic Act.

The FDA regularly issues warning letters to physicians and clinics that purchase from unauthorized sellers.[27] The core message is clear that, healthcare practitioners should immediately cease purchasing or using unapproved injectable drugs, especially from foreign internet sources. Legal, financial, and reputational consequences are severe, and the FDA will likely discover such violations through seized distributor records or repeat violations.

CONCLUSION

The rising number of cases related to counterfeit or unregulated BoNTA usage in non-healthcare settings underscores the significant dangers associated with these practices. There is a crucial need for unified national regulations in the United States, along with global standards, to establish clear guidelines on who is authorized to perform these procedures and under what conditions. Additionally, it is essential to enhance enforcement measures and increase public awareness to safeguard patients and maintain the highest safety standards.

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