AMERICAN SOCIETY OF PLASTIC SURGEONS ®
THE PLASTIC SURGERY FOUNDATION ™
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May 2, 2025

The Honorable Donna Bailey, *Chair*
The Honorable Kristi Mathieson, *Chair*
Committee on Health Coverage, Insurance and Financial Services
100 State House Station
Augusta, ME 04333

Re: Opposition to Legislative Document 1803

Dear Chairs Bailey and Mathieson:

On behalf of the American Society of Plastic Surgeons (ASPS), I am writing **in opposition to** Legislative Document 1803 (LD 1803). ASPS is the largest association of plastic surgeons in the world, representing more than 8,000 members and 92 percent of all board-certified plastic surgeons in the United States – including 24 board-certified plastic surgeons in Maine. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

As surgeons, we encourage you to maintain the highest level of patient care that has been established and preserve current standards that permit surgery in the ocular region only by licensed medical doctors (MDs) or doctors of osteopathic medicine (DOs) who meet appropriate education, training, and professional standards. If passed, LD 1803 would allow non-physician optometrists to perform surgical procedures that fall squarely within the practice of medicine.

Surgical procedures should only be performed by surgeons, a descriptor only granted following a core medical and surgical education that includes nine to ten years of training, increased responsibility and decision-making authority in the hospital setting, and at least three years of specialized surgical experience. It is through the depth and duration of residency training that physicians learn how to perform surgical procedures. Moreover, data shows that patients do not want optometrists doing invasive procedures. 79 percent of voters surveyed in the United States oppose allowing optometrists without medical degrees to perform eye surgery.[1]

Optometrists – who are not medical doctors – complete four years of optometry school education, with significantly less clinical exposure and responsibility, and no medical school training. It also includes no surgical training, which clearly makes optometrists unqualified to perform any ophthalmic surgical procedures, including those by injection. Due to this, optometrists are not equipped to diagnose or manage surgical complications, posing a direct threat to patient safety. Sadly, this threat was realized in the case of the many veterans at the Stanford/Palo Alto VA who lost vision due to inadequate recognition and care of glaucoma by optometrists.[2]

[1] AMA Scope Toolkit
[2] https://www.mercurynews.com/2009/07/21/va-says-glaucoma-patients-at-palo-alto-facility-suffered-severe-vision-loss-due-to-mistreatment/

Allowing optometrists to inject potent pharmaceutical agents into the eyelid and surrounding tissues puts patients at risk. While some injections are intended for cosmetic use, all injections are procedures that have an associated risk of complications. ASPS' policy statement on the administration of botulinum toxin neuromodulators (enclosed) outlines potential complications for injected pharmaceuticals, such as Botox. The statement also advises patients to have treatments with a qualified physician who understands neuromuscular and facial anatomy, facial aging and esthetics, as well as potential neurotoxicity of the product. Even the FDA identifies physicians as the only appropriately trained and licensed healthcare professionals who should administer botulinum toxin for cosmetic purposes.[3] Furthermore, the FDA advises patients to see a licensed dermatologist or plastic surgeon for dermal filler treatments,[4] which are also administered via injection.

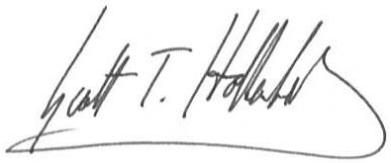
Unfortunately, our members are all too familiar with the nightmarish stories of patients who fall victim to undertrained individuals who perform procedures that fall squarely outside of their scope of practice. These patients are forced to deal with life-altering consequences, such as disfigurement and loss of vision, following botched surgical procedures, even when the procedures are only administered by injection. We encourage you to find and look at these stories[5] before proceeding with LD 1803.

Finally, the proposal would direct the State Board of Optometry to adopt rules regarding the scope of ophthalmic surgery within the practice of optometry. We believe it would be ill-advised to allow the board to promulgate rules regarding ophthalmic surgery, as it clearly falls within the scope of medicine. Moreover, allowing a non-medical board to oversee procedures that fall firmly within the practice of medicine is a dangerous, and unprecedented proposal, that the legislature must reject. Rather, surgery should be regulated by medical experts who have the background and training to adopt appropriate rules to keep patients in Maine safe.

Allowing optometrists to practice medicine and perform surgical procedures, including those by injection, would jeopardize patient safety, and lower the standard of care in Maine. It is critical that ophthalmic surgical procedures are only performed by physician surgeons who have the comprehensive training and board certification to safely treat patients and triage complications. Therefore, we urge you to oppose LD 1803.

We thank you for your leadership on this important issue. Please do not hesitate to contact Joe Mullin, ASPS State Affairs Manager, at jmullin@plasticsurgery.org or (847) 981-5412 with any questions or concerns.

Sincerely,



Scott T. Hollenbeck, MD, FACS
President, American Society of Plastic Surgeons

cc: Members, Committee on Health Coverage, Insurance and Financial Services

[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/103000s5109s5210lbl.pdf
[4] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049349.htm
[5] https://www.plasticsurgery.org/video-gallery/carols-story-who-to-trust-with-your-plastic-surgery-journey

AMERICAN SOCIETY OF PLASTIC SURGEONS

POLICY STATEMENT **ADMINISTRATION OF BOTULINUM TOXIN NEUROMODULATORS**

Background

Botulinum toxins are neuromodulators produced from the bacteria of the family Bacillaceae. There are at least seven different serotypes but only type A and type B have clinical applications. Clostridium botulinum, the agent that causes botulism in humans, produces powerful endotoxins which block the release of acetylcholine at the neuromuscular junction, thus inhibiting muscle contraction.[1-2] After over 30 years of research and development, clinical applications include: cervical dystonias, cranial nerve VII disorders (including hemifacial spasm), benign essential blepharospasm, general spasticity, strabismus, migraine headaches, hyperhidrosis, vocal cord dysfunction, anal fissures, urinary incontinence, bruxism, vasospastic disorders of the hand, and other conditions. Botulinum toxins are now an established component of facial rejuvenation.

The first FDA approval of Botulinum Toxin Type A, produced as Botox® ®, was in 1979 for treatment of strabismus. FDA approval followed in 2002 for Botox Cosmetic® to temporarily improve the appearance of moderate to severe frown lines between the eyebrows (glabellar lines)[3] and in 2013, for treatment of periorbital rhytides ("crow's feet").

As FDA actions for botulinum toxins are expected to increase, plastic surgeons should check to make sure they are up to date on the latest approvals. Any non-approved use is considered off-label.

As of 2016, FDA approved Botulinum Toxin Type A is available from three manufacturers:

- Botox®and Botox Cosmetic® (OnabotulinumtoxinA, manufactured by Allergan, Irvine, CA)
- Dysport® (abobotulinumtoxinA, manufactured byIpsen Ltd., Berkshire UK)
- Xeomin® (incobotulinumtoxinA manufactured by Merz Pharmaceuticals, Frankfurt, Germany)

FDA approved Botulinum Toxin Type B is available as Myobloc® (rimabotulinumtoxinB, Solstice Neurosciences, San Francisco, CA).

Other forms of Botulinum Toxin Type A and Type B are available worldwide but are NOT FDA approved and therefore not available in the United States. For purposes of this document, further discussion will be limited only to the three FDA approved Botulinum Toxin Type A (BTA): Botox Cosmetic®, Dysport®, and Xeomin®.

The biologic activities of the three BTA products are more similar than different but according to the FDA, they should not be considered interchangeable. For example, the number of units used for a clinical indication cannot be directly compared, as, 10 units of Botox Cosmetic or Xeomin applied to a particular facial region may require 20 to 30 units of Dysport to achieve similar clinical effects. Additionally, the onset and duration of clinically evident effects may also not be the same. BTA typically requires 7 to 10 days to see full effects and the results last 3 to 4 months. Patient may be re-evaluated 2 weeks after an injection to determine if more treatment is needed. A more detailed clinical comparison of BTA products and applications is available.[4]

Clinical decisions about the use of a drug are the purview of the physician.

Complications

Potential transient adverse local effects include but are not limited to: rash, pain, edema, erythema, ecchymosis, headache or hyperesthesia at the injection site. These are not necessarily related to the drug. There has also been a single report of a localized anaphylaxis in the lower limb following injection for foot dystonia.[5] Systemic complications may include flu-like symptoms or distant skin rashes.[6] There has also been one report of a respiratory arrest following the use of botulinum toxin type A for muscle spasticity.[7] Other rare but more frequently reported events are adverse or undesirable soft tissue effects that relate mostly to technique and result in temporary soft tissue malposition (such as blepharoptosis, brow ptosis, cheek ptosis, and lower eyelid ectropion or retraction, etc.) Care should be used in the periocular region as temporary upper and lower eyelid dysfunction may occur. In the event of upper eyelid ptosis after BTA injection, alpha 2-adrenergic agonist eye drops may be used to treat the ptosis.

Patients may develop non-responsiveness to BTA injections. This may be related to antibody formation but the specific mechanisms are not yet known.

Patient Selection

Not all individuals are candidates for BTA injections. Among those who should not receive such injections are those who are sensitive to the ingredients; patients with neuromuscular diseases (such as myasthenia gravis, Eaton-Lambert syndrome, or amyotrophic lateral sclerosis); and pregnant (also lactating/breast feeding) women. Injections should be applied with caution and discretion in those patients on anticoagulation/aspirin therapy; patients treated with aminoglycosides, penicillamine, quinine, or calcium channel blockers, as these drugs have been known to possibly potentiate clinical effects.[8,9] Patients who have unreasonable expectations or psychological issues that would preclude a satisfactory outcome should be excluded from treatment. Patients should understand that the effect of botulinum treatment can last several months but will not achieve a permanent change nor will it produce the same effect as surgical facial rejuvenation, including facelift. Surgical options should be considered if a more extensive change and longer-term result is desired.

Provider Qualifications

Despite the popularity and safety of BTA, it must be remembered that injection of BTA is a medical procedure. Patients are advised to have treatments with a qualified physician who understands neuromuscular and facial anatomy, facial aging and aesthetics, as well as potential neurotoxicity of the product. Under certain circumstances determined by the physician and applicable local and state professional practice regulations, injections may be administered by a licensed professional nurse or physician assistant. The individual physician of record, however, is ultimately responsible for both understanding and abiding by the applicable local and state professional practice regulations in determining the supervisory involvement required in each situation.

Risk Management Considerations

The injection of BTA is a medical procedure and is subject to the same precautions of any medical procedure. Treatment should be administered in the physician's office or other clinical setting with appropriate medical personnel and necessary equipment to safely observe patients and deal with possible complications. As with any medical procedure, a complete patient record should be maintained. Patients should be fully informed as to the temporary nature of botulinum injections, the risks, benefits, alternatives and reasoning for the proposed treatment as well as off-label uses. Each patient should sign an informed consent statement. Patient photographic documentation before starting treatment may be useful. The medical record should indicate the lot number, dosage, injection sites and any noted adverse reaction of any kind. Documentation of adverse events should include reporting of such incidents to the manufacturer when applicable. Patients should have continuing access to the provider and be medically supervised for several weeks following treatment, should an adverse event occur. Disposal of medical waste should be handled in accord with Occupational Safety and Health Administration (OSHA) regulations.

Although extremely unlikely, epinephrine or other precautionary methods should be available to treat anaphylactic reactions. Signs and symptoms of overdose may not be immediately apparent, but treatment should be initiated immediately when an overdose is realized.[10]

Most BTA injections are done in a physician's office but may also be done in a medical spa setting without a physician on site. State and local laws need to be followed in such cases. BTA injections in non-clinical settings (private homes, work events, group or social gatherings) may be inappropriate for several reasons, which include:

- inadequate patient selection by the provider
- inadequate individualized informed consent
- possible peer pressure for an individual to consent to treatment
- providers who are not trained in the administration of botulinum or qualified to assess or treat complications

The decision to have a medical procedure should be made without the influence of alcohol or peer pressure. If BTA is administered outside of a clinical setting, care should be taken to provide an appropriate environment for each patient and assure the same level of patient selection and informed consent as in a clinical environment.

Ethical Considerations

The Code of Ethics of the American Society of Plastic Surgeons states that a member may be subject to disciplinary action, including expulsion, if the member participates in a charity raffle, fund raising event, contest or other promotion in which the prize is any procedure.[11] For purposes of the Code of Ethics, BTA is NOT considered a medical procedure. However, the most current version of the Code should be reviewed prior to any such offering.[12]

Conclusion

BTA injections can be a safe and effective temporary treatment of fine facial lines and wrinkles, can produce a temporary improvement of facial and periorbital shape, and can serve as a useful adjunct in a variety of plastic surgical procedures.[13-14] Patients are advised to have treatments with a physician, or a provider designated by the physician, who is trained to give the injections and assess post- treatment effects. Board-certified plastic surgeons are ideally qualified to administer these injections because of their training.

Originally Approved by the American Society of Plastic Surgeons, Executive Committee, June 11, 2002.
Updated and reaffirmed: June 2016

References

1. Huang, W. et. al. Pharmacology of botulinum toxin. J. Am. Acad. Dermatol. 43: 249, 2000.

2. National Library of Medicine. Medline Database. Mesh terms. www.nlm.nih.gov

3. Food and Drug Administration talk paper. April 15, 2002. www.fda.gov.

4. Gart, M. Aesthetic Uses of Neuromodulators: Current Uses and Future Directions. PRS Journal. Volume 136, Number 5S. 62S-71S. November, 2015.

5. LeWitt, P.A. and Trosch, R.M. Idiosyncratic adverse reactions to intramuscular botulinum toxin type A injection. Movement Disorders. 12: 1064, 1997.

6. Matarasso, A., Deva, E.K. and the American Society of Plastic Surgeons DATA Committee. Botulinum toxin. Plast. Reconstr. Surg. 109: 1193, 2002.

7. Cobb, D.B., Watson, W.A. and Fernandez, M.C. Botulism-like syndrome after injections of botulinum toxin. Vet. Hum. Toxicol. 42: 163, 2000.

8. Matarasso, S.L. Complications of botulinum toxin type A exotoxin for the hyperfunctional lines. Derm. Surg. 24: 1249, 1998.

9. Klein, A.W. Complications and adverse reactions with the use of botulinum toxin. Semin. Cutan. Med. Surg. 20: 109, 2001.

10. Package insert, Botox Cosmetic. (Botulinum Toxin Type A) Purified Neurotoxin Complex (Glabellar Lines), Allergan Corporation, Irvine, CA 92715, 2002.

11. Code of Ethics, American Society of Plastic Surgeons, ASPS/PSEF Combined Member Roster, 305, 2002.

12. Code of Ethics, American Society of Plastic Surgeons, ASPS/PSF, March, 2012.

13. Fagien, S. Botox for the treatment of dynamic and hyperkinetic facial lines and furrows: adjunctive use in facial aesthetic surgery. Plast. Reconstr. Surg. 103: 701, 1999.

14. Fagien, S. Primary and adjunctive use of botulinum toxin type A (Botox) in facial aesthetic surgery. Clin. Plast. Surg. 28: 127, 2001.