

September 20, 2023

Senator Julian Cyr Chair, Joint Committee on Public Health 24 Beacon Street, Room 111 Boston, MA 02133 Julian.Cyr@masenate.gov Representative Marjorie C. Decker Chair, Joint Committee on Public Health 24 Beacon Street, Room 130 Boston, MA 02133 Marjorie.Decker@mahouse.gov

RE: Oppose S 1357 & H 2241 – An Act enabling trained dental hygienists to administer dermal fillers and botox

Dear Chairperson Cyr, Chairperson Decker and Members of the Joint Committee on Public Health:

On behalf of the undersigned physician organizations, we are writing to share our concerns regarding S 1357 and H 2241, which would allow dental hygienists under supervision to administer botulinum toxins and dermal fillers.

Procedures by any means, methods, devices or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitute the practice of medicine and surgery. This includes the use of foreign or natural substances by injection or insertion. ^{i,ii} The medical procedures dental hygienists are seeking to perform use FDA-regulated devices, such as those that can alter or cause biologic change or damage and should only be performed by a physician or appropriately trained non-physician personnel under the direct, on-site supervision of an appropriately trained physician.ⁱⁱⁱ This legislation jeopardizes patient safety and disregards what is considered adequate and appropriate medical education and training. Quality patient care includes evaluating a patient's needs and condition(s), selecting an appropriate course of treatment and providing adequate follow-up care.

With the growing public demand for facial fillers and neuromodulators, providing patients with properly trained, educated and supervised medical personnel is a safeguard Massachusetts should have for its citizenry. Fillers and neuromodulators can also be used to treat scars from injury and surgery, as well as from medical conditions; other applications include correcting facial asymmetries resulting from congenital, accidental or medical conditions. Our utmost concern is to ensure that these products are safely administered by licensed and qualified physicians or under the direct, on-site supervision of a licensed and qualified physician. "As with other cutaneous procedures, it is necessary to receive adequate training before using soft-tissue augmentation agents. In our opinion, physician injectors should first be made to demonstrate a detailed knowledge of anatomy and possible adverse events (such as sensitivity, infection and necrosis) through passing an American Board of Medical Specialties examination in one of the CORE aesthetic specialties after residency training in one of these disciplines."^{iv}

According to the American Dental Association, dental hygienists receive anywhere from two to four years of education, resulting in an associate's degree, baccalaureate, or master's degrees, in some cases.^v The focus of their education is on oral health, rather than the skin and facial tissue. Dental hygienists are not required to demonstrate competency in procedures involving skin and soft tissue augmentation involving products that can alter or damage such living tissue. It is of upmost importance that the health care provider performing procedures with botulinum toxin or dermal fillers have specific, long-term training (such as a medical residency in dermatologic surgery or plastic surgery). The education for dental hygienists does not include this type of intense

training; additionally, any short-term training program offered by manufacturers of these products does not adequately protect patient safety.

Physicians complete medical school, residency and in many cases specialized fellowship and then board certification in their specialty. Some medical specialties like dermatology, plastic surgery and facial plastic surgery have focused training in using fillers and neuromodulators involving the skin and adjacent structures, which prepares physicians to perform medical procedures using fillers and neuromodulators safely and effectively. Included in this training is proper technique, and the management of any adverse events. Furthermore, the American Medical Association states that, "Cosmetic medical procedures, such as botulinum toxin injections, dermal filler injections, and laser and intense pulsed light procedures, be considered the practice of medicine."^{vi}

During a 2021 meeting of the FDA's General and Plastic Surgery Committee on Soft-Tissue Fillers, the American Society for Dermatologic Surgery's Task Force on Soft-Tissue Fillers came to the conclusion that the topic of preventing and treating adverse events of injectable fillers requires the development of evidence-based clinical practice guidelines to support decision-making in daily practice. The Task Force also found that knowledge of vascular anatomy is *crucial* for all filler injections. **Intravascular injection is possible at any location on the face, but certain locations carry a higher risk, such as filler embolization; necrosis; visual abnormalities; blindness; and stroke.^{vii} Simply put, dental hygienists do not have the same extensive training physicians have, especially when it comes to adverse event management beyond the dental cavity. The FDA further updated consumer guidance in 2023 to state that anyone considering a neurotoxin or dermal filler should consult with a physician who is experienced in injecting dermal fillers, knowledgeable about fillers, anatomy, managing complications and knows the risks and benefits of treatment.^{viii}**

To best protect the citizens of Massachusetts from adverse events and ensure quality patient care, we urge you to oppose legislation that would allow dental hygienists to administer botulinum toxins and dermal fillers under supervision. Should you have any questions regarding this critical patient safety issue, please do not hesitate to contact Kristin Hellquist, Chief Advocacy Officer at the American Society for Dermatologic Surgery Association, at khellquist@asds.net.

Sincerely,

American Academy of Dermatology Association American Society for Dermatologic Surgery Association American Society of Plastic Surgeons Massachusetts Academy of Dermatology Massachusetts Medical Society

ⁱ ASDSA Position Statement on the Practice of Medicine. <u>https://www.asds.net/Portals/0/PDF/asdsa/asdsa-position-statement-definition-of-the-practice-of-medicine.pdf</u>

ⁱⁱ AADA Position Statement on Medical Spa Standards of Practice. <u>https://www.aad.org/Forms/Policies/Uploads/PS/PS-</u> Medical%20Spa%20Standards%20of%20Practice.pdf

iii ASDSA Position Statement on Delegation. https://www.asds.net/Portals/0/PDF/asdsa/asdsa-position-statement-delegation.pdf

^{iv} Gladstone H, Cohen J. Adverse Effects When Injecting Facial Fillers. Semin Cutan Med Surg. 2007 Mar;26(1):34-9.

^v Dental Hygienist Education and Training Requirements. Retrieved from <u>http://www.ada.org/en/education-careers/careers-in-</u> <u>dentistry/dental-team-careers/dental-hygienist/education-training-requirements-dental-hygienist</u>

^{vi} Addressing Safety and Regulation in Medical Spas. Retrieved Feb. 24, 2022. <u>https://policysearch.ama-assn.org/policyfinder/detail/dermal%20fillers?uri=%2FAMADoc%2Fdirectives.xml-0-1174.xml</u>

^{vii} Jones D, Fitzgerald R, Cox S, Butterwick K, et al. Preventing and Treating Adverse Events of Injectable Fillers: Evidence-Based Recommendations From the American Society for Dermatologic Surgery Multidisciplinary Task Force. Dermatol Surg 2021;47:214-26.

viii Filling in Wrinkles Safely. Accessed Sep. 11, 2023. Retrieved from https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049349.htm