February 18, 2013

Lisa P. Deem, D.M.D., J.D.
Chairperson
Pennsylvania State Board of Dentistry
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: Notice of Intent to Amend §33.217 – Administration of Botox and Dermal Fillers

Dear Chairperson Deem,

On behalf of the 12,600 U.S. members of the American Academy of Dermatology Association (AADA), I am writing to share our concerns with the notice of intent of the State Board of Dentistry to amend the Pennsylvania Code Title 49, Chapter 33, Section 217, regarding the administration of Botox and Dermal Fillers.

The proposed rules would allow dentists to administer cosmetic products including botulinum toxins (Botox) and dermal fillers. This proposal would allow dentists to practice medicine thereby endangering patient safety, and it would not prescribe adequate training requirements in order to administer such products.

Use of Injectable Products Constitutes the Practice of Medicine Not the Practice of Dentistry

With the growing public demand and appreciation for facial filler products such as collagen or botulinum toxin, establishing scope of practice standards on who can administer these products is critically important. In addition to the obvious cosmetic applications of these products, the AADA emphasizes their importance as treatments for scarring from injury, surgery and medical conditions such as cystic acne. Other applications include correcting facial asymmetries resulting from congenital, accidental, or medical conditions including HIV infection. Our utmost concern is to ensure that they are safely administered by licensed and qualified physicians or under the direct, on-site supervision of a licensed and qualified physician.

The AADA strongly believes the use of injectable products, such as botulinum toxins and dermal fillers, constitutes the practice of medicine, within the scope of dermatology. The practice of dermatology includes, but is not limited to, performing any act or procedure that can alter or cause biologic change or damage to the skin and subcutaneous tissue. Any procedure using any approved device that can alter or cause biologic change or damage should be performed only by an appropriately trained physician or under the direct, on-site supervision of an appropriately trained physician.
Short-Term Training is Not Adequate to Protect Patient Safety

Proper training to properly perform procedures using botulinum toxins or dermal fillers requires specific, long-term training, such as a residency, in cutaneous dermatologic procedures. A dentist’s education does not include the appropriate training to use botulinum toxins and dermal fillers. Additionally, a short term training program offered by manufacturers of these products would not be adequate to protect patient safety.

General dentists complete four years of dental school. In their third year, courses focus on restorative dentistry, pediatric dentistry, advanced dental surgery, and outcomes of treatment. In their fourth year, they must complete 10 months of required externships and clinical rotations in dentistry/oral health-related service. The focus of their education is on oral health, rather than the skin and facial tissue. Dentists are not required to demonstrate competency in procedures involving skin and soft tissue augmentation involving products which can alter or damage such living tissue.

In comparison, during their residency program following four years of medical school, a dermatologist receives in-depth education in procedures involving the skin and adjacent structures including but not limited to the oral tissues, preparing the physician to perform cosmetic medical procedures using injectable products such as botulinum toxins and dermal fillers. The educational background, including medical school, of a dermatologist or other specialty physician is far more comprehensive than that of a general dentist. This difference in education and training further demonstrates the inadequacy of dental education programs to adequately prepare dentists to perform complex medical procedures such as the administration of botulinum toxins and dermal fillers, intended to improve or correct human appearance.

In a 2007 paper, Drs. Hayes Gladstone and Joel Cohen note, “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.” (See Exhibit A attached).

The Proposed Rule Endangers Patient Safety

As dermatologists, our utmost concerns are quality patient care and patient safety. Quality patient care includes evaluating a patient’s needs and current condition, selecting an appropriate course of treatment, and providing adequate information and follow-up care. Each year more non-physician practitioners are gaining legal approval to do the same procedures dermatologists spend years in medical and surgical training to perform. Short-term, basic training on how to use a product is in no way equivalent to a physician’s training and understanding of a medical procedure and its implications for each patient. Ultimately, patient safety and quality of care are seriously compromised.
Physicians administering injectable products such as botulinum toxins and dermal fillers have years of training in residencies to medically recognize and address complications. Complications can occur in the best of hands, but it occurs too often when injected by professionals who are inadequately trained. A recent survey conducted by the Physicians Coalition for Injectable Safety found that 84 percent of physician respondents have seen at least one patient with complications from cosmetic injectables and 38 percent of coalition member physicians see complications arising from cosmetic injections administered by an unqualified or untrained provider. Understanding which injectable product is appropriate for each anatomic site and its particular limitations is fundamental in avoiding adverse effects, knowledge that dentists would not have acquired through limited continuing education courses. A number of the adverse events reported to the FDA and the device manufacturers imply that the administration of injectables were performed by untrained personnel or in settings other than health clinics or doctors’ offices.

All of the FDA-approved injectable fillers are approved for injection in the dermis or mid-to-deep dermis, requiring extensive knowledge of facial anatomy to ensure proper placement of the injections. Numerous studies have cautioned physicians on the use of dermal fillers, noting, “a physician's selection of facial filler(s) should be based on a solid understanding of the various filler products, appropriate patient selection, and the physician's proficiency in injection techniques.” (See Exhibit B attached) Moreover, in discussing these devices, the FDA’s Consumer Health Information materials suggest that patients should discuss fillers with a doctor who can refer the patient to a specialist in the fields of dermatology or aesthetic plastic surgery.

In order to protect the citizens of Pennsylvania from adverse events and ensure quality patient care, the AADA urges the Board to withdraw its intent to amend §33.217 – Administration of Botox and Dermal Fillers. I appreciate the opportunity to provide written comments to the Board on this issue. For further information, please contact Lisa Albany, Assistant Director of State Policy for the AADA, at LAlbany@aad.org or (202) 712-2615.

Sincerely,

Daniel M. Siegel, MD, FAAD
President
American Academy of Dermatology Association