

February 20, 2019

The Honorable Shane E. Pendergrass
Chair, Health and Government Operations
6 Bladen Street, Room 241
Annapolis, MD 21401

The Honorable Joseline A. Pena-Melnyk
Vice Chair, Health and Government Operations
6 Bladen Street, Room 241
Annapolis, MD 21401

RE: In opposition to H.B. 471

Dear Chair Pendergrass and Vice Chair Pena-Melnyk:

On behalf of the Maryland Society of Plastic Surgeons (MSPS) and the American Society of Plastic Surgeons (ASPS), we are writing to oppose H.B. 471. MSPS is the largest association of plastic surgeons in Maryland, and in conjunction with our national affiliate, ASPS, we collectively represent 177 board-certified plastic surgeons in the state. 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 high level of patient care that has been established and maintain current standards that permit only licensed Medical Doctors (MD) or Doctors of Osteopathic Medicine (DO) who meet appropriate education, training, and professional standards to perform surgery in the ocular region. If passed, H.B. 471 would allow non-physician optometrists to perform procedures that fall squarely within the practice of medicine.

When optometric scope of practice is improperly expanded, patients suffer. For example, research comparing the outcomes of laser trabeculoplasty (LTP) performed on a total of 1,384 eyes by optometrists versus ophthalmologists in Oklahoma has shown that the proportion of eyes treated by optometrists requiring additional LTP in the same eye (35.9 percent) was more than double the proportion of those treated by ophthalmologists (15.1 percent). Optometrist-treated eyes had a 189 percent increase in risk of requiring additional LTP.

Ophthalmologists and plastic surgeons must attain a core medical and surgical education while completing seven to ten years of training, which includes increasing responsibility and decision-making authority in the hospital setting. Board-certified plastic surgeons must: (1) earn a medical degree; (2) complete three to six years of full-time experience in a residency training program accredited by the Accreditation Council for Graduate Medical Education (ACGME); and (3) the last three years of training must be completed in the same program. Similar to the rigorous training requirements that plastic surgeons complete, ophthalmologists must undergo extensive training in order to perform surgical procedures. It is through this depth and duration of residency training that they learn how to perform complex surgical procedures.

However, optometrists – who are not medical doctors – only complete four to five years of education with significantly less clinical exposure and responsibility, and are not required to undergo postgraduate training. Optometrists, unlike plastic surgeons and ophthalmologists, are not surgically trained during optometry school. For example, looking again at the LTP procedure mentioned above, the ACGME

mandates that graduating medical residents perform a minimum of five LTPs,¹ while case logs show that the average ophthalmological resident performs 14 LTPs and 83 other laser procedures during residency training.² In Oklahoma, the only training that optometrists must complete to perform laser procedures involves a two-day course that consists of nine hours of lectures and four hours of laboratory sessions.

Equally concerning is that the bill would also allow optometrists to inject potent pharmaceutical agents into the eyelid and surrounding tissues. Optometrists may argue that injections are not surgical procedures. However, according to the American College of Surgeons, surgery is defined as follows³:

*Surgery is performed for the purpose of structurally altering the human body by incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. **Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery** (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel. Patient safety and quality of care are paramount, and the College therefore believes that patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.*

There are serious patient risks involved with allowing these injections into the optometric scope of practice given the fact that optometrists lack clinical training to perform surgery. For example, a surgical error of just a few millimeters can result in a punctured eyeball with resulting catastrophic vision loss. Such errors could also result in a perforated blood vessel, which connects to the back of the eye and can cause immediate and permanent vision loss. Another severe risk is misdiagnosing a cancerous lesion as benign, and then improperly injecting it, which can result in the spread of cancer.

While some injections are intended for cosmetic use, the risk of surgical error listed above still exists. In terms of cosmetic injections, ASPS's policy statement on the administration of botulinum toxin neuromodulators – enclosed for your review – goes into great detail on the background of the development of injecting botulinum toxins and other similar therapies. It took over 30 years of research and development to derive clinical uses of botulinum toxins to treat serious medical conditions, such as cervical dystonias, cranial nerve VII disorders, benign essential blepharospasm, general spasticity, strabismus, migraine headaches, hyperhidrosis, vocal cord dysfunction, anal fissures, urinary incontinence, bruxism, vasospastic

¹ Accreditation Council for Graduate Medical Education Review Committee for Ophthalmology. Frequently asked questions: ophthalmology. http://www.acgme.org/Portals/0/PDFs/FAQ/240_Ophthalmology_FAQs.pdf. Updated November 2015. Accessed May 4, 2016.

² Accreditation Council for Graduate Medical Education Department of Applications and Data Analysis. Ophthalmology/case logs: National Data Report. http://www.acgme.org/Portals/0/PDFs/240_National_Report_Program_Version.pdf. Updated September 23, 2015. Accessed May 4, 2016.

³ State of the states: Defining surgery. The Bulletin. <http://bulletin.facs.org/2012/05/state-of-the-states-defining-surgery>. Published June 6, 2016. Accessed December 19, 2017.

disorders of the hand, and other conditions. Botulinum toxins are now an established component of facial rejuvenation.

These injections are not “minor” procedures, but rather are surgical and carry serious consequences. In order to ensure patient safety, it takes a deeper understanding of the clinical uses and corresponding dangers of injecting botulinum toxins, dermal fillers, and other similar injectable therapies. This understanding is developed through a core medical and surgical education – which ophthalmologists and plastic surgeons attain – followed by seven to ten years of training (and thus 12-15 years of education). Board-certified plastic surgeons must: (1) earn a medical degree; (2) complete three to six years of full-time experience in a residency training program accredited by the Accreditation Council for Graduate Medical Education (ACGME); and (3) the last three years of training must be completed in the same program. Board-certified ophthalmologists must undergo a similar extensive training regimen in order to perform surgical procedures.

On the other hand, not all optometry schools even require a bachelor’s degree and thus optometrists may have only 4-5 years of education. Expertise in managing these types of serious complications cannot be obtained by going to optometry school, as the optometric training curriculum does not provide the sufficient training to perform these injections safely, or through an “add-on” weekend training course. Neither of these options provide the medical expertise to determine whether injected medication is even the proper treatment for medical conditions or whether the patient is a candidate for injectable surgical procedures.

MSPS and ASPS 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. For example, a patient named Carol went to a provider for a common cosmetic procedure – the kind that thousands of women and men have every day. However, she made the mistake that many people make: she didn’t consult a board-certified plastic surgeon. The provider injected substances into Carol’s face that were not FDA approved. She had a severe, adverse reaction that caused her face to become permanently distorted. Worse still, the provider had no idea what caused the reaction or how to treat it. Carol’s life changed forever. Unfortunately, individuals such as Carol have to deal with life-altering consequences such as disfigurement and loss of vision following botched surgical procedures, including those administered by injection only. We encourage you to watch Carol’s story yourselves at <https://www.plasticsurgery.org/video-gallery/carols-story-who-to-trust-with-your-plastic-surgery-journey>.

Moreover, the committee should consider that 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.⁴ Specifically, the FDA guides patients:

You should discuss the different types of FDA-approved dermal fillers and the results you want to achieve with your licensed health care provider, who can refer you to a licensed dermatologist or plastic surgeon. (You may want to contact the American Academy of Dermatology, the American Society of Plastic Surgeons, or the American Society for Aesthetic Plastic Surgery.)

⁴ <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049349.htm>

The FDA's own guidance also refers only to 'physicians' as being the appropriately trained and licensed healthcare professional who contemplated to administer Botulinum Toxin for cosmetic purposes.⁵ Lastly, the Physicians Coalition for Injectable Safety found that 84 percent of physician respondents had seen at least one patient with complications from cosmetic injectables and 38 percent had seen complications arising from cosmetic injections administered by an unqualified or untrained provider.⁶

Allowing optometrists to practice medicine and perform surgical procedures, including those with lasers, without the requisite medical school and residency training would jeopardize patient safety and lower the standard of care in Maryland, which has a history of being a leader in taking steps to protect patients. Passing H.B. 471 would be a significant step backward.

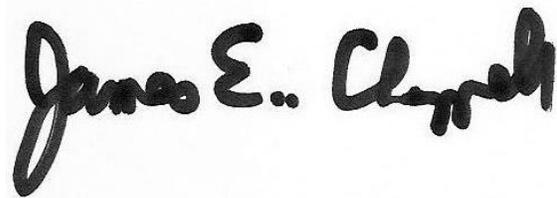
Due to patient safety issues, such as the possibility of complications arising from surgery and serious risk of vision loss, it is critical that such procedures are performed by physician surgeons who have the comprehensive training and board certification to handle those complications when they do occur.

For the reasons outlined above, we urge you to oppose H.B. 471. Please do not hesitate to contact Patrick Hermes, ASPS's Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions.

Sincerely,



Alan Matarasso, MD, FACS
President, American Society of Plastic Surgeons



James E. Chappell, MD, FACS
President, Maryland Society of Plastic Surgeons

cc: Members, Health and Government Operations Committee

⁵ https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/103000s5109s5210lbl.pdf

⁶ http://www.aafprs.org/media/press_release/150807.htm