



July 27, 2018

The Honorable Joseph B. Scarnati, III President Pro Tempore Pennsylvania State Senate Senate Box 203025 Harrisburg, PA 17120 The Honorable Jake Corman Majority Leader Pennsylvania State Senate Senate Box 203034 Harrisburg, PA 17120

## RE: Oppose S.B. 668

Dear President Pro Tempore Scarnati and Majority Leader Corman:

On behalf of the Robert H. Ivy Pennsylvania Society of Plastic Surgeons (Ivy Society) and the American Society of Plastic Surgeons (ASPS), we are writing to follow up with additional concerns regarding S.B. 668, which unfortunately passed out of the Senate Consumer Protection and Professional Licensure Committee. The Ivy Society is the largest association of plastic surgeons in the state, and in conjunction with our national affiliate ASPS, we represent 318 board-certified plastic surgeons in Pennsylvania. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

Our letter dated June 25, 2018, we went into detail about our patient safety concerns with allowing optometrists — who are NOT physicians or medical doctors and clearly are not trained surgeons — to perform surgery around the eye. (Ophthalmologists are physicians who treat eyes.) Sadly, in 2009, the notable gap in optometric training became apparent when optometrists at a VA facility provided patients with substandard treatment for glaucoma. As a result, 22 patients suffered from progressive vision loss.<sup>1</sup>

Equally concerning is that S.B. 668 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 follows<sup>2</sup>:

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* 

<sup>&</sup>lt;sup>1</sup> Dremann, Sue. VA investigates glaucoma patients' treatment: 'Exhaustive' internal review found inadequate referrals; optometry chief sidelined. Palo Alto Weekly, July 23, 2009.

<sup>&</sup>lt;sup>2</sup> State of the states: Defining surgery. The Bulletin. <u>http://bulletin.facs.org/2012/05/state-of-the-states-defining-surgery</u>. Published June 6, 2016. Accessed December 19, 2017.

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 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 patients is a candidate for injectable surgical procedures.

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.

These potentially devastating effects coupled with the fact that optometrists are insufficiently-trained are reason enough to maintain their current scope and not allow them to administer injections. Therefore, we again strongly urge you to oppose S.B. 668.

Thank you for your consideration of ASPS's comments. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at <u>phermes@plasticsurgery.org</u> or (847) 228-3331 with any questions or concerns.

Sincerely,

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