



AMERICAN SOCIETY OF
PLASTIC SURGEONS®

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MINNESOTA
SOCIETY
OF PLASTIC
SURGEONS

February 25, 2019

The Honorable Ruth Richardson
State Representative
403 State Office Building
St. Paul, MN55155

RE: In opposition to H.F. 891

Dear Representative Richardson,

On behalf of the Minnesota Society of Plastic Surgeons (MSPS) and the American Society of Plastic Surgeons (ASPS), we are writing in opposition to H.F. 891. The Minnesota Society of Plastic Surgeons is the largest association of plastic surgeons in Minnesota, and in conjunction with our national affiliate the American Society of Plastic Surgeons, collectively represent 129 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.F. 891 would allow non-physician optometrists to administer legend drugs intravenously, intramuscularly, or by injection into the human eye and adnexa. This includes procedures that fall squarely within the practice of medicine.

When optometric scope of practice is improperly expanded, patients suffer. Sadly, in 2009, several patients at a VA facility received inadequate treatment for glaucoma from optometrists. An investigation found that as a result of the poor treatment 22 patients were found to have progressive vision loss.¹ Unfortunately, this was not an isolated incident. 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

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

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. Equally concerning is that H.F. 891 would 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 follows²:

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

² 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.

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.

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 Minnesota House of Representatives 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.³ 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](#).)

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.⁴ Lastly, the Physicians Coalition for Injectable Safety found that 84 percent of physician respondents had seen at

³ <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049349.htm>

⁴ https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/103000s5109s5210lbl.pdf

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.⁵

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 Minnesota.

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 listed above, we urge you to withdraw H.F. 891. Thank you for your consideration of ASPS' comments. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions or concerns.

Sincerely,

Handwritten signature of Alan Matarasso, MD, in black ink. The signature is written in a cursive style and includes the initials "MS" at the end.

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

Handwritten signature of Sue Mi Tuttle, MD, in black ink. The signature is written in a cursive style and includes the initials "MS" at the end.

Sue Mi Tuttle, MD
President, Minnesota Society of Plastic Surgeons

⁵ http://www.aafprs.org/media/press_release/150807.htm