February 13, 2015

The Honorable Terry B. Gerratana
The Honorable Matt Ritter
Co-Chairs, Joint Committee on Public Health
Connecticut State Legislature
Legislative Office Building, Room 3000
Hartford, CT 06106

RE: OPPOSE HB 5905

Dear Co-Chairs Gerratana and Ritter:

On behalf of the Connecticut Dermatology and Dermatologic Surgery Society (CDS), the American Society for Dermatologic Surgery Association (ASDSA), the American Society of Laser Medicine and Surgery (ASLMS), and the American Academy of Dermatology Association (AADA) we are writing express our strong opposition to HB 5905, which would expand the scope of practice of electrologists to perform laser hair removal without physician supervision.

The Safety of Connecticut Patients is at Risk

CDS, ASDSA, ASLMS, and AADA believe that allowing electrologists to perform laser hair removal without physician supervision would jeopardize patient safety and disregard adequate and appropriate medical training. While these lasers are extremely safe and effective when used by medical professionals with appropriate training and oversight, in the wrong hands they can cause painful burns and permanent scarring.

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. When non-physician practitioners are given legal approval to do the same procedures dermatologists spend years in medical and surgical training to perform, patient safety is seriously compromised. Short term, basic training 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.

Additionally, laser hair removal causes more complications than any other medical laser treatment. According to a study published in *Skin and Aging*¹, hair reduction was the most commonly treated condition that resulted in complications (46%), followed by laser/light leg vein treatments (21%) and non-facial photorejuvenation (11%). Lower extremities were the most common location of complications (36%), followed by the face (22%) and neck (12%). Physicians performing these procedures have years of training in residencies to medically recognize and address complications, in addition to evaluating the patient to determine the most appropriate treatment. For example, laser hair

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removal procedures are less effective on individuals with light-colored hair, and those with tanned or dark skin may be more susceptible to burning.

With multiple medical laser devices available on the market, and as more and more devices become available, it is critical to ensure that patient safety remains the primary objective. CDS, ASDSA, ASLMS, and AADA feel strongly that cosmetic medical procedures, such as laser hair removal, are more safely performed in a dermatologist’s office by the physician or under direct, on-site supervision of the physician.

As reported in the National Law Journal, laser hair removal has recently become a “hot spot” for litigation, leading to costly and prolonged lawsuits. According to the article, “Laser hair removal in particular is triggering lawsuits, lawyers note, warning that even more litigation is on the horizon as the number of medical spas soars... In Arizona, a woman recently sued a spa in state court, alleging she was ‘severely burned and scarred’ during laser hair removal. Also in Arizona state court, a man sued a spa over scarring, ‘extreme pain’ and burning he allegedly suffered from laser hair removal on his back and shoulders.” According to a study published in the Journal of the American Medical Association Dermatology, the percentage of medical malpractice lawsuits involving the non-physician use of medical lasers has grown steadily over the past four years, from just 38 percent of lawsuits in 2008 to 78 percent of lawsuits in 2011. Perhaps most relevant is the fact that according to this same data, 89 percent of laser hair removal-related medical malpractice lawsuits in the year 2011 involved non-physicians performing laser hair removal.3

The Use of Medical Lasers is the Practice of Medicine

The American National Standards Institute classified IIIb and IV lasers and intense pulsed light devices are considered by the FDA to be “medical prescription devices.” A “prescription device,” is defined by the Code of Federal Regulations Section 801.109 as “a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device...” As such, use of these devices should be considered the practice of medicine, and should not occur outside the supervision of a licensed and appropriately trained physician.

Any procedure, including hair removal, which utilizes energy-based devices capable of damaging living tissue performed on human beings for cutaneous conditions should be considered as the practice of medicine.

Consideration of laser and light-based hair removal as the practice of medicine is consistent with the American Medical Association and the American College of Surgeon’s definition of surgery, as well as other AMA laser surgery policy as cited below.

H-475.983 Definition of Surgery
Our AMA adopts the following definition of “surgery” from American College of Surgeons Statement ST-11:

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Surgery is performed for the purpose of structurally altering the human body by the 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 transposition 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 reductions for major dislocations or fractures, or otherwise altered by 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 also is considered to be surgery (this does not include the administration by nursing personnel of some injections, 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 procedure 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, therefore, 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. (Res. 212; A-07)

H-475.989 Laser Surgery
Our AMA (1) adopts the policy that laser surgery should be performed only by individuals licensed to practice medicine and surgery or by those categories of practitioners currently licensed by the state to perform surgical services; and (2) encourages state medical associations to support state legislation and rulemaking in support of this policy. (Sub. Res. 39, I-90; Reaffirmed: Sunset Report, I-00)

H-475.988 Laser Surgery
The AMA supports the position that revision, destruction, incision or other structural alteration of human tissue using laser is surgery. (Res. 316, A-96; Reaffirmed: CSAPH Rep. 3, A-06)

Moreover, it is important to consider that in addition to the use of medical lasers themselves, laser hair removal also requires the use of a medical-grade topical anesthetic. In at least two cases, the dispersion of this anesthetic without appropriate supervision has resulted in patient deaths. In 2007, and again in 2009, the Food and Drug Administration (FDA) issued public advisories cautioning consumers about this issue. As stated in the advisory, “FDA is aware of two instances where women, aged 22 and 25 years old, applied topical anesthetics to their legs to lessen the pain of laser hair removal. These women then wrapped their legs in plastic wrap, as they were instructed, to increase the creams’ numbing effect. Both women had seizures, fell into comas, and subsequently died from the toxic effects of the anesthetic drugs. The skin numbing creams used in these two cases were made in pharmacies and contained high amounts of the anesthetic drugs lidocaine and tetracaine. The FDA also has received reports of serious and life-threatening side effects such as irregular heartbeat, seizures and coma, and slowed or stopped breathing following the use of these numbing products. These effects happened in both children and adults and when the anesthetic drug was used both for approved and unapproved conditions.”

Relevant Connecticut Law and Declaratory Ruling
The General Statutes of Connecticut outline the practice of medicine as:

Section 20-9. Who may practice medicine or surgery.

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(a) No person shall, for compensation, gain or reward, received or expected, diagnose, treat, operate for or prescribe for any injury, deformity, ailment or disease, actual or imaginary, of another person, nor practice surgery, until he has obtained such a license as provided in section 20-10, as amended, and then only in the kind or branch of practice stated in such license.”

Further, the Connecticut Medical Examining Board issued a declaratory ruling on December 17, 1997 stating that, “The Board finds that the use of lasers for hair removal is the scope of medical practice.” The cosigned urge you to maintain the current rulings and statutes related to the use of lasers, including for the purpose of hair removal, as the practice of medicine and not permit legislative or regulatory action to expand electrologists’ scope of practice.

For these reasons, CDS, ASDSA, ASLMS, and AADA strongly oppose HB 5905. Thank you for your consideration. Should you have any questions or need further information, please feel free to contact Debbie Osborn, CDS Executive Director, at 860 459-4377 or debbieosborn36@yahoo.com.

Sincerely,

Donna A. Aiudi, MD, President
Connecticut Dermatology and Dermatologic Surgery Society

George J. Hruza, MD, President
American Society for Dermatologic Surgery Association

Juanita J. Anders, PhD, President
American Society for Laser Medicine and Surgery

Brett M. Coldiron, MD, FAAD
American Academy of Dermatology Association

cc: Katherine J. Duerdoth, CAE, Executive Director, ASDSA
Lisle Thielbar, Director of State and Grassroots Advocacy, ASDSA
Dianne Dalsky, Executive Director, ASLMS
Debbie Osborn, Executive Director, CDS
Lisa Albany, Associate Director, State Policy, AADA