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PLAYING DOCTOR: THE DANGEROUS “MEDI-SPA” GAME WITHOUT RULES

*Lauren Numeroff**

“We manipulate nature as if we were stuffing an Alsatian goose. We create new forms of energy; we make new elements; we kill crops; we wash brains. I can hear them in the dark sharpening their lasers.” – Erwin Chargaff¹

INTRODUCTION

While biochemist Erwin Chargaff confronted science’s inevitable plunge into genetic engineering, he remarked that “feeble men, masquerading as experts . . . make enormously far-reaching decisions.”² Similarly, in the medi-spa industry,³ men and women approach science willingly to alter their natural physical appearances, often turning their bodies over to the care of

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¹ Kathleen McGowan, *Erwin Chargaff, Pioneer of DNA Research, Dies at 96*, GENOMEWEB DAILY NEWS, July 1, 2002 (quoting Erwin Chargaff), available at <http://www.genomeweb.com/issues/news/120456-1.html>.

² Erwin Chargaff, Letter to the Editor, *On the Dangers of Genetic Meddling*, 192 SCIENCE 938, 938 (1976).

³ “Medi-spas are the fastest-growing segment of the spa industry . . . [and] differ from day spas in that they have a doctor on staff.” Juliette Fairley, *Spas With a Twist*, TIME MAG., Feb. 9, 2004, § Inside Business/Beauty, at A13. “[M]ore traditional day spas” have responded to this competition by hiring part-time doctors to provide “more complicated and costly” medical procedures in the spa setting. *Id.*

nonphysicians—registered nurses, nurse practitioners, physicians assistants, cosmetologists, salon owners, or other technicians—who lack the medical training necessary to properly administer medical procedures.⁴ In fact, laser technology—what was once the stuff of science fiction⁵—has now become so commonplace, that one need not look far for a hair salon, spa or doctor’s office offering cosmetic laser enhancement.⁶

This advance is troubling because the lasers that are used for cosmetic procedures, specifically laser hair removal, laser tattoo removal, and laser skin resurfacing,⁷ are high-tech medical devices

⁴ In a 2001 survey of American Society for Dermatologic Surgery (ASDS) members, forty-five percent of respondents reported an increase in treatment of complications arising from cosmetic surgery procedures performed by nonphysician operators. Harold J. Brody et al., *Beauty Versus Medicine: The Nonphysician Practice of Dermatologic Surgery*, 29 *DERMATOL. SURG.* 319, 319–20 (2003).

⁵ See United Press International, *Laser Seen As Hope In Avoiding Surgery for Blocked Artery*, N.Y. TIMES, Sept. 24, 1982, at A14 (describing how it was “Obi-Wan Kenobi” wielding a “light-sabre” that inspired cardiologist, Garrett Lee, to research the use of lasers as a means of unblocking clogged coronary arteries, which made him a pioneer in the field of laser bypass surgery).

⁶ See, e.g., Irene Dinov Aveda Concept Salon and Day Spa Near Manhattan Wall Street, <http://iredinov.com/> (last visited Mar. 15, 2009); tres-belle, <http://www.tresbelleyou.com/> (last visited Mar. 15, 2009); Laser Removal Center Brooklyn, NY, <http://www.tattoos-removed.com/index.html> (last visited Mar. 15, 2009).

⁷ The majority of today’s cutaneous lasers operate by “selective photothermolysis.” Daniel Berg & Christopher A. Nanni, *Complications of Dermatologic Laser Surgery*, WEBMD, Feb. 16, 2007, <http://www.emedicine.com/DERM/topic525.htm>. This process targets laser light at the skin, where the light is absorbed and converted to thermal energy as the target chromophore (skin structure) absorbs heat so that the chromophore is damaged, but the “pulse duration of laser energy is shorter than the thermal relaxation of the target” and collateral damage is minimized. *Id.* In laser hair removal, the targeted chromophore “is the melanin in the follicular hair unit.” Noah Kawika Weisberg & Steven S. Greenbaum, *Pigmentary Changes After Alexandrite Laser Hair Removal*, 29 *DERMATOL. SURG.* 415, 415 (2003).

Similarly, “lasers remove tattoos by breaking up the pigment colors of the tattoo with a high-intensity light beam.” Charlotte E. Grayson, MD, ed., *Laser Tattoo Removal*, MEDICINENET.COM, <http://www.medicinenet.com/script/main/art.asp?articlekey=43246&pf=3&page=1> (last visited Mar. 15, 2009).

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being operated by nonphysicians.⁸ While it is common for physicians to delegate the delivery of medical services to nonphysician clinicians (“NPCs”) or physician extenders, nonphysician operators (“NPOs”) are different—NPOs principally provide cosmetic dermatologic treatments outside of a medical setting, whereas NPCs are registered nurses (“RNs”), nurse-practitioners (“NPs”), and physician’s assistants (“PAs”) generally operating under the supervision of a physician.⁹ NPOs may be trained to operate a laser, but since they lack any type of medical training, they may not be able to evaluate skin conditions, take care not to aggravate allergies (or recognize and treat allergic reactions), determine whether or not customers are appropriate candidates for laser treatment, or properly treat adverse reactions.¹⁰

Laser resurfacing allows removal of “not only wrinkles and lines caused by sun damage and facial expressions, but also acne scars, some folds and creases around the nose and mouth, and even precancerous and benign superficial growths” through “a very controlled burning procedure during which a laser vaporizes superficial layers of facial skin . . . creat[ing] a fresh surface over which new skin can grow.” Alexandra Greeley, *Cosmetic Laser Surgery: A High-Tech Weapon in the Fight Against Aging Skin*, 34 FDA CONSUMER 3 (2000), available at http://www.fda.gov/FDAC/features/2000/300_laser.html.

⁸ Ronni Barke, *Laser Surgery in Wrong Hands Can Be Dangerous*, CNN.COM, Sept. 20, 2007, <http://www.cnn.com/2007/HEALTH/09/20/berke.lasersurgery/>. Professional organizations such as “the American Society for Laser Medicine and Surgery and the American Society for Dermatologic Surgery” both “offer guidelines that allow non-physicians to perform cosmetic laser treatments, but only in states where this is allowed, and only under direct physician supervision.” John Jesitus, *Legal Issues Complicate Cosmetic Laser Treatments*, MODERN MEDICINE, June 1, 2006 (emphasis added), available at <http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=394760&sk=&date=&pageID=1>.

⁹ Brody et al., *supra* note 4, at 319. NPCs have been considered “invaluable . . . by managed care as a cost-effective means for providing medical services.” *Id.* at 322.

¹⁰ Joanne Kaufman, *The Light Fantastic?*, N.Y. MAG., Feb. 18, 2002, available at <http://nymag.com/nymetro/health/columns/strongmedicine/5720/>. Dr. Geronemus told the reporter that training is needed “in the problem that’s being treated as well as the device that’s being utilized,” and that the decisions involved in laser treatment vary from patient to patient, requiring practitioners to exercise clinical judgment, making cosmetic laser procedures ill-fitted for performance by NPOs. *Id.*

Although the United States Food and Drug Administration (“FDA”) regulates the manufacture, sale, and quality of lasers in the market,¹¹ it leaves licensing of the practice of laser surgery to the states.¹² While some states require a physician to either be on-call, on-site, in the room, or personally operating the laser, other states, including New York, have absolutely no regulations regarding who may fire a laser.¹³

The absence of a national standard has resulted in vast inconsistencies in state policies and confusion regarding both the clinical delivery and legal application of the proper standard of care.¹⁴ The medi-spa industry is growing rapidly, and as the FDA continues to approve medical devices for sale without setting minimum licensing standards for the use of potentially harmful medical devices, there is no structure in place to prevent medical device manufacturers and state legislatures from perpetuating exactly the type of problems that the lack of laser regulation has produced.¹⁵ Accordingly, the FDA needs to impose rigorous minimum standards for laser operation.

By allowing the FDA to approve light-emitting lasers for sale with the expectation that they would be used on human bodies,¹⁶ Congress has failed to consider the danger of not regulating the use

¹¹ Medical Device Amendments of 1976, 21 U.S.C. § 360c (2008) (regulating the processes for classification and approval of medical devices); 21 C.F.R. § 1040.11 (2009).

¹² See Greeley, *supra* note 7.

¹³ FEDERATION OF STATE MEDICAL BOARDS, USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS: REGULATION BY STATE 14 (2008) [hereinafter REGULATION BY STATE], http://www.fsmb.org/pdf/GRPOL_Laser_Regulation.pdf.

¹⁴ See *Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734, 737 (Ind. Ct. App. 2008) (citing *Witherspoon v. Teton Laser Ctr., LLC*, 149 P.3d 715, 727 (Wyo. 2007)).

¹⁵ Patricia King, *Prescription for Pampering*, L.A. TIMES, Sept. 20, 2004, § Health, at 1 (describing the medical spa’s popularity in the \$11.1 billion annum spa industry, the increasing number of burns and scarring resulting from laser treatments performed by nonphysicians, and in some cases, non-dermatologist physicians, and the difficulties that injured consumers/patients face in seeking redress for their injuries).

¹⁶ See 21 C.F.R. § 1040.11; Greeley, *supra* note 7.

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of these lasers.¹⁷ Since it has not provided minimum licensing standards for states to maintain, the states are not required to protect their citizens from improperly trained, enterprising, would-be tortfeasors¹⁸ nor their practitioners from being held to irrational standards.¹⁹ This policy has created an imbalance of justice by setting forth obstacles that prevent injured plaintiffs from successfully making out claims against such practitioners²⁰ and preventing non-negligent practitioners from appropriately defending themselves against unwarranted claims.²¹ The FDA must be permitted to require that only healthcare professionals²²

¹⁷ See, e.g., *Estate of John Doe v. Anonymous Physician*, 14–9 Metro Verdicts Monthly (Verdict Research Group) 36 (Va. Cir. Ct. Jan. 14, 2002) (settling wrongful death claim of twenty-year-old male who suffered anaphylactic shock as a result of topical anesthetic applied in connection with laser hair removal treatment); *Sanders v. Genesis Cosmetic Laser Surgery, L.L.C.*, 2005 Ohio Trial Rep. (Verdict Research Group) No. 02-CV-4690 (Ohio Ct. Common Pleas Apr. 20, 2004) (awarding damages to plaintiff suffering hypopigmentation who alleged that defendant fell below standard of care in providing treatment without adequate training and failing to provide informed consent); *Gottschalk v. Virden*, CV-99-05978 (Nev. Dist. Ct. Mar. 2003), reported in LEE S. GOLDSMITH, *MEDICAL MALPRACTICE GUIDE: MEDICAL ISSUES* § 160.100 (2009), available at LEXIS, 6-160 MEDISS § 160.100 (hereinafter *Gottschalk*) (returning verdict for defendant where plaintiff claimed permanent corneal abrasion resulted from a laser used around the eye area, despite lack of informed consent).

¹⁸ See Brody et al., *supra* note 4, at 319 (reporting an increase in treatment complications due to increase of treatments by nonphysician operators).

¹⁹ See text accompanying notes 231–33.

²⁰ See, e.g., *Gottschalk*, *supra* note 17; *Jones v. Fairhurst*, (Ill. Cir. Ct. June 2002), reported in LEE S. GOLDSMITH, *MEDICAL MALPRACTICE GUIDE: MEDICAL ISSUES* § 160.100 (2009), available at LEXIS, 6-160 MEDISS § 160.100 (hereinafter *Jones*); *Rector v. Ramey*, CJ-2000-1573 (Okla. Dist. Ct. July 2001), reported in LEE S. GOLDSMITH, *MEDICAL MALPRACTICE GUIDE: MEDICAL ISSUES* § 160.100 (2009), available at LEXIS, 6-160 MEDISS § 160.100 (hereinafter *Rector*). See also David J. Goldberg, *Legal Considerations in Cosmetic Laser Surgery*, 5 J. COSMETIC DERMATOL. 104, 106 (2006) [hereinafter *Legal Considerations*] (opining that the law on laser treatment is different in every state, making the standard of care for laser procedures an indefinite concept).

²¹ See text accompanying notes 231–33.

²² For the purposes of this Note, the terms “healthcare practitioners” and

licensed to perform laser treatment may operate a laser, and that an on-site physician must supervise treatment by licensed NPCs.

This Note examines the federal government's dangerous error of giving states wide discretion in their regulation of medical device operation, and the unfortunate consequences that have resulted from the failure to regulate the operation of lasers for cosmetic procedures. Part I describes the incredible rate at which the cottage industries of laser hair removal, laser tattoo removal and laser skin resurfacing have developed, and then explains the uses, risks, and potential adverse effects of cosmetic laser procedures. Part II shows how the states' different regulatory approaches have affected litigation of injuries resulting from negligent provision of care in laser cosmetic procedures and the current system's failure to appropriate responsibility for harm caused and effectively promote safer treatment. Finally, Part III explains the necessity for federally mandating minimum licensing standards for operation of medical devices such as the lasers used in cosmetic laser surgery.

PART I: INDICATIONS AND RISKS

A. Big Business: The Emergence of the "Medi-Spa"

The skin care industry has been dominated by laser procedures for some time now.²³ The states, however, have been slow—and at times, ineffective—in responding to this market trend.²⁴

1. The Laser Market

Lasers are big business.²⁵ While laser tattoo removal and laser

"healthcare providers" refer to physicians ("MDs"), registered nurses ("RNs"), nurse practitioners ("NPs") and physician assistants ("PAs").

²³ See Cosmetic Plastic Surgery Statistics, <http://www.cosmeticplasticsurgerystatistics.com/statistics.html> (last visited Mar. 15, 2009).

²⁴ See *infra* Part I.A.2.

²⁵ See RiShawn Biddle, *Smooth Operators*, FORBES, Apr. 3, 2000, at 56.

skin resurfacing account for many of the non-ablative²⁶ cosmetic procedures performed annually, laser hair removal is by far the most popular of the non-ablative treatments, with approximately 1.5 million procedures reported annually since 2004.²⁷ The increased volume at which the procedures are performed is one explanation for the high incidence of complications reported for laser hair removal in comparison to other cosmetic procedures.²⁸

Setting aside the comparative popularity of laser hair removal, the rate at which all laser procedures are performed has spiked tremendously since laser cosmetic procedures were introduced²⁹ to the consumer market.³⁰ In 2000, *Forbes* magazine documented the soaring rate at which the market for laser hair removal rose, “from an estimated 1,500 in 1996 to 500,000 [treatments] in 1998 and an expected 1 million [in the] next year.”³¹

²⁶ Ablative cosmetic procedures “remove surface skin layers,” while non-ablative cosmetic procedures like those discussed in this Note, target chromophores beneath the skin’s surface and the superficial layers of the skin, *see supra* note 7 and accompanying text, “leav[ing] the surface of the skin intact.” Harvard Health Publications, Online Medical Dictionary: Cosmetic Surgery, <http://www.health.harvard.edu/dictionary/Cosmetic-Surgery.htm>.

²⁷ *See* Cosmetic Plastic Surgery Statistics, *supra* note 23. The website “Plastic Surgery Research.info” reports that its statistics are provided by the American Society for Aesthetic Plastic Surgery (ASAPS). As these figures only represent those reported by the ASAPS, they are actually low-end estimates. Elizabeth Hayt, *Whose Hand Holds the Laser?*, N.Y. TIMES, Feb. 17, 2002, § 9, at 1 (“The [American Society for Dermatologic Surgery] says that nearly half its 2,400 members have reported an increase in treating burns, scarring and other injuries caused by nonphysicians doing high-tech beauty procedures.”). Trade newsletter *Medical Laser Insight* reported over five million treatments in 2001, generating \$1.3 billion, with the majority of laser hair removal procedures not performed under the care of a physician. *Id.*

²⁸ *See* Brody et al., *supra* note 4, at 320 (showing 111 noted adverse effects from laser hair removal procedures compared to 44 noted incidences of complications from skin resurfacing procedures).

²⁹ Since 1979, researchers have been experimenting with lasers in cosmetic dermatology, and in 1995 the “FDA cleared the first laser for hair removal in the US.” Andrea James, *Hair Removal Methods: Laser History and Current Issues*, <http://www.quackwatch.org/01QuackeryRelatedTopics/Hair/laserhistory.html> (last visited Mar. 15, 2009).

³⁰ *See* Cosmetic Plastic Surgery Statistics, *supra* note 23.

³¹ Biddle, *supra* note 25. *Forbes* also noted the advertisements populating

The increasing market demand for laser procedures has led to more physician purchases of lasers as business investments.³² Many physicians turn to cosmetic procedures in order to maintain lucrative pay,³³ as managed care reimbursements limit physicians' incomes³⁴ to the number of patients they are able to treat in a given time period.³⁵ Lasers, which may cost between \$85,000 and \$100,000 when factoring in maintenance costs,³⁶ have offered physicians high turnover rates on equipment investments³⁷ and "insurance-free living"³⁸ in a market where the demand for laser treatments continues to be strong.³⁹

When physicians started performing laser procedures, however,

urban magazines in an apparent "warpath against unsightly hair." *Id.* Even before lasers were marketed for hair-removal purposes, urban consumers were bombarded with ads of "laser-packing doctors." Douglas Martin, *The Region: How Did the Subways Get So Full of Such Depressing Ads?*, N.Y. TIMES, July 21, 1991, § 4, at 6.

³² Christian Raulin et al., *Ethical Considerations Concerning Laser Medicine*, 28 LASERS SURG. & MED. 100, 100 (2001).

³³ See Milt Freudenheim, *As Insurers Cut Fees, Doctors Shift to Elective Procedures*, N.Y. TIMES, Aug. 24, 1996, at 1. See also Michael S. Krivda, *A Facelift for Your Practice: Adding Cosmetic Procedures*, 14 SKIN & AGING (2006), available at <http://www.skinandaging.com/article/6272> (providing instructions for effectively generating income by offering cosmetic procedures to cash-paying patients).

³⁴ "Managed care has been cutting the flow of patients and sharply reducing fees for many specialists," determining that the elective procedures these specialists provide do not warrant health care coverage. Freudenheim, *supra* note 33.

³⁵ "When Goldman was accepting insurance, he packed in 40 to 50 patients a day. 'It was like working in a mill.' Now, says Goldman, he sees 15 to 20 patients a day. 'I'm not going on volume anymore. I'm going on quality.'" King, *supra* note 15.

³⁶ Krivda, *supra* note 33.

³⁷ Kaufman, *supra* note 10.

³⁸ King, *supra* note 15. Elective procedures such as laser treatment are not covered by health insurance and doctors are therefore not required to charge contracted fees to patients. Freudenheim, *supra* note 33.

³⁹ See Raulin et al., *supra* note 32, at 100 ("In these days of tight budgets, it is implied that lasers provide powerful sources of additional income outside of the field of managed care.").

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the demand for these services grew too fast to keep up.⁴⁰ As a result, physicians began to rely on physician extenders to meet the demands of the practice.⁴¹ Physicians trained their RNs, NPs, and PAs (collectively, “NPCs”) as physician extenders to provide care under physician supervision.⁴² A survey of the American Academy of Dermatology has reported that 33% of dermatologists utilize the services of physician extenders in their practice.⁴³

Dr. David Goldberg,⁴⁴ who served as president of the American Society for Laser Medicine and Surgery (ASLMS) from 1997 to 1998,⁴⁵ reports having taken heat for stating that with proper training and supervision, licensed health-care professionals who are not physicians “should be allowed to do less aggressive cosmetic laser procedures . . . under a doctor’s guidance.”⁴⁶ He concedes that the plan backfired, noting that “[n]ow you have [nonphysicians] in these spas doing treatments without supervision.”⁴⁷ Lacking regulations, laser hair removal markets have mushroomed, and NPOs, without training in medicine (or dermatology, for that matter), are aggressively advertising and performing cosmetic laser procedures.⁴⁸

Doctors have allowed licensed health-care professionals who are not physicians to conduct laser procedures because delegating services saves money and allows doctors to provide services to

⁴⁰ See Cosmetic Plastic Surgery Statistics, *supra* note 23. See *infra* text accompanying notes 46–47.

⁴¹ Brody et al., *supra* note 4, at 323 (growing “popularity of cosmetic procedures . . . led to a growing number of nonphysicians operating without oversight”).

⁴² *Id.* at 322.

⁴³ *Legal Considerations*, *supra* note 20, at 106.

⁴⁴ Dr. Goldberg is the Director of Laser Research at Mount Sinai School of Medicine’s Dermatology department. Bonnie Darves, *Delegating Laser Hair Removal*, 16 SKIN & AGING (2008), available at <http://www.skinandaging.com/article/8970>. He is both a dermatologist and healthcare attorney. *Id.*

⁴⁵ Skin Laser & Surgery Specialists of New York and New Jersey, Societies, Memberships, & Awards, http://www.skinandlasers.com/societies_memberships.htm.

⁴⁶ Kaufman, *supra* note 10 (internal quotations omitted).

⁴⁷ *Id.*

⁴⁸ Brody et al., *supra* note 4, at 323.

more patients.⁴⁹ Professional physician organizations such as the American Academy of Dermatology, the American Society of Laser Medicine and Surgery and the American Society for Dermatologic Surgery have each developed guidelines for delegating laser use to nonphysicians.⁵⁰ These groups advocate delegation of laser use to properly trained and supervised paramedical professionals, but do not support laser use by non-medically trained NPOs.⁵¹

In all areas of medicine, physicians are cutting costs by training and relying on the services of these “physician extenders.”⁵² While there is evidence to show that there is “no statistically significant differences in hair reduction, patient satisfaction, or complication rate between physician and nurse-treated patient groups,”⁵³ regulation restricting delegation to only those healthcare professionals licensed to perform laser treatment will ultimately lead to increased patient safety.⁵⁴ Physician advocates argue that the nature of the cosmetic laser industry as big business for untrained NPOs is demonstrative of how many people are at risk for injury and of the great need there is for more stringent regulations ensuring safety.⁵⁵

2. *The Market’s Institutional Support*

New York’s market has been saturated with NPO cosmetic laser services,⁵⁶ and has for some time been in the process of

⁴⁹ *Id.* at 322.

⁵⁰ Murad Alam et al., *Use of Cutaneous Lasers and Light Sources: Appropriate Training and Delegation*, 12 SKIN THERAPY LETTER (2007), available at <http://www.skintherapyletter.com/2007/12.5/2.html>.

⁵¹ *Id.*

⁵² See Thomas R. McLean, *Crossing the Quality Chasm: Autonomous Physician Extenders Will Necessitate a Shift to Enterprise Liability Coverage for Health Care Delivery*, 12 HEALTH MATRIX 239, 255 (2002).

⁵³ Bruce M. Freedman & Robert V. Earley, *Comparing Treatment Outcomes Between Physician and Nurse Treated Patients in Laser Hair Removal*, 2 J. CUTANEOUS LASER THERAPY 137, 139 (2000).

⁵⁴ See *infra* Part III.B.

⁵⁵ Alam et al., *supra* note 50.

⁵⁶ See Darves, *supra* note 44. Dr. Anderson, a New York City

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developing multi-sponsored legislation to regulate cosmetic laser procedures.⁵⁷ Former Assemblyman Steven Sanders recognized the problem in 2002 and told *The New York Times* that he planned to introduce a bill that session.⁵⁸ The proposed legislation is more aggressive than some of the policies active in many other states.⁵⁹ It limits laser operation to licensed individuals either authorized to practice medicine or under “direct [on site] supervision” of an individual authorized to practice medicine, and provides that use of “lasers and similar devices . . . be deemed to be the practice of medicine.”⁶⁰ The State Assembly justifies its proposed legislation as follows:

Over the past several years in New York, there has been a marked increase in the use of laser and other devices to do cosmetic, esthetic and other skin enhancement procedures. Simultaneously, there has been an increase in the number of injuries caused by the proliferation and use of these devices by untrained and unskilled personnel. Entrepreneurs, without medical training, are treating people with little or no oversight or regulation. Spas and self-styled “skin clinics” advertise these high-tech procedures using medical devices.⁶¹

While the bill’s summary articulates that New York is aware of the problem and is attempting to remedy it, the failure to follow through is more telling of the legislature’s unwillingness to interfere with the rights of those who have vested interests in what is already a strong and competitive commercial market.⁶² The bill

dermatologist, attributes the botched laser procedures she treats in her solo practice to the “free-for-all market” in New York. *Id.*

⁵⁷ REGULATION BY STATE, *supra* note 13, at 14.

⁵⁸ Hayt, *supra* note 27.

⁵⁹ See REGULATION BY STATE, *supra* note 13.

⁶⁰ A. 08142, 230th Assemb., Reg. Sess. (N.Y. 2007).

⁶¹ Sponsors Memo, A. 08142, 230th Assemb., Reg. Sess. (N.Y. 2007).

⁶² “Some dermatologists expect that the regulatory laxness, where it exists, will go away, but that’s unlikely to occur soon, given powerful lobbying forces. In Massachusetts, for instance, electrologists . . . are pushing for looser regulations.” Darves, *supra* note 44. See also Hayt, *supra* note 27 (“The [ASDS] last year began a campaign to have only physicians perform or directly supervise

was referred to the health committee in 2003, and as of 2009, New York has yet to move forward with it.⁶³

New York is not the only state to stall in its attempt to regulate laser treatments.⁶⁴ Other states have also fallen prey to the economic weight backing the cosmetic laser industry.⁶⁵ Despite patient safety concerns, small and large businesses in New York and throughout the country are generating significant revenues from laser procedures, and legislatures may be more concerned about causing widespread economic loss than preventing injuries on a much smaller scale.⁶⁶

In Texas, similar legislation has been enjoined from enactment, as Texas physicians have sued the Texas Medical Board for interfering with their practice of delegating the delivery of medical services.⁶⁷ The lawsuits were abated when compromising

cosmetic treatments The booming spa industry, which offers the high-tech treatments at 50 percent of doctors' fees or less, says physicians are threatened by the loss of patients and want to keep the lucrative beauty treatments for themselves 'Everyone wants a piece of the pie'" (quoting Mary Bemis, editor of *American Spa Magazine*)).

⁶³ See Sponsors Memo, A. 08142, 230th Assemb., Reg. Sess. (N.Y. 2007).

⁶⁴ See Texas Medical Board, *Laser Rule Update: Standing Delegation Orders and Rule 193.11 Use of Lasers*, available at <http://www.tmb.state.tx.us/rules/laserrule.php> (last visited Oct. 31, 2008).

⁶⁵ See Darves, *supra* note 44 (regarding "regulatory laxness" in Massachusetts, New York and New Jersey, in the section "Will the Regulatory Situation Improve?").

⁶⁶ See King, *supra* note 15 (attributing \$11.1 billion a year to the spa industry).

⁶⁷ See Texas Medical Board, *supra* note 64. In 2003, the Texas Medical Board ("TMB") introduced the "Laser Rule" which instituted guidelines for the use of lasers in laser hair removal, the delegation of health care tasks such as laser treatment to qualified nonphysicians by supervising physicians, and the regulation of laser hair removal facilities. *Id.* See also Laura Jeanne Sanger, Health Law & Policy Institute, University of Houston Law Center, *Laser Hair Removal*, HEALTH L. PERSPECTIVES (2008), available at [http://www.law.uh.edu/healthlaw/perspectives/2008/\(LSK\)%20laser.pdf](http://www.law.uh.edu/healthlaw/perspectives/2008/(LSK)%20laser.pdf). The Laser Rule was to take effect in November 2003, with a prospective enforcement date of December 2004. Prior to enforcement, two lawsuits challenged TMB's authority to regulate. After "the plaintiffs in *Laser Stakeholders* were granted a Temporary Restraining Order and an Order for Injunctive Relief," the plaintiffs in both the *Finder* and *Laser Stakeholders* cases

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legislation was proposed, but legislators have since decided not to enact the original or subsequent legislative acts.⁶⁸

This situation, in which states have failed to insulate their regulatory policies on laser treatment from industry pressure,⁶⁹ needs to be remedied in order to prevent further injuries from laser procedures.

B. Prevention and Treatment

Physician advocates for regulation of cosmetic laser treatments argue that NPOs are not trained to address safety concerns of operating a laser, thus making them incapable of providing an appropriate standard of care.⁷⁰ Generally, these arguments against allowing NPOs to operate lasers address NPOs' lack of medical knowledge necessary for effective risk prevention and damage control associated with laser procedures.⁷¹

1. Assessing Risks

To effectively prevent risks in cosmetic laser treatment, providers must first evaluate a patient to assess whether or not that patient is an appropriate candidate for the procedure⁷² and

agreed to abate the cases pending legislative action. *Id.* In February 2008, after successive proposed legislation failed to take effect, the Disciplinary Process Review Committee agreed to repeal the Laser Rule, leaving laser hair removal regulation in Texas "an open question." *Id.*

⁶⁸ Sanger, *supra* note 67.

⁶⁹ Alam et al., *supra* note 50 (regarding "increasing tension between dermatologists and electrologists over the training required to perform laser hair removal").

⁷⁰ Brody et al., *supra* note 4, at 319.

⁷¹ *Id.* at 323.

⁷² *See, e.g.,* Darves, *supra* note 44 (describing "[T]he standard fair-skinned, dark-haired patient" seeking laser hair removal as a "relatively straightforward case") (internal quotations omitted); Brody et al., *supra* note 4, at 323 ("[T]he standard of care required for any medical procedure . . . must be preceded by a physician evaluation and recommendation that such treatment is appropriate for the patient's condition.").

determine the proper laser settings for the patient's skin.⁷³ The decisions necessary at the outset of treatment require careful and experienced judgment, as there are risks of side effects even under the care of a skilled, medically trained practitioner.⁷⁴ The risks associated with inexperience and hurrying through these preventative measures include: burns, hypopigmentation,⁷⁵ scarring, delayed healing, herpes simplex eruptions,⁷⁶ impetigo,⁷⁷ and corneal and retinal⁷⁸ injuries.⁷⁹

Furthermore, patients seeking to remove acne or moles at skin care spas may inadvertently ask an untrained NPO to blast away the warning signs of cancer.⁸⁰ Of course, this is extremely dangerous.⁸¹ According to New York dermatologist Dr. Laurie Polis, "[h]aving a laser and taking off an undiagnosed pigmented lesion is like having a gun in your hand."⁸²

⁷³ See Freedman & Earley, *supra* note 53, at 137 ("The physician selected the laser setting for all patients.").

⁷⁴ See Brody et al., *supra* note 4, at 323.

⁷⁵ Hyperpigmentation and hypopigmentation are pigmentary disorders by which an increase or a decrease in melanin results in respective darkening or lightening of the skin. Cleveland Clinic, Hyperpigmentation/Hypopigmentation, http://my.clevelandclinic.org/disorders/Hyperpigmentation/hic_Hyperpigmentation-Hypopigmentation.aspx (last visited Mar. 15, 2009). These conditions are sometimes permanent. *Id.*

⁷⁶ Herpes simplex viruses in latent stage will not produce symptoms or spread to others, but when triggered will cause an outbreak of blisters and the virus will be contagious to others. N.Y. Times Health Guide, Herpes Simplex, <http://health.nytimes.com/health/guides/disease/herpes-simplex/symptoms.html> (last visited Mar. 15, 2009).

⁷⁷ Impetigo is a contagious infection that results from bacteria entering broken skin and growing within the skin. N.Y. Times Health Guide, Impetigo, <http://health.nytimes.com/health/guides/disease/impetigo/overview.html> (last visited Mar. 15, 2009).

⁷⁸ Lasers destroy tissue by targeting pigment. Weisberg & Greenbaum, *supra* note 7, at 415. When used too close to the eye area, the pigment in the iris can absorb the laser light and damage the eye. Jesitus, *supra* note 8.

⁷⁹ Alam et al., *supra* note 50.

⁸⁰ Brody et al., *supra* note 4, at 323.

⁸¹ Hayt, *supra* note 27.

⁸² *Id.* (internal quotations omitted).

The pigment in a dangerous lesion is a signal to the dermatologist that

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Even physicians who feel perfectly comfortable delegating laser operation to physician extenders see the need to intervene when the patient is not “the standard fair-skinned, dark-haired patient” with a large exposed surface area to be treated.⁸³ These physicians also insist on seeing patients personally for a pre-treatment assessment.⁸⁴ Despite support from the medical profession, the use of physician extenders in laser treatment is not considered a casual delegation of medical responsibilities.⁸⁵ In an informal survey of members of the Texas Society of Plastic Surgeons regarding delegation and supervision, while only fifty-five percent of the participating physicians responded that “only physicians should perform laser procedures” more than ninety percent “felt a patient should be seen by a physician before treatment to evaluate that patient for a specific laser treatment or procedure” and that “a physician should at least be on-site” when laser procedures are performed by nurses, licensed aestheticians, and licensed cosmetologists.⁸⁶ These attitudes reflect physicians’ opinions that laser procedures must be viewed as medical treatments.⁸⁷

Typically, failure to adequately assess risks through a physician’s evaluation of a patient prior to treatment will result in adverse effects.⁸⁸ For example, in 2001, an African American woman from New York filed a \$125 million lawsuit against an upscale Manhattan spa after laser hair removal treatment

the lesion needs surgical removal and biopsy. Having one of these self-proclaimed, so-called laserists remove the warning sign, and now depigmented malignancy can spread through the body to the brain and kill someone in later months or years.

Id.

⁸³ Darves, *supra* note 44.

⁸⁴ *See id.*

⁸⁵ *See id.* (“Other dermatologists have either elected not to delegate or to be exceedingly selective about which patients are treated by non-physician staff, for safety and liability reasons.”).

⁸⁶ Rod J. Rohrich & A. Jay Burns, *Lasers in Office-Based Settings: Establishing Guidelines for Proper Usage*, 109 PLASTIC & RECONSTRUCTIVE SURG. 1147, 1147 (2002).

⁸⁷ Weisberg & Greenbaum, *supra* note 7, at 419.

⁸⁸ King, *supra* note 15.

performed by a cosmetologist left her with first and second degree burns.⁸⁹ The spa advertised “medical oversight,” but no physician was on the premises when she received her treatment, so no one there had the proper medical knowledge needed to accurately assess the risks associated with treating her darker skin.⁹⁰

Practitioners also blame the business practices of skin care spas for the rise of adverse incidents.⁹¹ The spa culture has so invaded the retail industry that patients approach laser treatments as consumers, not realizing that they are patients purchasing low quality medical care and not properly evaluating the risks they contract.⁹² Many are lulled into feeling that the procedures are safe, when in fact they involve serious risks.⁹³

In fashioning its still-pending legislation, the New York State Assembly explains:

More and more media reports and exposes [sic] are reporting an increase in malpractice cases, a result of adverse outcomes related to inappropriately rendered treatment by clinicians in New York. The majority of cases are the result of a lack of experience, lack of training, poor judgment, and/or inappropriately selected technology for a particular procedure. The burns and other injuries which can result from the inappropriate use of these devices by unqualified persons can cause permanent scarring, disfigurement and disability.⁹⁴

While New York may be deficient in its readiness to regulate laser technology, it is not alone in its high incidence of malpractice claims resulting from negligent performance of cosmetic laser procedures.⁹⁵ These are not simply ominous warnings—people are

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Brody et al., *supra* note 4, at 323.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ Sponsors Memo, A. 08142, 230th Assemb., Reg. Sess. (N.Y. 2007).

⁹⁵ *See, e.g.*, *Greenwood v. Babar*, 1 Med. Litig. Alert (Jury Verdict Rev. Publ'ns, Inc.) No. L-0799-89 (N.J. County Ct. Aug. 7, 1992); *Sanders v. Genesis Cosmetic Laser Surgery, L.L.C.*, 2005 Ohio Trial Rep. (Verdict Research Group) No. 02-CV-4690 (Ohio Ct. Common Pleas Apr. 20, 2004);

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suffering injuries from the hazards cautioned by the legislature and laser practitioners have seen an increase in cost for insurance premiums as a result of the malpractice claims brought against them.⁹⁶

In the late 1990s, the disconnect between the overwhelming incidence of medical injuries resulting in death in New York hospitals and overall malpractice liability claims filed in New York drew attention through the Harvard Medical Practice Study and the Institute of Medicine's report, *To Err Is Human*.⁹⁷ One result of these studies was awareness of the fact that even "quality" health care is far from perfect.⁹⁸ The alarming incidence of medical injuries is evidence of a certain degree of inevitable error and powerlessness, as physicians cannot be in control of every aspect of a patient's health.⁹⁹ Nevertheless, NPOs performing laser surgeries create an even more disturbing situation, since they lack the requisite skill and education to take the care and appropriate precautions that physicians have been trained to provide.¹⁰⁰

2. *Treating Emergencies*

Physicians who argue against laser treatment by NPOs fault not only the NPOs' inability to provide effective pre-treatment, but

Estate of John Doe v. Anonymous Physician, 14–9 Metro Verdicts Monthly (Verdict Research Group) 36 (Va. Cir. Ct. Jan. 14, 2002).

⁹⁶ Hayt, *supra* note 27 (quoting president of company providing skin care spa insurance coverage on increase in costs due to high settlements and jury verdicts).

⁹⁷ See HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK: THE REPORT OF THE HARVARD MEDICAL PRACTICE STUDY TO THE STATE OF NEW YORK (1990); COMMITTEE ON QUALITY HEALTH CARE IN AMERICA, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

⁹⁸ See sources cited *supra* note 97.

⁹⁹ "It's not like it doesn't happen to a physician, but it's less likely." Hayt, *supra* note 27 (quoting clinical professor of dermatology, Dr. William Coleman).

¹⁰⁰ See *id.* (regarding the adverse incidents resulting from care provided by NPOs who lack medical training).

also argue that NPOs risk further harm when care is provided outside of a medical setting without a physician present because they are unable to treat emergencies.¹⁰¹ Without formal training in wound-care, NPOs are unable to effectively treat burns, prevent scarring and recognize complications.¹⁰²

Because laser treatments are, as physicians argue, medical procedures,¹⁰³ medical problems may arise in the course of these treatments.¹⁰⁴ Therefore, it is necessary for a physician to be present during treatment.¹⁰⁵ A sampling of lawsuits arising over laser-induced injuries illustrates the importance of a physician's presence.¹⁰⁶ The woman in Manhattan who sued her upscale spa for the treating NPC's failure to appropriately treat her darker skin suffered additional injury when she was "incorrectly prescribed a bleaching agent for her burns."¹⁰⁷ An Ohio jury awarded \$85,000 to a woman for a dermatologist's failure to provide informed consent regarding the risk of hypopigmentation to her legs.¹⁰⁸ There, the plaintiff argued that the physician was not adequately trained to use the equipment and incorrectly advised that keeping the area moisturized would alleviate the hypopigmentation.¹⁰⁹ Just last year, a district court in Michigan denied summary judgment in a medical malpractice action where a physician extender was allegedly negligent in passing the laser over the plaintiff's face, "carving deep facial ruts and transverse facial lines and/or grooves" and failing to listen to the plaintiff's warning of an aloe vera allergy, causing further injury by negligence in follow-up care.¹¹⁰

¹⁰¹ Brody et al., *supra* note 4, at 323.

¹⁰² *Id.*

¹⁰³ Weisberg & Greenbaum, *supra* note 7, at 419.

¹⁰⁴ Brody et al., *supra* note 4, at 323.

¹⁰⁵ *Id.*

¹⁰⁶ *See infra* Part II.C.

¹⁰⁷ King, *supra* note 15.

¹⁰⁸ Sanders v. Genesis Cosmetic Laser Surgery, L.L.C., 2005 Ohio Trial Rep. (Verdict Research Group) No. 02-CV-4690 (Ohio Ct. Common Pleas Apr. 20, 2004).

¹⁰⁹ *Id.*

¹¹⁰ Dipasquale v. Rechner, No. 2:07-CV-0033, 2008 U.S. Dist. LEXIS

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In 2002, a Virginia plaintiff received \$728,000 in settlement of a wrongful death action when the defendant plastic surgeon “failed to (1) recognize signs of anaphylaxis;¹¹¹ (2) treat the anaphylaxis with Epinephrine, which would have resulted in a more than 95% chance of survival; and (3) perform standard life-saving techniques” when a twenty year old male suffered an allergic reaction to the anesthetic cream applied during a laser hair removal treatment.¹¹²

These injuries and the resulting litigation reflect the notion that cosmetic laser procedures are not as safe as haircuts or manicures that can be performed without the expertise of a physician to adequately provide follow-up care in the event an adverse reaction were to occur. They also draw attention to the importance of a regulatory system to ensure safe laser procedures.

PART II: STATE REGULATION’S ROLE IN THE DETERMINATION OF
THE APPLICABLE STANDARD OF CARE

The messy patchwork of assorted regulatory policies toward laser procedures throughout the states is unsafe and in discord with prevailing principles of responsibility and redress¹¹³—“[i]t’s kind

47018, at *3 (W.D. Mich. June 17, 2008).

¹¹¹ “Anaphylaxis is a severe, potentially life-threatening allergic reaction” in which “[t]he flood of chemicals released by [the] immune system” may cause shock, a sudden drop in blood pressure and a narrowing of airways, “blocking normal breathing.” MayoClinic.com, Anaphylaxis, Sept. 5, 2008, <http://www.mayoclinic.com/health/anaphylaxis/DS00009>. If not immediately treated, “it can lead to unconsciousness or even death.” *Id.*

¹¹² Estate of John Doe v. Anonymous Physician, 14–9 Metro Verdicts Monthly (Verdict Research Group) 36 (Va. Cir. Ct. Jan. 14, 2002). Although this extreme result is not common in laser treatment, it is common for spas to recommend that patients use such numbing creams when they find the sensation of laser hair removal intolerable. *See, e.g.*, Bare Beauty Laser Hair Removal, Astoria NY, <http://www.barebeautylaser.com/> (follow “FAQ’s” [sic] hyperlink; then follow “Does Laser Hair Removal Hurt?” hyperlink) (last visited Mar. 14, 2009); Romeo and Juliette Laser Hair Removal, New York, New York, <http://romeojuliettelaserhairremoval.com/faq.htm> (last visited Mar. 14, 2009).

¹¹³ TOM BAKER, THE MEDICAL MALPRACTICE MYTH 113 (2005) (“Responsibility lies at the heart of tort law. A tort lawsuit is a public statement that a defendant has not accepted responsibility, coupled with a demand to do

of the wild, wild West.”¹¹⁴ Although one might assume that states without any regulation at all pose the greatest threat to patient safety, that is not necessarily the case.¹¹⁵ Even in states like New Jersey, where only a physician may operate a laser,¹¹⁶ patients who suffer harm due to a physician’s negligence may face barriers in litigation when attempting to prove the proper standard of care since many states do not require laser operators to be physicians.¹¹⁷ While these laws are nuanced and vary greatly from state to state, they appear at first glance to fall into three separate categories: physician operators, supervising physicians, and no regulation.¹¹⁸ However, the majority of states requiring supervision only mandate off-site supervision, which in effect turns out to be no regulation at all, as there is no oversight and usually no meaningful supervision taking place.¹¹⁹ As a result, there are effectively only two categories of regulation: medical and non-medical treatment.¹²⁰ The distinction between these two categories is crucial, because in many states, licensed NPCs may practice medicine only when operating under the direction and supervision of a licensed physician.¹²¹ Therefore, NPCs operating without

so. Malpractice lawsuits ask doctors and hospitals to take responsibility for their mistakes, not just to prevent future mistakes or to compensate the patient, but also because taking responsibility is the morally proper thing to do.”).

¹¹⁴ King, *supra* note 15.

¹¹⁵ See *infra* text accompanying note 116.

¹¹⁶ See *Greenwood v. Babar*, 1 Med. Litig. Alert (Jury Verdict Rev. Publ’ns, Inc.) No. L-0799-89 (N.J. County Ct. Aug. 7, 1992); REGULATION BY STATE, *supra* note 13, at 12–13.

¹¹⁷ See *Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734, 737 (Ind. Ct. App. 2008) (citing *Witherspoon v. Teton Laser Ctr., LLC*, 149 P.3d 715, 727 (Wyo. 2007)); REGULATION BY STATE, *supra* note 13.

¹¹⁸ Brody et al., *supra* note 4, at 322 fig.2. The diagram entitled “State Boards of Medicine Regulations of the Practice of Laser Procedures” depicts four different policies. For purposes of this Note, “[s]tates permitting MDs to delegate laser procedures under direct supervision” and “[s]tates permitting MDs to use their discretion when delegating laser procedures” have been combined into the supervising physician category. *Id.*

¹¹⁹ *Id.* at 321.

¹²⁰ See *id.*

¹²¹ See David J. Goldberg, *Laser Physician Legal Responsibility for Physician Extender Treatments*, 37 LASERS SURG. & MED. 105, 107 (2005)

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supervision are not practicing medicine, are not held to a heightened standard of care, and do not bind the supervising physician with his or her actions.¹²²

Furthermore, whether the treatment is medical or non-medical will inform the standard of care applied in litigation: courts will look to both the facts of the case and the definition of “health care” or the “practice of medicine,”¹²³ as explained in each state’s malpractice statute, to determine whether the plaintiff will need to present expert medical testimony to prove that the defendant breached the appropriate standard of care.¹²⁴ When the treatment does not constitute health care within the statute and is therefore not a medical malpractice action, plaintiffs need not establish “the acceptable standard of *medical* care” to which the defendant will be held, and the expert testimony of a witness without a medical background “may be of aid to a trier of fact.”¹²⁵

*A. Medical Treatment**1. Physician Operators*

In 2001, when cosmetic procedures were still relatively new, fourteen states required that physicians perform laser procedures.¹²⁶ Now, only New Jersey has maintained that standard.¹²⁷ In order to meet the rising demand of patients interested in these procedures while reducing costs and increasing

[hereinafter *Legal Responsibility*], available at <http://www.skinandlasers.com/asp/Upload/publication/Laser%20Physician%20Legal%20Responsibility%20for%20physician%20extender%20.pdf>.

¹²² See *id.*

¹²³ State malpractice statutes rely on the definition of either “health care” or “the practice of medicine,” see *Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734, 736 (Ind. Ct. App. 2008); *Witherspoon v. Teton Laser Ctr., LLC*, 149 P.3d 715, 726 (Wyo. 2007), and accordingly the terms are used here interchangeably in relation to determining the applicable standard of care.

¹²⁴ *Witherspoon*, 149 P.3d at 727.

¹²⁵ See, e.g., *id.* at 726–27 (emphasis added). See also *infra* notes 165–75 and accompanying text.

¹²⁶ Brody et al., *supra* note 4, at 321.

¹²⁷ REGULATION BY STATE, *supra* note 13, at 12–13.

output, the lobbying forces of professional physician organizations have effectively persuaded legislatures to enact regulations that allow physician extenders to operate lasers under physician supervision.¹²⁸

Even a medical degree may not be enough to ensure patient safety.¹²⁹ It is possible for injuries to result from care provided by physicians when physicians lack appropriate training in laser technology, laser surgery, dermatology and dermatological surgery.¹³⁰ This is especially important in medical malpractice litigation when a plaintiff bears the burden of establishing that the physician breached the standard of care owed to the patient-plaintiff.¹³¹

David Goldberg, both a dermatologist and healthcare attorney,¹³² warns that if injury stems from laser treatment performed by a gynecologist, for example, courts will determine whether the gynecologist performed the treatment according to the standard by which a reasonable dermatologist would provide treatment, and not the standards for a physician with training in gynecology.¹³³ But despite the considerable specialty training that accompanies board certification in a particular area, such as dermatology, lack of public knowledge regarding the specialized qualifications has made it easier for physicians providing care in areas for which they have not received board certification to *not* be held to the heightened standard of care associated with board certification.¹³⁴

¹²⁸ See Darves, *supra* note 44. See also *infra* Part I.A.2.

¹²⁹ See COMMITTEE ON QUALITY HEALTH CARE, *supra* note 97, at 57 (“Correct performance and error can be viewed as ‘two sides of the same coin.’ . . . [A]ccidents may occur.”).

¹³⁰ See Kaufman, *supra* note 10 (regarding “internists, endocrinologists, and OB/GYNs” who “take those weekend courses,” David Goldberg “would argue that they’re potentially no better than nonphysicians.”). “In fact, Upper East Side [NY] dermatologist Stephen Kurtin recently treated a patient for burns during a facial resurfacing performed by an oral surgeon.” *Id.*

¹³¹ *Legal Considerations*, *supra* note 20, at 105–06.

¹³² Darves, *supra* note 44.

¹³³ Jesitus, *supra* note 8.

¹³⁴ William P. Gunnar, Note, *The Scope of a Physician’s Medical Practice: Is the Public Adequately Protected by State Medical Licensure, Peer Review,*

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On the other hand, requiring that practitioners be licensed to perform laser procedures ensures fairness in that practitioners will not be held to a standard of care higher than that which they have been trained to provide.¹³⁵ In New Jersey, where a plaintiff claimed that the defendant plastic surgeon breached his duty by opting not to use a laser that allegedly would have lowered the risk of scarring to the plaintiff's neck, the defendant's expert was able to show that the defendant had not breached the standard of care, possibly because a medical expert is better suited to articulate the appropriate standard of care than someone without medical training.¹³⁶ Conversely, the requirement for medical expert testimony "may be too burdensome to a plaintiff who might not be able to penetrate the 'conspiracy of silence,' . . . alleged to exist in the medical community."¹³⁷

The fact that injuries are reported even when physicians perform the laser procedures supports the argument that only medically trained practitioners licensed to perform laser procedures should be able to fire lasers, as the margin of error is much greater when the procedures are performed by untrained NPOs.¹³⁸ Lasers are powerful medical devices capable of causing harm even when well-trained physicians take the utmost care in performing treatments.¹³⁹ Patients undergoing such treatment need

and the National Practitioner Data Bank?, 14 ANN. HEALTH L. 329, 354, 355, 358 (2005).

¹³⁵ Phyllis Coleman & Ronald A. Shellow, *Extending Physician's Standard of Care to Non-physician Prescribers: The Rx for Protecting Patients*, 35 IDAHO L. REV. 37, 79 (1998) (describing the position courts have taken in deciding that holding a practitioner to the standard of care expected of a practitioner who has had more training and education is unfair and therefore undesirable).

¹³⁶ *Greenwood v. Babar*, 1 Med. Litig. Alert (Jury Verdict Rev. Publ'ns, Inc.) No. L-0799-89 (N.J. County Ct. Aug. 7, 1992) (finding that defendant had not breached the standard of care, but awarding \$20,000 for plaintiff's informed consent claim).

¹³⁷ Elizabeth Sudbury Langston, Note, *Changes in the Arkansas Law of Informed Consent: What's Up, Doc?* Aronson v. Harriman, 321 Ark. 359, 901 S.W.2d 832 (1995), 19 U. ARK. LITTLE ROCK L.J. 263, 274 (1997) (internal citation omitted).

¹³⁸ See Brody et al., *supra* note 4, at 322.

¹³⁹ Hayt, *supra* note 27 (quoting clinical professor of dermatology, Dr.

a physician to take appropriate precautions and recognize and appropriately respond if complications arise.

2. *On-Site Physician Supervision of Licensed Healthcare Providers*

Many states have misleading regulations, which require that only physicians may operate a laser, but allow physicians to delegate performance of laser procedures either at their discretion, or to properly trained RNs, NPs or PAs.¹⁴⁰ These regulations also require varying degrees of supervision—some states require that a doctor be “on-site,” and some do not.¹⁴¹ Of the states requiring on-site supervision, there are many cautionary restrictions placed on such delegation, including requirements that nonphysician operators are covered by the physician’s medical malpractice insurance, are trained to follow written office protocol in treating patients, and in some cases, are themselves health professionals (RNs, NPs, or PAs).¹⁴²

“On-site” physician supervision of licensed healthcare providers is preferable to other forms of supervision because of the safety concerns associated with laser treatments.¹⁴³ Many of the centers where physician extenders perform laser procedures have physicians initially evaluate patients and provide prescriptive

William Coleman).

¹⁴⁰ See REGULATION BY STATE, *supra* note 13.

¹⁴¹ See *id.* For example, Arizona requires “direct supervision” by a physician, but does not define “direct.” *Id.* at 2–3. Under Arkansas’ statutes, “continuous” physician supervision need not be maintained by a physician on the premises. *Id.* at 4. “Title 50 of the [North Dakota Administrative Code], Chapter 50-03-01-12 states that the code does not prohibit a physician from delegating any tasks or functions to a qualified person otherwise permitted by state law or established by custom.” *Id.* at 15.

¹⁴² See *id.* Alabama, Alaska, California, New Mexico, South Carolina and Washington all require physicians to remain on-site when a patient is treated by a nonphysician, however Washington’s statute stipulates that “a supervised professional may complete the initial treatment if the physician is called away to attend to an emergency.” *Id.* at 23.

¹⁴³ See *infra* Part II.B.

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directions for the nonphysician.¹⁴⁴ These evaluations are specific to the patient's needs in terms of "the device to be used and the initial settings—and specif[y] under which patient-tolerance circumstances settings can be increased."¹⁴⁵ Physicians operating under these circumstances are comfortable designating laser treatment to trained professionals as long as they are on-site.¹⁴⁶

B. Non-Medical Treatment

Twenty-seven of the forty-seven states with physician supervision laser regulations in effect do not require on-site supervision of nonphysicians.¹⁴⁷ In terms of patient safety, this model is completely undesirable.

Although New York may seem to be the outlier with no regulation, it is in effect regulated similarly to many of the twenty-seven states without on-site supervision, because off-site supervision is not being enforced.¹⁴⁸ States do not actively execute their policies to ensure that the off-site supervision is, in fact, supervision at all.¹⁴⁹ It is easy for spas to operate with virtually no

¹⁴⁴ Darves, *supra* note 44. Some states have gone so far as to require physicians to conduct these initial evaluations when delegating treatment of laser procedures. *See, e.g.*, WASH. ADMIN. CODE § 246-919-605(1)(b)(6) (2009) ("Prior to authorizing treatment with [a laser, light, radiofrequency, or plasma] device, a physician must take a history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent (including informing the patient that a nonphysician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record."); Conn. Med. Examining Bd., Declaratory Ruling on Use of Lasers for Hair Removal (Dec. 17, 1997) (citing CONN. GEN. STAT. ANN. § 20-9 (West 1995)) ("[A] licensed physician with appropriate knowledge, experience, and training should assess each patient prior to and during the course of hair removal treatment with laser therapy.").

¹⁴⁵ Darves, *supra* note 44.

¹⁴⁶ *Id.*

¹⁴⁷ REGULATION BY STATE, *supra* note 13.

¹⁴⁸ *See id.*; *see also* Brody et al., *supra* note 4, at 323.

¹⁴⁹ *See* Darves, *supra* note 44 ("[H]aving an 'M.D. on-site' may mean little . . .") (quoting David Goldberg); *see also* Brody et al., *supra* note 4, at 321 ("What statutes or guidelines do exist are vague, lack uniformity, and are

oversight through the use of so-called “rent-a-medical-director” services.¹⁵⁰ Because the FDA limits the sale of lasers to anyone other than a licensed practitioner within the state’s definition of an individual licensed to perform laser procedures,¹⁵¹ a “common arrangement” has developed, under which physicians will, for a fee, act as a nominal medical director in order to purchase lasers and other medical supplies.¹⁵² This is the mechanism by which NPO operations function, and serves as the greatest source of danger with respect to nonphysicians performing laser procedures without medical training or oversight.¹⁵³

C. Proving the Standard of Care

Inconsistent regulatory policies inevitably lead to unpredictability in litigation.¹⁵⁴ At the center of this unpredictability is the indefinite concept of a standard of care¹⁵⁵ in a field that lies somewhere in between medicine and cosmetics.¹⁵⁶

seldom monitored or enforced.”) (internal citation omitted).

¹⁵⁰ Brody et al., *supra* note 4, at 323 (internal quotations omitted); *see also* Darves, *supra* note 44 (quoting Dr. Goldberg’s advice to patients “that they should ask what kind of physician is on-site”) (internal quotations omitted).

¹⁵¹ U.S. Food and Drug Administration CDRH Consumer Information, Laser Facts, *available at* <http://www.fda.gov/cdrh/consumer/laserfacts.html> (last visited Mar. 15, 2009).

¹⁵² Brody et al., *supra* note 4, at 323.

¹⁵³ *See id.*

¹⁵⁴ “[I]n most situations the standard of care is neither clearly definable nor consistently defined.” *Legal Considerations*, *supra* note 20, at 104. As “the standard of care may vary from state to state, [but is] typically defined as a national standard by the profession at large,” that the “laws vary from state to state” makes a national standard inherently indefinite. *Id.* at 104, 106.

¹⁵⁵ *Id.* at 106.

¹⁵⁶ The FDA describes a cosmetic laser as a medical device, as opposed to a cosmetic, because it is

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not

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To prove negligence, a plaintiff must show that the defendant owed a duty to adhere to the requisite standard of care, and that the defendant's failure to adhere to that standard of care caused actual injury.¹⁵⁷ Patients who have been injured as a proximate result of a provider's failure to adhere to the requisite standard of care may not necessarily make the best plaintiffs, since "many lawyers believe that jurors—especially those more concerned about grocery bills and basic medical care than hair and wrinkle-free skin—will have little sympathy for the alleged victims of botched elective procedures."¹⁵⁸ But when a physician is accused of negligence, a court will charge the physician with a standard of care "requiring that degree of knowledge, skill, care, and judgment that is usually possessed and exercised under like or similar circumstances by a reasonably competent provider in the same class, with due regard for the advances in the state of health science at the time."¹⁵⁹

Problems arise when lasers are operated by healthcare providers who are not physicians, because the different expectations and requirements for these similarly situated professionals creates difficulty in determining the applicable standard of care to a patient who is injured in the course of treatment by a nonphysician.¹⁶⁰ A consistent definition of laser treatment as "health care" or "the practice of medicine" would eliminate this unpredictability.

Generally, a nonphysician will not be held to a higher standard of care than he or she is capable of providing; they will instead "be

dependent upon being metabolized for the achievement of its primary intended purposes[.]

U.S. Food and Drug Administration, Warning Letters Highlight Differences Between Cosmetics and Medical Devices (citing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) (2007)), available at <http://www.cfsan.fda.gov/~dms/cos-derm.html> (last visited Mar. 15, 2009).

¹⁵⁷ Robert J. Fowkes & M. Martin Halley, *The History and Development of Tort Law*, in *MEDICAL MALPRACTICE SOLUTIONS: SYSTEMS AND PROPOSALS FOR INJURY COMPENSATION* 5, 14 (M. Martin Halley, et al., eds., 1989).

¹⁵⁸ King, *supra* note 15.

¹⁵⁹ Fowkes & Halley, *supra* note 157, at 14–15.

¹⁶⁰ McLean, *supra* note 52, at 272.

held to the standard of care of a ‘reasonably prudent’ professional of similar experience and training.”¹⁶¹ When there has been a misrepresentation of some kind, though, judges may hold nonphysicians to the physician standard of care because they are performing the tasks of a medical doctor.¹⁶² Courts will also look to medical practice guidelines in professional negligence cases, but a local standard, as opposed to a national standard, has traditionally been applied in tort law.¹⁶³

Most states do not require a physician to perform laser treatment, so the issue in litigation becomes whether or not laser treatment constitutes “health care”¹⁶⁴ or the “practice of medicine.”¹⁶⁵ This issue is significant since many states’ malpractice statutes will only apply to actions constituting health care, presumably making practitioners potentially liable for ordinary negligence, but not professional negligence.¹⁶⁶ Some states define laser treatment as the “practice of medicine,”¹⁶⁷ making this question an easy one to answer.¹⁶⁸ When NPCs are licensed professionals providing care under the direction and supervision of a physician, the treatment may generally be considered health care.¹⁶⁹ However, the many states that either do

¹⁶¹ Coleman & Shellow, *supra* note 135, at 72.

¹⁶² *Id.* at 73–74.

¹⁶³ FRANK A. SLOAN & LINDSEY M. CHEPKE, *MEDICAL MALPRACTICE* 91 (2008).

¹⁶⁴ See *Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734, 737 (Ind. Ct. App. 2008) (citing *Witherspoon v. Teton Laser Ctr., LLC*, 149 P.3d 715, 727 (Wyo. 2007)) (distinguishing the issue of whether cosmetic laser hair removal constituted “health care” within the meaning of the Indiana statute from the determination in *Witherspoon* that laser hair removal did not constitute health care by calling for an independent interpretation of Indiana’s statute).

¹⁶⁵ See *supra* note 123.

¹⁶⁶ See *Ob-Gyn Assocs.*, 885 N.E.2d at 736; *Witherspoon*, 149 P.3d at 726.

¹⁶⁷ See, e.g., IND. CODE ANN. § 25-22.5-1-1.1(a)(1)(C) (West 2009); MINN. STAT. ANN. § 147.081 (West 2009); WASH. ADMIN. CODE § 246-919-605(1)(b)(2) (2009) (“Because [a laser, light, radiofrequency or plasma] device penetrates and alters human tissue, the use of an LLRP device is the practice of medicine.”).

¹⁶⁸ Darves, *supra* note 44.

¹⁶⁹ See *Legal Responsibility*, *supra* note 121, at 105–07.

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not require physician supervision or require abstruse physician involvement in laser treatment make it more difficult for courts to determine the standard of care to which physicians and nonphysicians will be held.¹⁷⁰

Medical societies—specifically, the American Academy of Dermatology, American Society of Laser Medicine and Surgery, and the American Society for Dermatologic Surgery—have developed standards that may be presented at trial to represent the standard of care to which physicians and nonphysicians may be held.¹⁷¹ However, when a state does not define laser treatment as the practice of medicine, and courts interpret their state's malpractice statutes to encompass laser treatment, these more demanding standards will not necessarily apply.¹⁷² Furthermore, when state laws set standards that are lower than the medical practice guidelines, state law will supersede the guidelines.¹⁷³

The manner in which the plaintiff must establish the standard of care will invariably depend on whether the laser treatment constitutes “health care”¹⁷⁴ or “the practice of medicine”—a question of law generally determined through an interpretation of the state's laser regulations, and sometimes a more searching factual inquiry.¹⁷⁵ Courts in Wyoming, where a supervising physician need not be on-site, and Indiana, where a physician must be on-site and may only delegate laser treatment performance to a supervised employee,¹⁷⁶ have recently addressed the issue of whether laser treatment constitutes health care.¹⁷⁷

In Wyoming, defendants challenged patient-plaintiff Christine Witherspoon's expert witness testimony on the grounds that as an owner of a Laser College and teacher of laser hair removal, but not

¹⁷⁰ REGULATION BY STATE, *supra* note 13.

¹⁷¹ *Legal Considerations*, *supra* note 20, at 105.

¹⁷² See *Ob-Gyn Assocs.*, 885 N.E.2d at 737 (citing *Witherspoon*, 149 P.3d at 727).

¹⁷³ *Legal Responsibility*, *supra* note 121.

¹⁷⁴ *Ob-Gyn Assocs.*, 885 N.E.2d at 736.

¹⁷⁵ *Witherspoon*, 149 P.3d at 727.

¹⁷⁶ REGULATION BY STATE, *supra* note 13, at 8.

¹⁷⁷ See *Ob-Gyn Assocs.*, 885 N.E.2d 734; *Witherspoon*, 149 P.3d 715.

a physician, the witness was not a qualifying expert.¹⁷⁸ The court struck the testimony on other grounds,¹⁷⁹ and on appeal did not address the plaintiff's argument that laser treatment does not fit within the definition of the "practice of medicine," since a medical license is not required to operate a laser in the state of Wyoming.¹⁸⁰ The plaintiff argued that this exception solidified her claim in negligence rather than medical malpractice and that her expert witness thus was not required to possess a medical degree.¹⁸¹ On appeal, the court held that striking the witness's testimony was an abuse of discretion in that it deprived the plaintiff of the ability to establish the applicable standard of care.¹⁸²

In Indiana, defendants Ob-Gyn Associates ("Ob-Gyn") contended that cosmetic laser hair removal was "health care"¹⁸³ and therefore the plaintiff was required to file her negligence claim against them with the state's medical malpractice board rather than the Indiana trial court.¹⁸⁴ The plaintiff, Ransbottom, attempted to use precedent from Wyoming to establish that laser hair removal was not health care and that, contrary to the defendant's argument,¹⁸⁵ the litigation did not have to be filed with a medical

¹⁷⁸ See *Witherspoon*, 149 P.3d 715.

¹⁷⁹ *Id.* at 719–20 (reporting the transcription of a dispute regarding the honesty of plaintiff's counsel in procuring stipulation for the witness to testify by telephone).

¹⁸⁰ *Id.* at 726. The Wyoming statute includes "any person who in any manner: . . . (b) [o]ffers or undertakes to prevent, diagnose, correct or treat, in any manner, by any means, method or device, any human disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition, injury, deformity or ailment," in the definition of what constitutes "[p]racticing medicine." WYO. STAT. ANN. § 33-26-102(a)(xi) (2008).

¹⁸¹ *Witherspoon*, 149 P.3d at 726.

¹⁸² *Id.*

¹⁸³ IND. CODE ANN. § 34-18-2-18 (West 2009) ("'Malpractice' means a tort or breach of contract based on health care or professional services that were provided, or that should have been provided, by a health care provider, to a patient.").

¹⁸⁴ *Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734, 736 (Ind. Ct. App. 2008).

¹⁸⁵ Ind. R. Trial P. 12(B)(1).

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review panel.¹⁸⁶

The plaintiff argued that her claims against Ob-Gyn sounded in ordinary negligence and not malpractice because the laser treatment did not constitute “health care.”¹⁸⁷ The only case the plaintiff presented to address the main legal issue was *Witherspoon*, on which she attempted to rely for its inclusion of the lower court’s ruling that since a person may perform laser hair removal without a medical license, the claim was not a medical malpractice action.¹⁸⁸ Upon examination of the plaintiff’s argument from *Witherspoon*, the court determined two things.¹⁸⁹ First, it held that it could not base its decision on the Wyoming trial court’s statement in *Witherspoon* that the action was not medical malpractice because the Wyoming Supreme Court did not squarely address the merits of that issue.¹⁹⁰ Second, the court held that even if the merits of *Witherspoon*’s argument had been addressed, the states have different medical malpractice statutes and laser regulations, and an interpretation of the statute and regulation in one state would not necessarily yield the same outcome in another.¹⁹¹

Ultimately, the Indiana court held that under Indiana’s Medical Malpractice Act, the lack of a doctor-patient relationship kept Ransbottom’s claim out of the statute.¹⁹² Despite the absence of this relationship, the supervising physician would be vicariously liable if the court determined that the treatment fell below the applicable standard of care.¹⁹³ Although it only ruled on this narrow issue, the court attempted to flesh out the arguments presented by Ransbottom and Ob-Gyn.¹⁹⁴

¹⁸⁶ *Ob-Gyn Assocs.*, 885 N.E.2d at 736.

¹⁸⁷ *Id.*

¹⁸⁸ *See id.* at 737 (citing *Witherspoon*, 149 P.3d at 727).

¹⁸⁹ *Id.* at 737–38.

¹⁹⁰ *Id.* at 737.

¹⁹¹ *Id.* at 737–38.

¹⁹² *Id.* at 740.

¹⁹³ *See* Lynn D. Linsk, *A Physician’s Respondeat Superior Liability for the Negligent Acts of Other Medical Professionals—When the Captain Goes Down Without the Ship*, 13 U. ARK. LITTLE ROCK L.J. 183 (1991).

¹⁹⁴ *Ob-Gyn Assocs.*, 885 N.E.2d at 738.

Ob-Gyn argued that the procedure constituted health care because Ransbottom's treatment: (1) was administered in a medical facility (2) by a registered nurse employed by a health-care provider (3) with equipment that required skill and training, and (4) involved medical implications and risks.¹⁹⁵ The court said that while "the location of the occurrence is indeed one factor to consider in deciding whether it falls within the purview of the Medical Malpractice Act, it is not determinative."¹⁹⁶ With respect to the risks involved with operating the laser, the court found that regardless of "the fact that the laser machine is a piece of equipment intended to work on the human body and its misuse could cause injury," the fact that "physicians were not involved in [her] treatment, and the operator of the laser machine was not required to be a healthcare worker or possess healthcare credentials such as medical degrees, medical licensure, or medical certification in order to operate the machine" was a more compelling argument.¹⁹⁷ The court found "marginal significance" in Ransbottom's argument that an "entirely cosmetic procedure" did not constitute "health care."¹⁹⁸

Earlier this year in Texas, where physicians have enjoined legislation that would prohibit delegation of laser treatment,¹⁹⁹ a physician argued that the claim of negligent provision of laser treatment constituted a "health care liability claim"²⁰⁰ and that the patient-appellee was required to bring her suit before the state's malpractice board.²⁰¹ Had Texas enacted its proposed legislation on schedule, laser treatment would certainly have constituted "health care,"²⁰² and the physician would have prevailed at trial.²⁰³

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 739.

¹⁹⁸ *Id.*

¹⁹⁹ *See supra* note 63.

²⁰⁰ TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(13)(a) (Vernon 2009).

²⁰¹ *Tesoro v. Alvarez*, No. 13-08-00091-CV, 2009 WL 620682 (Tex. Ct. App. Mar. 12, 2009).

²⁰² Standing Delegation Order, 22 TEX. ADMIN. CODE §§ 193.1, 193.11 (2004), *available at* <http://www.tmb.state.tx.us/rules/docs/Board-Rules-Effective-05-12-2008.pdf>. Rule 193.11 stated, "the use of lasers/pulsed light

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While physicians wanted this distinction in laser regulations, they sought to enjoin the legislation because of the limits the Texas Medical Board placed on their ability to delegate laser procedures.²⁰⁴ Until a compromise is reached, though, patient-plaintiffs will not have to bring competent medical experts to testify as to the standard of care to prove a physician's negligence.²⁰⁵

The potential consequences of such unpredictability in standard of care is unacceptable for prospective patients²⁰⁶ as well as for physicians,²⁰⁷ NPCs, NPOs,²⁰⁸ and insurance providers.²⁰⁹ There must be greater guidance to ensure that patients can rely on the fact that they will receive treatment by providers obliged to follow heightened standards. Likewise, providers need guidance for practice to ensure that they provide non-negligent care and can rely on the law to hold them to the appropriate standard, no more and no less.

PART III: REGULATING NATIONAL STANDARDS FOR QUALITY

In recent years, states have been more active in developing legislation to address the problems arising from this unregulated medical practice.²¹⁰ The publicized death of a twenty-two year old

devices is the practice of medicine." *Id.*

²⁰³ Defendant physician moved to dismiss under section 74.351(a) of the Texas Civil Practice Code when plaintiff failed to file an expert report within the mandatory 120-day deadline for health care claims. Brief of Appellant-Defendant, *Tesoro v. Alvarez*, No. 13-08-00091-CV (Tex. Ct. App. Mar. 12, 2009); TEX. CIV. PRAC. & REM. CODE ANN. § 74.351(a) (Vernon 2008).

²⁰⁴ See Sanger, *supra* note 67 and accompanying text.

²⁰⁵ See *Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734 (Ind. Ct. App. 2008); *Witherspoon v. Teton Laser Ctr., LLC*, 149 P.3d 715 (Wyo. 2007).

²⁰⁶ See *supra* text accompanying notes 138–39.

²⁰⁷ See *supra* text accompanying notes 135–36.

²⁰⁸ See *infra* text accompanying note 228.

²⁰⁹ See *supra* note 96 and accompanying text.

²¹⁰ See Darves, *supra* note 44; Beth Kapes, *Who's Managing Medspas?*, 8 COSMETIC SURG. TIMES 1, Apr. 2005, available at <http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=1>

college student in North Carolina provided the initiative for many states to tighten their regulations.²¹¹ At the time, laser procedures in North Carolina could be “performed only by a physician or by an individual having *adequate* training and experience under the supervision of a physician who should be on-site or readily available”²¹² But even in the wake of a tragedy brought on by loose regulation, North Carolina still does not require that a supervising physician remain on-site during treatment.²¹³

Despite the increase in regulation throughout the states, the regulations have not proven themselves to be effective.²¹⁴ To remedy the untamed nature of the varying regulations,²¹⁵ it is necessary to set a national standard that classifies laser procedures as the practice of medicine and correspondingly require that, they must be performed by a healthcare practitioner licensed to perform laser procedures—either a physician or under the on-site supervision of a similarly licensed physician. Such regulations will ensure safety and streamline litigation for negligent treatment, which will also aid in improving patient safety.²¹⁶ While the FDA does not currently have the power to regulate in this area,²¹⁷ the

52134&pageID=1&sk=&date=.

²¹¹ Kapes, *supra* note 210. The young woman, Shiri Berg, suffered a seizure from an overdose of the lidocaine numbing cream she used prior to her laser hair removal treatment. *Id.* The lidocaine was obtained by a physician connected with the spa, which had “established a protocol where spa patients could get it without a prescription or a physical exam.” Amanda Lamb, *Doctor Linked to Spa Lidocaine Death Reprimanded*, WRAL.COM, Aug. 15, 2007, <http://www.wral.com/news/local/story/1705962/>.

²¹² REGULATION BY STATE, *supra* note 13, at 15 (emphasis added).

²¹³ *Proposed Laser Hair Removal Guidelines to Hold Doctors More Accountable*, WRAL.COM, July 20, 2005, <http://www.wral.com/news/local/story/118589/>. The new regulations require that “laser hair practitioners must complete a minimum of 30 hours of laser training at a board-certified school and renew certification annually.” Lamb, *supra* note 210.

²¹⁴ See *supra* Part II.B.

²¹⁵ King, *supra* note 15 (quoting Dr. Jay Calvert).

²¹⁶ COMMITTEE ON QUALITY HEALTH CARE, *supra* note 97, at 19, 57 (arguing that instead of creating “lax or conflicting standards,” regulations “can be designed to be safer so that accidents are very rare”).

²¹⁷ The FDA was established “[t]o prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, *devices*, and cosmetics,

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safety and justice concerns implicated by this lack of power with respect to cosmetic laser procedures are inevitable as the FDA continues to approve new innovative medical devices.²¹⁸ To remedy the current problem in the cosmetic laser industry by providing redress for injured patients and preventing future harm and injustice, Congress should enable the FDA to set minimum standards obligating the states to devise nationally accepted licensing schemes for the operation of medical devices.

A. Redress

Two of the goals of medical malpractice law are to provide litigants with a sense of corrective justice and to compensate victims of negligence for their losses.²¹⁹ In its current state, laser regulation in the U.S. has spawned an unjust litigious landscape in which meritorious claims may fail²²⁰ and non-meritorious claims

and for other purposes.” Food Drug and Cosmetic (Humphrey-Durham) Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 321 (2008)) (emphasis added). However,

[u]nder the 10th Amendment of the U.S. Constitution, states have the authority to regulate activities that affect health, safety and welfare of their citizens. To protect the public from the unprofessional, improper, unlawful, fraudulent and/or incompetent practice of medicine, states provide laws and regulations that outline the practice of medicine and the responsibility of the medical board to regulate that practice in the state’s “Medical Practice Act.”

Federation of State Medical Boards, *The Role of the State Medical Board*, http://www.fsmb.org/grpol_talkingpoints1.html (last visited Mar. 15, 2009). *See also* U.S. CONST. amend. X.

²¹⁸ *See generally* 21 C.F.R. § 807.22 (2009) (instructing how and where to initially register a medical device for approval by the FDA).

²¹⁹ TROYEN A. BRENNAN & DONALD M. BERWICK, *NEW RULES: REGULATION, MARKETS, AND THE QUALITY OF AMERICAN HEALTH CARE* 70 (1996).

²²⁰ *See, e.g., Gottschalk, supra* note 17 (finding in favor of defendant where plaintiff seeking laser resurfacing around the eyes allegedly sustained an eye injury for which she underwent two unsuccessful corneal transplants); *Jones, supra* note 19 (finding for defendant alleged to have caused hypertrophic scarring when removing plaintiff’s tattoo with laser); *Rector, supra* note 19 (returning defense verdict where plaintiff undergoing laser resurfacing sustained

succeed,²²¹ upturning these principles of redress and compensation.²²²

The problem lies in the absence of consistent standards.²²³ As popular as these treatments have become, courts have not yet had an opportunity to develop a coherent body of case law to apply to new claims.²²⁴ As a result, courts will look to laser treatment injury cases in other states for persuasive precedent, but find that the differences between their respective regulations and malpractice laws prevent them from being able to build upon an already established standard.²²⁵ This disconnect hurts both patients and providers.

Patients' rights to redress are effectively altered when, in a state where a nonphysician negligently performs laser treatment, courts will apply a standard of care lower than the reasonable physician standard of care.²²⁶ Further, physician extenders are generally under-insured, which results in diminished amounts of compensation.²²⁷ Indeed, in the case of NPCs, malpractice insurers typically do not cover procedures performed without physician supervision.²²⁸

On the other hand, when a physician does perform the procedure, but the state law does not require physician operation, courts may not hold even the physician to the standard of care a reasonably prudent physician would be expected to provide.²²⁹ In

injuries and alleged that defendant plastic surgeon used the laser equipment improperly and failed to inform her of the risks involved with the procedure).

²²¹ *Witherspoon v. Teton Laser Ctr., LLC*, 149 P.3d 715, 727 (Wyo. 2007) (permitting a non-medical expert to define the standard of care to which a physician will be held liable).

²²² BRENNAN & BERWICK, *supra* note 219, at 70.

²²³ Brody et al., *supra* note 4, at 319.

²²⁴ *See Ob-Gyn Assocs. of N. Ind., P.C. v. Ransbottom*, 885 N.E.2d 734, 737 (Ind. Ct. App. 2008) (citing *Witherspoon*, 149 P.3d at 727).

²²⁵ *See id.*

²²⁶ McLean, *supra* note 52, at 263.

²²⁷ *Id.* at 271–72.

²²⁸ Brody et al., *supra* note 4, at 323–24.

²²⁹ *Witherspoon*, 149 P.3d at 727 (reversing trial court's decision to strike expert testimony, thus holding that a hair removal specialist may testify as to the proper standard of care the defendant doctor is alleged to have breached).

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Witherspoon, the court allowed a non-medical expert to define the standard of care the defendant physician allegedly breached, because the court determined that the applicable standard was not “the accepted standard of medical care,” but “the standard of care applicable to [intense pulsed light] hair removal treatment,” which by state law could be performed without a license to practice medicine.²³⁰

The lack of consistent standards also distorts malpractice law’s ability to instill corrective justice when the confusion behind the standards allows patients to recover damages when a physician has not necessarily been negligent.²³¹ Since many states do not define laser procedures as the practice of medicine, patient-plaintiffs may argue the standard of care before a court without a qualified medical expert.²³² This expert’s testimony may be persuasive in setting out an unreasonable standard beyond what should be expected of an appropriately trained physician specialist.²³³

Physicians who have lobbied for consistency in regulations have insisted that despite the safety concerns associated with NPO laser practice, delegation is appropriate when NPCs have been properly trained and qualified to perform laser procedures.²³⁴ These physicians argue that they “cannot allow entrepreneurial interests to supplant good medicine. Professional and ethical obligations require taking action against these practices by inadequately trained nonphysician personnel that could jeopardize

²³⁰ *Id.* at 726, 727.

²³¹ “[F]igures convey a sense of how frequently non-physicians are doing these procedures, and, therefore, the potential for lawsuits, . . . invariably, should something go wrong, [b]ecause that physician extender works for the doctor, the doctor would be held responsible for the actions of the physician extender.” Jesitus, *supra* note 8 (quoting David Goldberg).

²³² *Witherspoon*, 149 P.3d at 727 (reversing trial court’s decision to strike expert testimony, thus holding that a hair removal specialist may testify as to the proper standard of care the defendant doctor is alleged to have breached).

²³³ “[A]s a result of the increased reliance on laser technology by the cutaneous laser surgeon and unrealistic expectations by the public, physicians may sometimes run the risk of being held to an unrealistic and unattainable standard of care.” *Legal Considerations*, *supra* note 20, at 104.

²³⁴ Brody et al., *supra* note 4, at 322, 324; Rohrich & Burns, *supra* note 86, at 1147.

the safety and health of patients or compromise the quality of medical care they receive.”²³⁵

In light of the complications these regulations cause in terms of redress, and the questionable degree of safety in NPC treatment, it is practical for healthcare practitioners in this lucrative cash business to absorb the cost of adhering to tighter regulations which to assure that treatment is performed according to a medical standard.²³⁶

B. Lower Incidence of Injury

1. Healthcare Provider Competence

Above all, safety is at issue when states do not require trained physicians to treat patients seeking laser services. “Recent studies suggest that a proportionately greater number of complications are arising from dermatologic care delivered by physician extenders,”²³⁷ and far more complications in laser treatment arise when such treatment is provided outside of a medical setting.²³⁸ By definition, a board certified dermatologist is more prepared to provide safer and higher quality care than both NPCs and NPOs.²³⁹

²³⁵ Brody et al., *supra* note 4, at 324.

²³⁶ King, *supra* note 15.

²³⁷ Alam et al., *supra* note 50.

²³⁸ Brody et al., *supra* note 4, at 323–24.

²³⁹ To be a physician, one must obtain a doctorate level of training. Physicians must not only attend four years of college but must also attend an accredited medical school for four years of additional postgraduate education. To receive a license to practice medicine, a physician must work under supervision for an additional year as an intern and then pass a licensing examination . . . To become board certified, a physician has to attend an accredited residence program for an additional two to six years (depending on the specialty) of training to become board eligible. A board certification examination is given to board eligible candidates anywhere from six months to two years after the completion of residency. . . . Physician extenders, unlike physicians, have no formal postgraduate training. Physician extenders do not have to complete an internship or residency program. While there is some state-to-state [sic] variability, a physician extender

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Courts generally find it unfair to hold physician extenders to the standard of a reasonably prudent professional with a physician's education and training—an open acknowledgement that there is a higher quality of care associated with medical training and a greater degree of safety in physician treatment as opposed to nonphysician treatment.²⁴⁰ In that same vein, courts will only hold MDs such as gynecologists or internists to the standard of a reasonably prudent physician, rather than a reasonably prudent dermatological surgeon or physician trained to perform laser surgery.²⁴¹ It seems patently absurd that anyone performing laser treatment would not be held to the standard of someone providing “health care” or “practicing medicine,”²⁴² trained to diagnose and treat the skin, and perhaps most importantly, trained to perform laser treatments.²⁴³ However, as long as states fail to set these

generally only needs to graduate from an accredited nursing program and achieve a passing score on the licensing exam to begin practice.

McLean, *supra* note 52, at 257–60.

²⁴⁰ *Id.* at 261–62.

²⁴¹ Gunnar, *supra* note 134, at 358. “Unfortunately, at the present time, physicians who fail to meet the standards established by the professional specialty boards may practice that specialty under the broad privilege of a state medical license.” *Id.*

²⁴² *See supra* note 123.

²⁴³ Only a handful of states have required, or even gone as far as suggesting that providers obtain specialized training and/or licenses to perform laser treatment. *See, e.g.*, GA. CODE ANN. § 43-34-247 (West 2007) (“The practice of providing cosmetic laser services is declared to be an activity affecting the public interest and involving the health, safety, and welfare of the public . . . [and] when engaged in by a person who is not licensed as a cosmetic laser practitioner or otherwise licensed to practice a profession which is permitted under law to perform cosmetic laser services is declared to be harmful to the public health, safety, and welfare.”); N.C. GEN. STAT. ANN. § 88A-11.1(a)(2) (West 2009) (“Any person seeking licensure by the Board as a laser hair practitioner shall have . . . [c]ompleted a minimum 30-hour laser, light source, or pulsed-light treatment certification course approved by the Board”); WASH. ADMIN. CODE § 246-919-605(1)(b)(4) (2009) (“A physician must be appropriately trained in the physics, safety and techniques of using [laser, light, radiofrequency, and plasma] devices prior to using such a device, and must remain competent for as long as the device is used.”); OR. BD. OF MED. EXAMINERS, STATEMENT OF PHILOSOPHY: MEDICAL USE OF LASERS 3 (2002), <http://www.oregon.gov/OMB/newsletter/WinterSpring02.pdf> (“Physicians using

minimum requirements, such standards will not apply.

The increased growth rate of the laser industry that incited the shift toward treatment by nonphysicians has brought a dramatic increase in the complication rate in laser procedures.²⁴⁴ The complications arising from laser procedures are best avoided or minimized when healthcare providers administer these procedures and properly trained physicians provide immediate oversight.²⁴⁵

2. Deterrence

Requiring that only licensed healthcare providers may conduct laser procedures is also imperative since these providers, unlike NPOs or NPCs, who do not operate as supervised agents of a physician, are checked by the possibility of professional liability and thus have a greater incentive to adhere to the appropriate standard of care.²⁴⁶ This capability of malpractice liability to

lasers should be trained appropriately in the physics, safety and surgical techniques of using lasers and intense pulsed light devices, as well as pre- and post-operative care.”); R.I. Dep’t of Health, Policy Statement on Office Based Esthetic Procedures, http://www.cqc.state.ny.us/counsels_corner/cc66.htm (last visited Apr. 4, 2009) (“Physicians [or other practitioner acting within his/her scope of practice] who perform and supervise such procedures must be able to demonstrate appropriate training and experience.”).

²⁴⁴ See *Legal Responsibility*, *supra* note 121, at 105; Kaufman, *supra* note 10.

²⁴⁵ See *supra* Part II.

²⁴⁶ “[D]octors believe that malpractice liability affects how they practice medicine. The most common effects that they mention are maintaining more detailed patient records, spending more time with patients, referring more cases to specialists for consultation, [and] increasing the number of diagnostic tests” BAKER, *supra* note 111, at 121. Such “assurance behaviors” along with “avoidance behaviors,” whereby physicians try to prevent malpractice litigation by restricting their practices to lower-risk patients and procedures, have been criticized for unnecessarily driving up the costs of healthcare and “divert[ing] medical resources from more urgent needs.” William M. Sage, *Malpractice Reform as a Health Policy Problem*, 12 WIDENER L. REV. 107, 113 (2004). However, it is also argued that these very practices are “good medicine” and “if defensive medicine means practicing in a way that reduces unnecessary injury to patients, it is beneficial and should be applauded by the medical profession.” Harvey F. Wachsman, *Individual Responsibility and Accountability: American Watchwords for Excellence in Healthcare*, 10 ST.

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effectively deter negligent treatment has been a controversial issue and a major focus of tort reform.²⁴⁷ However, studies purporting to prove that malpractice liability does not promote patient safety are not based on hard empirical evidence.²⁴⁸ These arguments have failed to consider that the threat of malpractice liability has deterred negligence in a way that is not necessarily quantifiable,²⁴⁹ and malpractice litigation itself has improved patient safety by identifying areas of risk and warning physicians of the outcomes of taking those risks.²⁵⁰

It is essential that individuals performing laser treatments are professionally liable for negligence because there are real deterrent factors associated with professional liability.²⁵¹ Namely, “increased coverage costs, increased premiums, increased deductibles, refusal of future coverage, pressure by insurance companies on doctors to adopt better risk-management practices and sensitivity to publicized findings of liability (or fear of damage to one’s professional reputation)” are all factors licensed healthcare

JOHN’S J. LEGAL COMMENT. 303, 311 (1995). Furthermore, it is argued that studies purporting to expose the negative effects of defensive medicine are inconclusive, and that “none of the researchers who have studied defensive medicine have claimed that they are able to separate the bad, wasteful effects of malpractice lawsuits from the good, injury prevention effects.” BAKER, *supra* note 111, at 119.

²⁴⁷ See Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595 (2002).

²⁴⁸ See *id.* at 1604.

²⁴⁹ It is argued that

medical liability is an indication of the overall success of modern medicine, not its failure. For roughly 150 years, malpractice liability tracked the ability of health care to benefit patients. You cannot do something negligently if you cannot do it at all. Liability arising from the non-use or misuse of technology has accelerated in the last twenty or thirty years, as patients’ expectations rise, as opportunities for error proliferate, as the potential for treating an injury that might occur expands, and as the costs of such remedial treatment increases.

Sage, *supra* note 244, at 110.

²⁵⁰ BAKER, *supra* note 111, at 99.

²⁵¹ *Id.*; Andrew Brine, Note, *Medical Malpractice and the Goals of Tort Law*, 11 HEALTH L.J. 241, 248 (2003).

providers must consider in providing care to patients, making it difficult not to exercise an appropriate level of care.²⁵²

Additionally, professional liability promotes safety by allowing for malpractice litigation to identify dangerous conditions and draw greater caution to these areas.²⁵³ Tom Baker, author of *The Medical Malpractice Myth*, argues that there is a pattern in publicized malpractice litigation, where there was “an unsafe condition that health-care professionals knew about but did not correct [which] took a serious injury and malpractice lawsuit to bring the unsafe condition (and previous failure to act) to light.”²⁵⁴ In each of these cases, “the lawsuit prompted corrective action that we can be fairly confident would not otherwise have occurred.”²⁵⁵

When standard regulations make way for the establishment of a legal doctrine of recovery for negligent laser treatment, lawsuits brought within that doctrine will make physicians aware of certain unknown risks so they can take action to prevent similar liability.

C. Federal Oversight of State Licensing Standards

When left alone to protect the safety of their citizens, the states have seemingly rolled onto their backs to let the medi-spa industry tickle their bellies, and at considerable costs.²⁵⁶ There must be standards for the delegation of laser treatment to NPCs. Healthcare practitioners may argue that meeting licensing standards and on-site physician supervision is more costly and not necessarily safer,²⁵⁷ but these arguments are unpersuasive.

²⁵² Brine, *supra* note 249, at 248.

²⁵³ BAKER, *supra* note 111, at 99.

²⁵⁴ *Id.*

²⁵⁵ *Id.* at 99–100.

²⁵⁶ *See supra* Part I.

²⁵⁷ *See* Coleman & Shellow, *supra* note 133, at 53 (“Non-physician professionals seeking authority . . . claim that reduced education costs enable other health care practitioners to treat patients more cheaply than doctors attempting to repay massive student loans.”); Freedman & Earley, *supra* note 51, at 140 (“We believe that both properly trained physicians and properly trained nurses can safely and effectively perform this procedure while assuring a level of care that satisfies both patient and medico-legal concerns.”).

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First, the use of physician extenders has been a response to the overwhelming need to provide access to cost-effective, quality care among underserved populations such as poor, rural and inner city populations and the elderly.²⁵⁸ Even though laser treatments have become popular and relatively common,²⁵⁹ they are elective cosmetic procedures, and there is not an apparent need to dramatically increase access for patients in this luxury field as there is in the underserved populations where physician extenders are typically utilized.²⁶⁰ Furthermore, once NPO treatment has been eliminated, there will not be the same competition driving healthcare practitioners to keep up with spas and salons offering these treatments.²⁶¹ Finally, there is conflicting research regarding whether or not NPC laser treatment is as safe as physician treatment.²⁶²

While setting medical licensing standards is traditionally a state function, it is certainly reasonable to demand that the states responsibly execute this very significant regulatory power.²⁶³ Moreover, in fashioning legislation, legislators are in a position to learn from past mistakes and avoid the derivative ills from the lack of, and inconsistent, laser regulations²⁶⁴ by not giving states the chance to independently regulate licensing standards for medical devices going forward.

²⁵⁸ Coleman & Shellow, *supra* note 133, at 51–57.

²⁵⁹ See King, *supra* note 15.

²⁶⁰ Coleman & Shellow, *supra* note 133, at 55–58.

²⁶¹ Alam et al., *supra* note 48, at 5 (regarding “increasing tension between dermatologists and electrologists over the training required to perform laser hair removal”).

²⁶² See Freedman & Earley, *supra* note 51; *Legal Responsibility*, *supra* note 119, at 105–06.

²⁶³ Federation of State Medical Boards, Overview, http://www.fsmb.org/smb_overview.html (last visited Mar. 15, 2009) (“To protect the public from the unprofessional, improper, unlawful, fraudulent and/or incompetent practice of medicine, each of the 50 states, the District of Columbia, and the U.S. territories has a medical practice act that defines the practice of medicine and delegates the authority to enforce the law to a state medical board.”). A complete directory of state medical boards is available at http://www.fsmb.org/directory_smb.html (last visited Mar. 15, 2009).

²⁶⁴ See *supra* Parts I.B & II.

Driving the necessity for federal regulation of these procedures is the particular nature of the medi-spa industry. Lasers are not cosmetics²⁶⁵—they physically alter the particles of the skin²⁶⁶—yet they are marketed for the performance of cosmetic treatments.²⁶⁷ It is unlikely that people will purchase medical devices such as electrocauteries²⁶⁸ or staplers²⁶⁹ for use outside of a medical setting, but since the laser is utilized for conditions that both dermatology and the cosmetics industry compete with each other to treat,²⁷⁰ there is now the dangerous situation of NPOs practicing medicine without licenses and without medical supervision.²⁷¹ It is not so far-fetched to imagine that there will continue to be technological advances that appeal to those markets where cosmetics and dermatology overlap,²⁷² and the unknown dangers

²⁶⁵ See U.S.C. § 321(i) (2007).

²⁶⁶ The majority of today's cutaneous lasers operate by "selective photothermolysis." Berg & Nanni, *supra* note 7.

²⁶⁷ Cathy Booth, *Light Makes Right*, TIME MAG., Oct. 3, 1999, § Health, at 67 ("At least 50 different laser systems are currently being marketed for cosmetic purposes.").

²⁶⁸ Electrocauteries are "apparatus[es] for surgical dissection and hemostasis, using heat generated by a high-voltage, high-frequency alternating current passed through an electrode." The Free Dictionary by Farlex, Electrocautery, <http://medical-dictionary.thefreedictionary.com/electrocautery> (last visited Mar. 15, 2009). They must be approved for sale and distribution through the same FDA clearance processes as cosmetic lasers. U.S. Food and Drug Administration, Getting to Market with a Medical Device, <http://www.fda.gov/cdrh/devadvice/3122.html> (last visited Mar. 15, 2009).

²⁶⁹ "The i45V Intelligent Surgical Instrument is a reusable, autoclavable linear stapler designed for use in endoscopic surgery and . . . in minimally invasive general, gynecological, urologic, thoracic, and colon and rectal surgical procedures for transection and occlusion of vascular structures." *Power Medical Interventions Receives FDA Clearance for i45V*, ENDONURSE, Aug. 1, 2008, available at <http://www.endonurse.com/hotnews/power-medical-receives-fda-clearance.html>.

²⁷⁰ Alam et al., *supra* note 48, at 5 (regarding "increasing tension between dermatologists and electrologists over the training required to perform laser hair removal").

²⁷¹ See *supra* Part I.

²⁷² See, e.g., Bud Brewster, *January's Skin Care Patent Picks*, COSMETICS & TOILETRIES, Jan. 6, 2009, available at <http://www.cosmeticsandtoiletries.com/research/patents/37170124.html?page=2> ("Skin beautification cosmetic

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that may result from future technologies call for firmer regulation.

For the FDA to promulgate these regulations, Congress would need to authorize the FDA to set standards designating that laser treatments constitute “health care” or “the practice of medicine.”²⁷³ The Food Drug and Cosmetic Act (“FDCA”) grants the FDA authority to “prohibit the movement in interstate commerce of adulterated and misbranded . . . devices.”²⁷⁴ This may not come across as a “clear plain statement,” through which Congress has vested power in the FDA to set standards in an area of traditional state regulation.²⁷⁵ However, such precision is not necessary when the FDA would seek only to require that states identify laser treatments as health care or the practice of medicine.²⁷⁶ Rather than supplant the total functions of state medical boards, the FDA regulation would specify that physicians or licensed healthcare providers under physician supervision would be able to perform the procedures, leaving state medical board licensing standards intact.²⁷⁷ This would empower the FDA to set forth regulations restricting laser operation to healthcare professionals licensed to provide laser treatment, who are either physicians or supervised by on-site physicians.

system using iontophoresis device, ultrasonic facial stimulator, and cosmetic additive.”).

²⁷³ The FDA may only regulate in this area if Congress gives it the authority to do so. *See* U.S. CONST. amend. X. All terminology contemplated by state malpractice statutes (e.g., “health care” or “the practice of medicine”) should be incorporated into the FDA’s regulations.

²⁷⁴ Federal Food Drug and Cosmetic (Humphrey-Durham) Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 321 (2008)).

²⁷⁵ *See* William N. Eskridge, Jr. & Philip P. Frickey, *Quasi-Constitutional Law: Clear Statement Rules as Constitutional Lawmaking*, 45 VAND. L. REV. 593, 607 (1992). Despite a presumption against preemption of “a state’s exercise of its police power,” when a federal statute expresses “the clear and manifest purpose of Congress,” the federal law will supersede the state’s exercise of its “historic police powers.” *Id.*

²⁷⁶ *Cf.* *City of Philadelphia v. New Jersey*, 437 U.S. 617, 621 n.4 (1978) (explaining that where “Congress expressly . . . provided that ‘the collection and disposal of solid wastes should continue to be primarily the function of State, regional and local agencies’” there was not a conflict in federal regulation over the traditional state function of waste disposal).

²⁷⁷ *Id.*

CONCLUSION

The current milieu of regulation throughout the states in the growing field of laser cosmetic treatments has set the stage for unsafe conditions in which consumers are receiving medical care from inexperienced providers without legal protection from negligent medical treatment.²⁷⁸ Regulation will improve quality and reduce injury while allowing a meaningful body of law to emerge within which injured plaintiffs may properly seek redress.²⁷⁹ In order to achieve these goals and promote safety as new technologies are approved for use in hybrid medical markets such as the medi-spa industry, Congress must enable the FDA to regulate the use of medical devices.²⁸⁰ With this authority, the FDA can set forth regulations to amend the current predicament in the cosmetic laser industry and prevent problems from developing with the advent of new medical devices.²⁸¹ While the interference in state medical licensing laws marks a departure from the current system, the states have proven themselves to be too easily swayed by industry pressures to properly police within their borders without a mandate to institute these very necessary minimum standards.²⁸² Ultimately, the FDA may need to play a much larger role in regulating the operation of medical devices to maintain some delineation between the practice of medicine and the beauty industry, as technology works hard at blurring the lines between them.

²⁷⁸ See *supra* Part I.B.

²⁷⁹ See *supra* Part III.A–B.

²⁸⁰ See *supra* Part III.C.

²⁸¹ See *supra* Part III.C.

²⁸² See *supra* Part III.C.