

From Creams to Lasers: Regulating the Beauty Industry in the New Millennium

(Winter Paper done in conjunction with Peter Hutt's Food & Drug Law Seminar).

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Abstract

The paper examines the development and use of lasers for cosmetic procedures. Given the lack of legal and regulatory literature in this important and growing area, the sole focus of this author in writing the paper is to highlight current dangers inherent in the widespread use of cosmetic lasers, as well as to raise considerations that need to be addressed by the government and FDA vis-à-vis the laser industry itself. The use of lasers on the eye, which presents different issues in and of itself, is not discussed except where it reflects generally on the issues relating to cosmetic lasers, and is mentioned briefly in this paper only for the sake of completeness.

Part I provides an overview of the regulation of medical devices in the US; part II discusses the use, development, and regulation of medical lasers in the cosmetic industry, and part III details the dangers involved in the current practice of laser treatment, as well as providing a critical overview of the laser industry itself.

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“Fashion is a form of ugliness so intolerable that we have to alter it every six months.”

- *Oscar Wilde*

“They say God made humans in His image, and humans have been trying to repair the handiwork ever since.”

- *Tony Simmons, The News Herald* ¹

“Looking good is a sign of virtue. The body . . . has become not only a window into the soul but an expression of it.”

- *Judith Gaines, The Boston Globe Magazine* ²

“It’s been clear all along that with changing demographics and pressures to remain youthful, lasers have the potential to penetrate the consumer market nearly as quickly as the beam of light they emit.”

- *Pam Reynolds, The Boston Globe* ³

INTRODUCTION: COSMETIC SURGERY TODAY ⁴

Where Aristotle once said that “beauty is the gift of God”, today it is the gift of cosmetic surgeons. In the new millennium, we are increasingly treating our bodies like works of art, to be redesigned and sculptured where nature and nurture have failed us. In our quest for youth and perfection, so much can be done to alter the skin’s texture, color, shape and look that our body and face can be manipulated at will.

Cosmetic surgery, once considered within the exclusive domain of the rich and famous, has over the last few decades been made available to the public at large, thanks to the advent of technology. No more is cosmetic surgery considered a luxury, for now the bottom line when deciding on cosmetic surgery is not how much will it cost you, but how much do your physical imperfections bother you.

The idea that you could let a total stranger permanently alter your face and body used to be generally feared, but is now embraced. Traditionally cosmetic surgery involved days, if not weeks, of surgery, but

²Judith Gaines, Body Works, The Boston Globe Magazine, February 6, 2002.

³Pam Reynolds, Zapping Away The Years, The Boston Globe, June 11,1996, p.69.

⁴To avoid repetition, please note that all websites referenced in these footnotes were last visited between March 25 – 29 2002.

today, many cosmetic procedures are over in an hour enabling you to have a quick transformation during your lunch break. The factors that formerly made us reluctant to alter our appearance have disappeared – no more do we accept ourselves just as nature made us; no more is vanity a sin; and no more is cosmetic surgery an extravagant use of money⁵. Spas offering cosmetic services are springing up as fast as Starbucks, and with roughly the same clientele⁶.

While traditionally we relied on creams and herbs to cure our physical imperfections, today, thanks to improved medical devices, we can perfect our face and body through such techniques as liposuction for fat removal⁷; abdominoplasty (the “tummy tuck”) to remove excess wrinkled skin and fatty tissue from the body⁸; breast surgery for the augmentation, reduction, and lifting of breasts⁹; chin and cheek augmentation to improve the appearance of the chin¹⁰; laser resurfacing and dermabrasion¹¹ to reduce and smooth scars; rhytidectomy to lift the face and neck¹²; forehead lift to lift the forehead skin and remove excess skin¹³; hair transplants or replacement to help treat hair loss for both men and women¹⁴; otoplasty to correct protruding ears¹⁵; sclerotherapy to remove spider veins, varicosities, broken capillaries or sunburst vessels¹⁶; and, blepharoplasty to remove baggy eyelids¹⁷.

Laser treatment is an exciting “futuristic” surgery. No instrument in medicine has the sex appeal of a laser, or is surrounded by such an inordinate amount of hype. Patients think of it as a magical tool that will somehow eliminate their cosmetic problem without pain¹⁸.

⁵For an excellent discussion of the psychology relating to cosmetic surgery, see ROBERT A. YOHO MD AND JUDY BRANDY-YOHO RN, A NEW BODY IN ONE DAY: A GUIDE TO SAME-DAY COSMETIC SURGERY PROCEDURES, Chapter 1 (1st ed. 1998).

⁶For an interesting discussion of the increasing cultural acceptance of cosmetic surgery, see Judith Gaines, Body Works, The Boston Globe Magazine, February 6, 2002, where she addresses the question of “How did Americans, who two generations ago rarely even pierced their ears, come to embrace all this cutting, sucking, and sanding of their flesh?”

⁷According to the American Academy of Cosmetic Surgery, approximately 300,000 people a year had liposuction in the US in the 1990s.

See <http://www.cosmeticsurgery.org/procedures/liposuction.asp?mn=pc>.

⁸For further information, see American Academy of Cosmetic Surgeons information sheets at http://www.cosmeticsurgery.org/procedures/abdominoplasty_tummy_tuck_.asp?mn=pc.

⁹See id. at http://www.cosmeticsurgery.org/procedures/breast_surgery.asp?mn=pc.

¹⁰This is accomplished by inserting a small synthetic implant over the natural bone. See id. at http://www.cosmeticsurgery.org/procedures/chin_and_cheek_augmentation.asp?mn=pc.

¹¹See http://www.cosmeticsurgery.org/procedures/laser_surfacing_and_dermabrasi.asp?mn=pc.

¹²Id. at http://www.cosmeticsurgery.org/procedures/rhytidectomy_face_lift_.asp?mn=pc.

¹³Id. at http://www.cosmeticsurgery.org/procedures/forehead_lift.asp?mn=pc.

¹⁴Id. at http://www.cosmeticsurgery.org/procedures/hair_replacement.asp?mn=pc.

¹⁵Id. at http://www.cosmeticsurgery.org/procedures/otoplasty_ear_surgery_.asp?mn=pc.

¹⁶Id. at http://www.cosmeticsurgery.org/procedures/sclerotherapy_vein_surgery_.asp?mn=pc.

¹⁷See the Cosmetic Eyelid Resource Guide at <http://www.cosmetic-eyelid-surgery-resource.info/>.

¹⁸See Barry A. S. Lycka, Shaping a New Image: The Practice of Cosmetic Surgery, Chapter 13 (1st ed. 1999).

Today, in our consumer-driven and time-demanding culture, for many, life is about finding the quickest and easiest way to do something. In fact, many medical treatments that currently exist are geared towards youthifying individuals quickly. Whether trying to regrow hair (Propecia), gain an erection (Viagra) or lose weight (Fen-Phen) people are incredibly willing to open their wallets and subject themselves to some questionable treatments in order to regain a part of their youth without properly evaluating the pros and cons of such treatment¹⁹.

This paper examines the development and use of lasers for cosmetic procedures. Given the lack of legal and regulatory literature in this important and growing area, the sole focus of this author in writing this paper is to highlight current dangers inherent in the widespread use of cosmetic lasers, as well as to raise considerations that need to be addressed by the government and FDA vis-à-vis the laser industry itself. The use of lasers on the eye, which presents different issues in and of itself, is not discussed except where it reflects generally on the issues relating to cosmetic lasers, and is mentioned briefly in this paper only for the sake of completeness.

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I. MEDICAL DEVICE REGULATION IN THE US

A. Overview

The U.S. Food & Drug Administration (“FDA”²⁰) currently regulates the manufacture and marketing of medical devices in the United States under the Federal Food, Drug and Cosmetic Act²¹ (“FDCA”). In 1976,

¹⁹See Michael J.Ward, The History and Controversial Future of Refractive Surgery, SURE Program (1999) (available at http://www.sciencenet.emory.edu/undergrad/SURE/Articles/1999_art_ward.html).

²⁰See <http://www.fda.gov/> for an overview of the FDA.

²¹21 U.S.C. 301 et seq. It was not until 1938, that medical devices were subject to federal regulation. However, even after this law, the degree of regulation was generally perceived as unsatisfactory, thereby entailing further amendments in 1976, 1990,

partly in response to the widely-publicized IUD and pacemaker failures, Congress passed the Medical Device Amendments²² (“MDA”) giving the FDA broad authority over medical devices. The new law also required that in most cases marketing of a device could not legally begin until the FDA finds that the device is safe and effective. The law was most significantly amended in 1990 by the Safe Medical Devices Act (“SMDA”)²³; in 1992 by the Medical Device Amendments²⁴ and, yet again in 1997 by the Food and Drug Administration Modernization Act (“FDAMA”)²⁵ to further expand the FDA’s authority, increase its enforcement powers, and require device manufacturers and others to report adverse device experiences to the FDA.

The main changes introduced by this new device regulatory framework included the following: (1) devices would now be classified into three distinct classes based on their perceived risk to patients; (2) a premarket notification system was introduced to enable the FDA to assess the safety and effectiveness of products prior to marketing; and (3) a premarket approval system, distinct from the New Drug Premarket Approval requirements for drugs, was introduced for high-risk devices.

B. FDA Classification of Devices²⁶

The MDA of 1976 required the FDA to classify all devices into one of three regulatory control categories, depending on the degree of regulation necessary to provide reasonable assurance of the device’s safety and effectiveness. Under the classification provisions, all products marketed prior to implementation of the 1976 MDA were categorized by a series of advisory committees.

1992, and 1997 which led to the establishment of a comprehensive system of reviewing and approving the marketing of medical devices in the US.

²²Pub. L. No. 94-295, 90 Stat. 539 (codified at 15 U.S.C. Sec.55 (1994); 21 U.S.C. Sec.31, 331, 334, 351, 352, 358, 360, 360c-k, 374, 379, 379a, 381). The MDA incorporated the recommendations of the Study Group on Medical Devices, Medical Devices: A Legislative Plan. (U.S. Dept. of Health, Education, and Welfare 1970), generally referred to as the ‘Cooper Committee’.

²³Pub. L. No. 101-629, 104 Stat. 4511 (codified at 21 U.S.C. Sec. 301 note, 321, 333, 333 note, 351, 353, 360, 360c, 360c note, 360d-i, 360i note, 360j, 360j note, 360l, 360gg-hh, 360hh note, 360ii-ss, 383, 383 note; 42 U.S.C. §§ 263b-n (1994)).

²⁴Pub. L. No. 102-300, 106 Stat. 238 (codified at 21 U.S.C. Secs 301 note, 321, 331, 334, 346a, 352-353, 356-357, 360c-d, 360g-i, 360i notes, 360l, 360mm, 371-372, 372a, 376, 381; 42 U.S.C. Sec 262).

²⁵Pub. L. No. 105-115, 111 Stat. 2296 (1997), as amended 21 U.S.C. Secs 301-394 (1997)).

²⁶For a more comprehensive overview of this area, see PETER B. HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW CASES AND MATERIALS pp.742-792 (2nd ed. 1991); Robert Higgs, Wrecking Ball: FDA Regulation of Medical Devices, Policy Analysis No. 235 (August 7, 1995); William F. Pritchard & Ronald F. Carey, Primer on Medical Device Regulation: U.S. Food and Drug Administration and Regulation of Medical Devices in Radiology, 205 RADIOLOGY 27 (1997); Lee H. Monsein, Primer on Medical Device Regulation, Part II: Classification, 205 RADIOLOGY 1, (1997); John J. Smith, Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act, 55 Food & Drug L.J. 245; and Rodney R. Munsey, Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years, 50 Food & Drug L.J. 163.

Class I devices²⁷, considered relatively safe and low-risk to patients, are only subject to general controls designed to achieve safety and effectiveness through control of manufacturing, labeling and related issues²⁸ including FDA's Good Manufacturing Practices (GMP)²⁹. Examples of Class I devices include bandages, x-ray grids³⁰, breath alcohol tests³¹, and manual and electric toothbrushes³². Devices under this class are generally regulated by device type³³. Class I devices, unless specifically exempted by regulation, must also be cleared by the FDA prior to marketing through a premarket notification filing³⁴.

Following the FDAMA (which amends the FDCA), most Class I and certain low risk Class II devices are exempt from the pre-notification requirement³⁵. **All other devices are still subject to the notification requirement**³⁶.

A premarket Notification filing must be submitted to the FDA before a manufacturer can market its device in the United States, or before any significant changes are made to an existing device that could significantly affect the safety or effectiveness of the device or would be a major change or modification in the intended

²⁷Defined as products that are not purported or represented to be for a use that is of substantial importance in preventing impairment of human health, and that do not present a potentially unreasonable risk of patient injury (FDCA § 513(a)(1)(A)(ii) (21 U.S.C. § 360c(a)(1)(A)(ii)).

²⁸General controls include: prohibition against adulteration and misbranding (FDCA §§ 501 and 502); banned devices (§ 516); notification, repair, and replacement or refund (§ 518); records and reports (§ 519); and restricted devices (§ 520). Unless specifically exempted by regulation, general controls contain requirements for device manufacturers or other designated persons to: (i) register their establishment with FDA; (ii) list their devices with FDA; (iii) comply with labeling regulations in 21 C.F.R. pts. 801, 809, or 812; (iv) submit a premarket notification to FDA; and (v) design and produce devices under good manufacturing practices. See generally Lee H. Monsein, Primer on Medical Device Regulation, Part II: Classification, 205 RADIOLOGY 2 (1997); Rodney R. Munsey, Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years, 50 Food & Drug L.J. 163, 166 (1995); CDRH, FDA, Device Advice (see www.fda.gov/cdrh/devadvice).

²⁹The FDA's Good Manufacturing Practices (GMP) regulation requires all domestic and foreign manufacturers of medical devices (except certain exempted Class I devices) that are commercially distributed in the United States to have in place a quality assurance program. Adequate specifications and controls must be established and finished devices must meet these specifications. The FDA may periodically inspect the operations and records of domestic and foreign manufacturers to determine compliance with the GMP regulation.

The GMP regulation covers the methods, facilities, record-keeping (such as complaint, device master-record, and production history files), and controls used in manufacturing, packaging, labeling, inspecting, storing, and installing medical devices. All devices must meet general GMP requirements, but critical devices must meet additional GMP requirements.

³⁰21 CFR 892.6500.

³¹21 CFR 862.3050.

³²21 CFR 872.6855, 872.6865.

³³Under the FDAMA §510(l), most Class I devices are § 510(k) exempt. However, even when such devices are subject to the 510(k) process, they are regulated by the type of medical product, though they are approved individually. In contrast, a Class III device that is subject to a premarket approval application (PMA) is subject to general controls and, depending on the novelty of the device, a unique set of regulatory controls.

³⁴See *id.*

³⁵FDAMA § 206.

³⁶*i.e.* nonexempt Class I and II devices, and Class III devices, are subject to the premarket notification requirement.

use of the device.

The general controls discussed above are relevant for all types of devices and also apply to devices in Classes II and III.

Class II devices which present a greater risk of injury to the patient than class I devices must comply with both the general controls discussed above, as well as certain “special controls”³⁷ which may be established by FDA regulation. Class II devices are also subject to the premarket notification procedures³⁸. Examples of Class II devices include oxygen masks³⁹; artificial eyes⁴⁰ and, other devices that do not by themselves maintain life, such as cardiac monitors.

Class III devices are defined as those used for “supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or those devices that “present a potentially unreasonable risk of illness or injury”⁴¹. Given that such devices entail the most significant risks, in addition to meeting the above requirements, they must also be shown to be safe and effective before being marketed. Class III devices are therefore subject to a premarket approval (“PMA”) process by which the FDA reviews clinical evidence as to the safety and effectiveness of the device before granting approval for the device to be marketed or manufactured⁴². Examples of Class III devices include replacement heart valves⁴³ and extended wear contact lenses⁴⁴.

Medical lasers, depending on their application, are usually categorized in Class II or III⁴⁵. Manufacturers can, however, request a reclassification from the FDA⁴⁶.

The MDA further distinguishes between those devices legally marketed before implementation of the leg-

³⁷An example of such controls include performance standards (if adopted by the FDA) requiring the device to meet certain functional characteristics (the FDA has been notoriously lax in adopting such standards); postmarket surveillance; patient registries; development and dissemination of guidelines; recommendations; and other appropriate actions. In the absence of any special controls established by regulation, only general controls apply to class II devices. See FDCA §513(a)(1)(B) (21 U.S.C. § 360c(a)(1)(B)(ii)).

³⁸As with Class I devices, Class II device are evaluated individually under § 510(k) (if applicable), and then regulated by the type of medical product. See supra note 33

³⁹21 CFR 868.5580.

⁴⁰21 CFR 886.3200.

⁴¹See FDCA §513(a)(1)(C)(ii) (21 U.S.C. §360c(a)(1)(C)(ii)).

⁴²21 U.S.C. §360e(b).

⁴³21 CFR 870.3925.

⁴⁴21 CFR 886.5925.

⁴⁵The Gray Sheet, Vol.12, No. 46, pp. 9-11 (available at <http://www.fdcreports.com/grayout2.shtml> -Subscription required).

⁴⁶21 C.F.R. Sec. 860.123.

isolation in May 1976 (pre-1976 devices) and those marketed after that date (post-1976 devices). Pre-1976 Class III devices can continue to be legally marketed until FDA requests data (clinical or otherwise) that demonstrates safety and effectiveness⁴⁷. Any new device after 1976 is automatically treated as a Class III device, and must go through the PMA process requiring demonstration of reasonable assurance of safety and effectiveness⁴⁸ before it may be marketed in the United States.

However, by way of an exception, certain Class III devices that are “substantially equivalent” to a pre-1976 device will be placed in the class of its “predicate” product⁴⁹ and may be marketed immediately, subject to existing regulations imposed on the predicate product.

C. Substantial Equivalence

Since the PMA process is time-consuming and expensive, most manufacturers generally attempt to avoid it by claiming their device is “substantial equivalent” to a “predicate” (pre-1976) device. If this is the case, the new device will be placed in the predicate’s class and can be marketed immediately subject to any regulations applicable to the predicate device. As one commentator has noted: “*510(k) submission has become the option of choice for bringing a new device to market*”⁵⁰. However, devices without predicates and not judged to be substantially equivalent to a pre-1976 device, are placed automatically in Class III and are subject to the PMA process.

The term “substantial equivalence”, although originally undefined and left to the interpretation of the FDA⁵¹, was eventually defined in the SDMA of 1990. A device is “substantially equivalent” if, in comparison to a predicate device it (1) has the same intended use and technological characteristics⁵² as the predicate device; or (2) has different technological characteristics that do not raise new questions of safety and effectiveness, and the manufacturer demonstrates that the device is as safe and effective as the legally marketed device⁵³.

⁴⁷See id. § 360c(a)(1)(C)(ii) (FDCA § 513(a)(1)(C)(ii)).

⁴⁸See 21 U.S.C. § 360c(a)(1)(C) (FDCA § 513(a)(1)(C)).

⁴⁹See § 360c(f)(1)(A)(ii) (FDCA § 513(f)(1)(A)(ii)).

⁵⁰Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510, at 514 (1984) (Hereinafter “Kahan, Premarket Approval etc”).

⁵¹See PETER B. HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW CASES AND MATERIALS* pp.754-756 (2nd ed. 1991).

⁵²For the purpose of this definition, the term different technological characteristics means that when compared to the predicate device it can be shown that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device. See CDRH Device Advice at: <http://www.fda.gov/cdrh/devadvice/>.

⁵³21 U.S.C. §360c(i). See CDRH Device Advice at: <http://www.fda.gov/cdrh/devadvice/>. Detailed information on how

Once the device is determined to be substantial equivalent, it can then be marketed in the U.S and is generally subject to the same regulatory requirements as its predicate⁵⁴. However, if FDA determines that a device is not substantial equivalent, the device is placed in Class III and must go through the PMA process (alternatively, the applicant may resubmit another 510(k) with additional data, petition for reconsideration or reclassification, or seek judicial review⁵⁵).

Significantly, prior to the 1990 amendments, the FDA did not generally require human clinical trials in determining substantial equivalence⁵⁶. However, following the 1990 amendments, the FDA were given express authority to require the submission of performance data, including data from clinical trials, in order to make a substantial equivalence determination⁵⁷.

Furthermore, in addition to this lack of a mandatory requirement for clinical human testing, the introduction of “piggybacking”, a process that allowed post-1976 devices judged substantially equivalent to pre-1976 devices to serve as predicates themselves⁵⁸, made it even easier for manufacturers to market their products and avoid the FDA PMA process. The significance of this applies particularly to cosmetic lasers (as will be discussed later) given that laser manufacturers are able to avoid the more demanding premarket approval process by making incremental changes to the lasers and relying on the substantial equivalence procedure to obtain marketing approval.

It should further be noted that the legislative history of substantial equivalence reveals that the introduction of the concept was not to insure safety and effectiveness, but rather was a concession to industry to treat pre- and post-amendment devices equally⁵⁹. Indeed, the effect of the introduction of the substantial equivalence

FDA determines substantial equivalence can be found in the Premarket Notification Review Program 6/30/86 (K86-3) blue book memorandum at: <http://www.fda.gov/cdrh/k863.html>. The FDAMA made some amendments to the legislative definition of substantial equivalence, which are discussed below. e.g. enabling the CDRH to request clinical data as part of the substantial equivalence determination, but limiting the type of data requested to the “least burdensome” data needed to determine substantial equivalence – therefore information not directly relevant to substantial equivalence, e.g. information regarding absolute safety and effectiveness of a device, may not be requested.

⁵⁴Although with individually regulated Class III devices, the situation is more complicated. If the predicate is a pre-1976 device for which the FDA has not requested safety and effectiveness data, the new device may be marketed legally after the product has received §510(k) clearance (see John J. Smith, Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act, 55 Food & Drug L.J. 245).

⁵⁵See *id.*

⁵⁶See John J. Smith, Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act, 55 Food & Drug L.J. 245.

⁵⁷See 21 U.S.C. §360c(i)(1)(A)(ii)(I). See *id.*

⁵⁸See *supra* note 56.

⁵⁹See SUBCOMM. ON OVERSIGHT & INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY & COMMERCE, LESS THAN THE SUM OF ITS PARTS: REFORMS NEEDED IN THE ORGANIZATION, MANAGEMENT, AND RESOURCES OF THE FDA’S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, H.R. REP. NO. 103-N, at 60 (1993)

requirement was to enable manufacturers to evade the more stringent PMA requirements giving them a fast-track for getting their products on the market⁶⁰. A 1988 General Accounting Office report stated that of the 36,000 medical devices marketed after FDA review, only 6% went through the PMA process while the other 94% went through the substantial equivalence procedure⁶¹. Furthermore, the FDA rarely found that a new device was not substantially equivalent to a predicate device selected by the applicant. The rejection rate was approximately 2%⁶².

Criticism arose as to use of the substantial equivalent test for deciding whether a device should be marketed, especially given the fact that the test did not focus on the most relevant question, namely is the device safe and effective? Instead, the test focuses on a secondary question, namely, is the device substantially equivalent to a pre-enactment device with regards to safety and effectiveness⁶³? Furthermore, there was general criticism of CDRH's unofficial policy to reject only 2% of 510(k) applications which "encouraged approvals in all but the most obviously deficient 510(k) applications."⁶⁴

The FDAMA addressed the issue of delays in premarket notification review time⁶⁵, and the need to speed up the introduction of new technologies. An important FDAMA provision required the FDA to consider only the "least burdensome means" of evaluating effectiveness that would have a reasonable likelihood of resulting in approval⁶⁶. The FDAMA amended the definition of substantial equivalence by enabling the CDRH to request clinical data as part of the substantial equivalence determination, but limiting the type

("LESS THAN SUM OF ITS PARTS"); and David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 *New Eng. J. Med.* 357, at 359 (1987) ("The decision to include a 'substantial equivalence' provision in the statute was made to ensure fair treatment of post-amendment devices").

⁶⁰See supra note 50, Kahan, *Premarket Approval etc.*, at 510 ("The proof is in the numbers: in calendar year 1977, the first full year under the Amendments, [FDA] received 2433 requests to allow marketing of new devices. Only 11 of those invoked the [PMA] mechanism . . . FDA projects that in . . . 1985 it will review only 95 PMAs, while during the same period it expects to review 5200 notifications under the 510(k) mechanism.")

⁶¹GENERAL ACCOUNTING OFFICE, *MEDICAL DEVICES: FDA'S 510(K) OPERATIONS COULD BE IMPROVED*, PEMD-88-14, at 2 (1988)

⁶²See supra note 50, Kahan, *Premarket Approval etc.*, at 515-6 (rate of rejection form 1976-1983).

⁶³Richard M. Cooper, *Clinical Data Under Section 510(k)*, 42 *Food Drug Cosm. L.J.* 192 (1987), at 199-200 ("Richard Cooper etc").

⁶⁴LESS THAN SUM OF ITS PARTIS, supra note 59, at 37-8 (revealing that 2% was considered to be the "acceptable rejection rate" and that a finding of no substantial equivalence by a reviewer was subject to more scrutiny by supervisors than a finding of substantial equivalence).

⁶⁵According to the Senate Report, prior to the implementation of the FDAMA (See S. REP. No. 105-43, at 20 (1997)), premarket notification classification review time increased 100% between 1990 and 1996, despite the number of applications remaining steady. Time for premarket approvals more than doubled in the same time period, although submissions dropped by nearly half.

⁶⁶See 21 U.S.C. § 360c (a)(3)(D)(ii) (FDCA § 513(a)(3)(D)(ii); FDAMA § 205). See John J. Smith & Anne M. Shyjan, *Defining Least Burdensome Means Under The Food And Drug Administration Modernization Act Of 1997*, 55 *Food & Drug L.J.* 435.

of data requested to the “least burdensome” data needed to determine substantial equivalence – therefore information not directly relevant to substantial equivalence, e.g. information regarding absolute safety and effectiveness of a device, may not be requested⁶⁷. Thus, the Senate report, prior to the implementation of the FDAMA, stated that the FDA “must ask for the least burdensome type of valid scientific evidence that will meet Congress’ criteria for effectiveness.”⁶⁸

This drive for efficiency so as to ease the process by accelerating device approval, as well as to reduce the cost for private companies to get their products on the market was, in this writer’s opinion, to the detriment of the public welfare in terms of proper assessment of device safety and effectiveness, even though supporters of the FDAMA stated that this improved patient access to important new technologies.

A further development introduced by the SMDA and the Medical Device Amendments of 1992 was the requirement for users (i.e. manufacturers, distributors, hospitals and clinics) to report to FDA any deaths or serious injuries caused by a device. Annual reports of such events to the FDA also are mandated. However, by narrowing it to only reporting of “serious injuries”, severely limits post-market surveillance of devices like lasers, which have the capacity for causing injury but on a more moderate level⁶⁹.

However, the position with substantial equivalence remains very much the same with the FDA requiring submission of clinical data for only a small percentage of 510(k) applications, and, in complying with the “least burdensome means” test to establish substantial equivalence, pre-clinical data is generally considered satisfactory for most applications⁷⁰.

D. Investigational Device Exemptions

Another route used by device manufacturers is the Investigational Device Exemption (IDE) (or an exemption from the IDE regulations themselves, such as for certain diagnostic or custom devices) which permits clinical study of unapproved devices (or study of new uses for approved devices). The exemption in an IDE is from certain regulatory requirements that would otherwise apply to such a device, such as PMA, performance

⁶⁷See 21 U.S.C. §360c(i)(1)(D); and Richard Cooper etc at supra note 63.

⁶⁸S. REP. NO. 105-43, at 25 (1997)

⁶⁹See 21 U.S.C. §360i(b) and §360(i)(a)(3).

⁷⁰See CDRH Device Advice: Premarket Notification [510(k)], at:
http://www.fda.gov/cdrh/devadvice/314.html#link_2.

standards, and GMP regulations, though an effective quality assurance system must be in place that, in anticipation of premarket approval by the FDA, should be based on or exceed the GMP requirements. Extensive record-keeping, reporting, and monitoring of the clinical studies is also required.

E. Special Issues For Radiation-Emitting Devices

Particularly pertinent for lasers, any device that emits radiation must additionally comply with the Radiation Control for Health and Safety Act passed in 1968⁷¹ which is also administered by the FDA and which authorizes the development of performance standards and general controls for ionizing radiation products. The Act was designed to protect the public from the dangers of electronic product radiation. Devices that either intentionally emit radiation (such as x-ray equipment) or emit radiation as a consequence of their operation (such as CRTs and television sets) are covered. Furthermore, certain light-emitting products, which emit intense, directed radiation, such as lasers⁷², sunlamps⁷³, and ultraviolet lighting⁷⁴ are also covered. In addition to specific emissions standards, and to prevent unnecessary exposure to such radiation due to the use of these products⁷⁵, manufacturers and distributors of products meeting the definition of electronic product radiation⁷⁶ are required to comply with certain formalities, for example, record keeping, specific labeling requirements, and reporting to the Center for Devices and Radiological Health (“CDRH”)⁷⁷.

II.

LASERS IN COSMETIC SURGERY: ONE SMALL WRINKLE FOR MAN, ONE GIANT STEP FOR MA

⁷¹42 U.S.C. Sec. 263b.

⁷²For performance standards for lasers, see 21 CFR 1040.10 and 1040.11. In determining the applicable reporting category for a laser product, the CDRH bases its decision on the worst-case hazard present within the laser product.

⁷³For an overview of the regulation of tanning salons in the US, see Leigh R. Fraser, *Should Tanning Salons Be Banned?* (1995), Unpublished, but stored at Harvard Law School’s Food & Drug Law Archives held by Peter Hutt (email: phutt@cov.com).

⁷⁴Other examples of radiation emitting electronic products subject to the provisions of the FDCA and therefore regulated by FDA are listed in 21 CFR 1000.15.

⁷⁵For an overview of this area, see CDRH Device Advice on products emitting radiation at: <http://www.fda.gov/cdrh/devadvice/311.html>; and PETER B. HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW CASES AND MATERIALS* pp.794-805 (2nd ed. 1991).

⁷⁶FDCA §531.

⁷⁷The final regulations are contained in 21 CFR 1000- 1299.

A. Overview

Over the last decade, lasers have gradually been transformed from a figment of science fiction to a powerful medical tool for surgeons and dermatologists in the fight for skin perfection. In this short time span, medical lasers have been used for removal of birthmarks (port wine stains), moles, tattoos, acne scars and other blemishes. Lasers are also used for a growing number of other cosmetic procedures including hair removal, treatment of wrinkles, and tooth whitening⁷⁸.

Indeed, according to the American Academy of Cosmetic Surgery in Chicago, nearly 170,000 Americans underwent laser resurfacing of the face in 1998, which is approximately twice the number of the more traditional surgical facelifts performed in the same year⁷⁹.

Compared to traditional surgical tools, lasers offer significant advantages. First, unlike a knife or scalpel, a laser can cut through tissue without causing excessive bleeding. In fact, lasers can actually coagulate tissue to stop bleeding – something which a knife cannot do⁸⁰. Second, lasers can reach or impact areas of the body more easily than with a scalpel, a fact that is today increasingly important with many internal procedures. Third, lasers are more precise, enabling surgeons to pinpoint the laser light on a specific area, such as a mole or hair follicle, without affecting the neighboring tissue⁸¹. Precision is vital when it comes to invasive or cosmetic surgery.

B. What is a Laser?

The term ‘laser’ is an acronym for ‘Light Amplification by Stimulated Emission of Radiation’. Put simply, a laser tool emits a beam of light which, when focused on the skin, will “vaporize” its target⁸². This is made possible because of the way lasers interact with electrons. The beam of light is sensitive to different colors thereby allowing lasers to remove colored or pigmented areas on the skin, such as brown spots (known by

⁷⁸See CDRH, Laser Facts, May 2001 at: <http://www.fda.gov/cdrh/consumer/laserfacts.html>.

⁷⁹Alexandra Greeley, FDA Consumer, May-June 2001.

⁸⁰See id.

⁸¹See id.

⁸²ROBERT A. YOHO MD AND JUDY BRANDY-YOHO RN, A NEW BODY IN ONE DAY: A GUIDE TO SAME-DAY COSMETIC SURGERY PROCEDURES, Chapter 14 (1st ed. 1998) (hereafter “A NEW BODY IN ONE DAY”).

dermatologists as café-au-lait marks) and tattoos⁸³.

There are many different types of lasers, some designed to remove discolorations and other imperfections on the skin, whilst others designed for resurfacing the skin by vaporization of the skin's upper layer⁸⁴. It is beyond the scope of this paper to attempt to describe the many different kinds of lasers available, and therefore the descriptions in this paper are confined to the essential basics.

C. Common Cosmetic Uses for A Laser: Quick Fixes To Old Problems

1. Wrinkles and Scars - Skin Resurfacing

Prior to lasers, there were few safe and effective solutions to help remove or improve wrinkles or scars (caused by acne, chicken pox or trauma), as well as for improving the appearance of photo damaged skin. Dermabrasion was one often-used solution. This involves using a tiny electric sander revolving at high speeds which literally “sands” the surface of the skin thereby removing or reducing wrinkles and scars. However, dermabrasion produces significant bleeding, and scarring is common⁸⁵. Another solution, acid peeling, which, rather than sanding the skin surface, applies one of two acids⁸⁶ to produce an injury to the old skin. Unfortunately, permanent color loss occurs in most cases with patients often ending up with a white patch on their faces⁸⁷, and some patients experiencing scarring. Despite this, superficial or light trichloroacetic (TCA) peels, are generally successful with very low concentrations of TCA being used on the face for minor skin complaints⁸⁸.

Lasers have superseded these two solutions by introducing an arguably safer and more predictable procedure to remove wrinkles and facial scars⁸⁹. Laser resurfacing offers a number of advantages over other resurfacing methods: precision, little (if any) bleeding; less post-operative discomfort⁹⁰; and allowing more accurate

⁸³See id.

⁸⁴For more information on how a laser works, see the Lawrence Livermore National Laboratory (a U.S. Department of Energy national laboratory operated by the University of California) website at: <http://www.llnl.gov/nif/library/aboutlasers/how.html>.

⁸⁵See supra note 82, A NEW BODY IN ONE DAY, Chapter 5. See also the Plastic Surgery Information Service at <http://www.plasticsurgery.org/surgery/dermabra.htm>; and the Cosmetic Surgery Education Center at <http://www.dryoho.com/>.

⁸⁶Usually phenol or trichloroacetic (TCA). See id.

⁸⁷See supra note 85, A NEW BODY IN ONE DAY.

⁸⁸See id.

⁸⁹Iain McKay FRCS, Laser Skin Resurfacing, Skinlaser Directory (produced by the Disfigurement Guidance Centre in the UK) available at: <http://www.skinlaserdirectory.org.uk/resurfacing.htm>.

⁹⁰See Plastic Surgery Information Service at <http://www.plasticsurgery.org/surgery/lasersrg.htm>.

depth control with distinct color changes in the skin⁹¹.

Laser resurfacing is a controlled burning procedure during which the laser vaporizes superficial layers of facial skin (generally the epidermis and papillary dermis⁹²), removing not only wrinkles and lines, but also acne scars, folds and creases around the nose and mouth. Effectively, the laser resurfacing creates a fresh surface over which new skin can grow⁹³.

An explanation of the procedure is provided by Dr. Robert Yoho:

*“The laser zaps small areas on the face as the doctor moves carefully from one area to the next, treating each in turn, making sure to blend everything evenly. In the past, lasers could only work on very small spots, about an eighth of an inch at a time. But now, the technology has improved to the point where we can laser spots about 1.5 centimeters (about two-thirds of an inch) in diameter, using a laser pattern generator. . . . The laser doesn’t actually burn the skin, because there’s very little heat transfer involved. Instead, it vaporizes the skin surface by making the water boil inside the skin. During the process, the treated skin changes in a way that allows the doctor to wipe off the top layers with a wet gauze pad. With each zap of the laser, the doctor can see new, fresh skin appear. Almost no bleeding occurs. Each laser zap lasts a fraction of a second . . . The whole process lasts about an hour”*⁹⁴

Carbon Dioxide (“CO2”) and Erbium⁹⁵ lasers are the two lasers generally used in laser resurfacing, each, with different effects.

Several manufacturers have received FDA clearance to advertise their lasers for the treatment of wrinkles, while others may claim skin resurfacing more generally.

Overall, as one surgeon notes:

⁹¹See id.

⁹²although for deeper resurfacing, the upper levels of the reticular dermis is also removed. See Plastic Surgery Information Service at <http://www.plasticsurgery.org/surgery/lasersrg.htm>.

⁹³See supra note 82.

⁹⁴See supra note 82, A NEW BODY IN ONE DAY, chapter 5. See also Iain McKay FRCS, Laser Skin Resurfacing, Skinlaser Directory (produced by the Disfigurement Guidance Centre in the UK): “All patients will have a raw, weeping, uncomfortable superficial burn for about one week. . . skin erythema (redness) will last for 5 weeks to 6 months depending on which laser is used, the depth of injury and individual variation.”

⁹⁵As with the Carbon Dioxide laser, the Erbium laser reacts with the water moisture in the skin to create a vaporization effect. However, the Erbium laser treats the skin in much smaller increments, allowing for finer control of the resurfacing, and creates much less heat damage than the CO2 laser. This usually allows for faster post-op healing time and faster disappearance of the red face of healing often seen with resurfacing. The trade-off may be less wrinkle and scar removal than with the CO2 lasers. See id. A NEW BODY IN ONE DAY, Chapter 15.

*“Used properly . . . resurfacing lasers are a useful additional tool in managing patients with disfiguring problems such as acne scarring, with a degree of control not previously possible.”*⁹⁶

2. Tattoo Removal

Lasers which are sensitive to different colors are used to remove tattoos⁹⁷, with different lasers being used to remove the different colors of the tattoo⁹⁸. The lasers used deliver extremely high energy which shatters the tattoo ink particle or pigment without destroying the surrounding skin. However, although these procedures have a high rate of patient satisfaction, the side effects sometimes include a change in skin texture or pigment⁹⁹.

3. Red Marks on the Face or Body

Lasers can treat vascular or abnormal blood vessels and red birthmarks on the skin surface. A flash lamp pulsed dye laser is generally used on the most common birthmark, known as a ‘port wine stain birthmarks’ (the Gorbachov birthmark), as well as other red marks¹⁰⁰. Effectively, the laser used produces a wavelength of light which is selectively absorbed by the hemoglobin in the birthmark thereby fading the redness on the skin¹⁰¹.

4. Freckles, Moles, Age or Sun Spots and Other Pigment Irregularities

Using a laser that responds to color (usually the Q-Switched Yag and Q-Switched Alexandrite lasers), will often remove freckles, age spots, moles and other colored marks, as well as fading the appearance of brown birthmarks (known as café-au-lait marks)¹⁰².

⁹⁶See supra note 92.

⁹⁷See supra note 82, A NEW BODY IN ONE DAY, Chapter 15.

⁹⁸The Q-Switched Yag laser is used to fade red inks, while the Q-Switched Ruby and Alexandrite lasers fade the green colors. All three lasers can remove the dark blue/black inks. See id. A NEW BODY IN ONE DAY, Chapter 15.

⁹⁹See id. A NEW BODY IN ONE DAY, Chapter 15. See also David H. McDaniel, M.D, Lasers in Dermatology, Skinlaser Directory (produced by the Disfigurement Guidance Centre in the UK) available at: <http://www.skinlaserdirectory.org.uk/Lasers.htm>.

¹⁰⁰See id. A NEW BODY IN ONE DAY, Chapter 15.

¹⁰¹See David H. McDaniel, M.D, Lasers in Dermatology, Skinlaser Directory (produced by the Disfigurement Guidance Centre in the UK, available at: <http://www.skinlaserdirectory.org.uk/Lasers.htm>).

¹⁰²See supra note 82, A NEW BODY IN ONE DAY, Chapter 15.

5. Hair Removal

Apart from for cosmetic reasons, hair removal can be a medical necessity in many cases, such as for skin graft preparation and for ingrown hairs which cause infections.

In August 1997, the FDA approved the Cynosure Photogenica LPIR, a long-pulse Alexandrite laser which offers quick and relatively painless laser hair removal¹⁰³. Lasers are becoming the most convenient, economical, and less painful method to remove hair from large sections of the body as well as from the face, underarms, and bikini areas (especially when one considers the more traditional methods of hair removal including shaving, depilatories which chemically dissolve hair, waxing, and tweezing).

The primary principle behind laser hair removal is “selective photothermolysis” (literally destruction from heat caused by light). Lasers can cause localized damage by selectively heating dark target matter in the area that causes hair growth while not heating the rest of the skin¹⁰⁴.

Given the increasing popularity of laser hair removal, many laser manufacturers have sought FDA clearance for their lasers for this indication. The market is growing so quickly that the FDA cannot maintain an up-to-date list of all laser manufacturers whose devices have been cleared for hair removal, as this list continues to change daily¹⁰⁵.

Furthermore, given that laser hair removal is relatively new compared to other laser treatments, the longest observation period reported in the scientific literature (as of 1998) is two years. Four out of the seven patients followed up still had stable hair loss¹⁰⁶. Hair follicles are not completely destroyed by laser treatment, and therefore it is difficult to claim that laser hair removal is permanent; indeed most people will experience

¹⁰³Andrea James, Hair Removal Methods: Laser Hair Removal Overview, August 2001 (available at: <http://www.quackwatch.com/01QuackeryRelatedTopics/Hair/lasermain.html>).

¹⁰⁴See id. For a detailed look at laser hair removal, see Ross EV, Ladin Z, Kreindel M, Dierickx C., Theoretical Considerations In Laser Hair Removal. *Dermatological Clinics* 17(2): 333-355, 1999; and Littler CM, Hair Removal Using The Nd:YAG Laser System, *Dermatological Clinics* 17(2):401-430, 1999.

¹⁰⁵To learn if a specific manufacturer has received FDA clearance, you can check FDA's Website at <http://www.fda.gov/cdrh/databases.html> under the 510(k) database.

¹⁰⁶Laser Hair Removal, *Skinlaser Directory* produced by the Disfigurement Guidance Centre in the UK, available at: <http://www.skinlaserdirectory.org.uk/hairemoval.htm>. See also Whitney D. Tope and Maria K. Hordinsky, A Hair's Breadth Closer?, *Archives in Dermatology* 1998; 134:867-869.

some regrowth within a year¹⁰⁷.

6. *Dental Treatments*

FDA has given clearance for argon and carbon dioxide lasers to activate tooth-bleaching solutions and to treat gum disease. Several lasers have clearance for hard tissue use on teeth¹⁰⁸. In May 1997, FDA cleared the first laser system for treating tooth decay, an erbium YAG laser made by Premier Laser Systems¹⁰⁹. Recently, American Dental Technologies received FDA clearance to market its “PulseMaster” laser for caries (decay) removal¹¹⁰.

According to studies conducted by the manufacturers, the laser is as safe and effective as a high-speed drill for removing dental decay and preparing a cavity for a filling. Furthermore, fewer patients require a local anesthetic¹¹¹.

7. *Eye Surgery*¹¹²

Lasers are also used to remove tissue in eye surgery, including removing tumors and cataracts. Several manufacturers have lasers cleared for photorefractive keratectomy (PRK) and Laser-Assisted In Situ Keratomileusis (LASIK), two procedures for correcting nearsightedness, farsightedness, and astigmatism. The laser is used to reshape the cornea and focus images correctly on the retina¹¹³.

¹⁰⁷See id.

¹⁰⁸See supra note 78, CDRH, Laser Facts, May 2001.

¹⁰⁹See Premier Laser Systems site at: <http://www.premierlaser.com/>.

¹¹⁰See American Dental Technologies site at: <http://www.americandentaltech.com/PulseMaster.htm>>1.

¹¹¹See supra note 78, CDRH, Laser Facts, May 2001.

¹¹²As mentioned in the introduction, the use of lasers in eye surgery presents other issues which are not dealt with here given the confines of this paper. The topic is only mentioned briefly for the sake of completeness.

¹¹³See supra note 81. For information on laser eye surgery and which lasers have received clearance, see FDA’s Website at: <http://www.fda.gov/cdrh/LASIK>.

D. How does the FDA Regulate Lasers?

It is important to note that the FDA only regulates the sale and marketing of medical devices and does not regulate physicians or nurses in the practice of medicine or in the use of a device.

Before a laser can be legally sold in the U.S., the company wishing to sell or market the laser must seek approval from the FDA. Medical lasers, depending on their application, are usually categorized in Class II or III¹¹⁴ and must have premarket approval or premarket clearance from the FDA prior to marketing for any indication. The majority of laser manufacturers manage to market their lasers through the substantial equivalence procedure discussed earlier. However, there are two minor exceptions to this. Certain unapproved, nonsignificant risk Class III medical devices may be distributed in the U.S. to individual practitioners who have approval from an Institutional Review Board (IRB) for the investigational clinical use of the device¹¹⁵. Alternatively, lasers may be distributed to investigators participating in a study under an IDE approved by the CDRH¹¹⁶ (although various IDE requirements need to be complied with ¹¹⁷).

Generally, as discussed in part I, to gain FDA approval under the PMA process, a laser manufacturer must present evidence that the laser is reasonably safe and effective for a particular use (or indication”). Once the FDA approves a particular laser, the manufacturer is allowed to promote the medical use of their laser only for the specifically approved indication (as will be discussed later, a physician may nevertheless use the laser for treatments outside the laser’s approved applications)¹¹⁸.

By way of a further regulatory hurdle, all laser devices distributed for both human and animal treatment in the U.S. are subject to Mandatory Performance Standards. Laser manufacturers therefore have to meet the federal laser product performance standard and must submit an initial report to CDRH’s Office of Compliance prior to distributing the laser¹¹⁹. This performance standard specifies the safety features and labeling that all lasers must have in order to provide adequate safety to users and patients, and includes

¹¹⁴The Gray Sheet, Vol.12, No. 46, pp. 9-11 (available at <http://www.fdcreports.com/grayout2.shtml> -Subscription required. Last visited March 1, 2002).

¹¹⁵See supra note 81.

¹¹⁶as specified in 21 CFR 812.

¹¹⁷such as monitoring investigations, maintaining records, making reports, and complying with prohibitions on promotion and commercialization of investigational devices. See 21 CFR 812. See supra note 81.

¹¹⁸See The Laser Training InstituteTM, FDA Rules (available at: <http://www.lasertraining.org/fdarules.htm>).

¹¹⁹See 21 CFR 1000-1040.11 and 21 CFR 1040.10 H2II. See supra note 81.

various technical and service requirements¹²⁰. A laser product manufacturer must certify that each laser model has passed a quality assurance test and complies with the performance standard before introducing the laser into the market. This includes distribution for use during clinical investigations prior to device approval¹²¹.

The company/manufacturer certifying a laser assumes responsibility for product reporting to CDRH¹²²; record keeping, and notification of defects, noncompliances, and accidental radiation occurrences¹²³.

However, as will be discussed later in part III, once the FDA has approved a laser, a doctor may decide to use that laser for other indications if he/she feels it is in the best interest of a patient. The use of an approved device for other than its FDA-approved indication is called off-label use. The FDA does not regulate the practice of medicine¹²⁴. Therefore, the FDA does not have the authority to regulate a doctor's practice and activities (and therefore cannot regulate what doctors tells their patients; require the patient to be provided with the patient information booklet from the laser manufacturer prior to treatment; make recommendations for training or credentialing laser practitioners; nor can the FDA maintain or have access to lists of people performing laser surgery¹²⁵).

The FDA does, however, regulate the claims manufacturers assert for their devices. Thus, for hair "removal" lasers, a manufacturer may not claim that laser hair removal is "permanent", unless the FDA determines that there is sufficient data to demonstrate such result. Nevertheless, several manufacturers have received FDA permission to claim permanent reduction, but not permanent removal for their lasers. This means that although laser treatments with these lasers will permanently reduce the total number of body hairs, they will not result in a permanent removal of all hair¹²⁶.

Indeed, in the early 1970s, laser-like devices for hair removal which selectively targeted individual hair follicles by delivering energy through a wire-thin fiberoptic probe were rushed through the market without adequate

¹²⁰For further details of the FDA Technical and Service Requirements relating to laser power calibrations and service manuals, see The Laser Training InstituteTM, FDA Rules (available at <http://www.lasertraining.org/fdarules.htm>).

¹²¹See supra note 81.

¹²²Reporting guides and related regulatory information are available from the CDRH website at: <http://www.fda.gov/cdrh/devadvice>. See supra note 81.

¹²³as specified in 21 CFR 1000-1010.

¹²⁴See CDRH Information Sheet at: <http://www.fda.gov/cdrh/lasik/what.htm>.

¹²⁵See id.

¹²⁶Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing after a treatment regime, which may include several sessions. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treatment area. See supra note 81.

testing and were illegally marketed by making claims that the treatment was “painless and permanent”¹²⁷.

Other claims made in relation to hair removal lasers that the FDA have disallowed (in the absence of published clinical data to substantiate such claims) include the claim that treatment is “painless”, or that the use of the laser “guarantees 0% regrowth.”¹²⁸

In 1995, FDA cleared the first laser for hair removal in the US, the SoftLightTM Nd:YAG produced by ThermoLase¹²⁹. The device was rushed to the market without adequate testing of effectiveness and was marketed illegally as being “painless and permanent” until the FDA stepped in¹³⁰. By the time a medical paper appeared in 1997 which criticized the effectiveness of the laser and observed full regrowth of all hair in patients, consumers had already spent thousands of dollars on treatments¹³¹.

In 1998, ThermoLase was sued by a consumer (in a class action suit) alleging that the company advertised its SoftLight laser as having a “long lasting” effect knowing that such treatments did not achieve that result¹³². The case was later settled. However, following a number of other lawsuits, the company stopped marketing its SoftLight laser¹³³.

Improvements in laser technology following 1997, together with the publication of clinical observations on laser safety and effectiveness, have led to improvements in the overall effectiveness of treatment for patients.

E. Other Regulation

Although beyond the scope of this paper, brief mention will be made of other mechanisms available to an aggrieved consumer.

A laser manufacturer who designs and markets a medical laser that causes injury to a patient may be held

¹²⁷Andrea James, Hair Removal Methods: Laser History and Current Issues, August 2001 (available at: <http://www.quackwatch.com/01QuackeryRelatedTopics/Hair/lasermain.html>).

¹²⁸See supra note 81.

¹²⁹See FDA Docket K950019 (5 April 1995).

¹³⁰For a description of the treatment using this laser, see Andrea James, Hair Removal Methods: Laser History and Current Issues, August 2001, p.1 (available at: <http://www.quackwatch.com/01QuackeryRelatedTopics/Hair/lasermain.html>).

¹³¹See id. Andrea James citing Nanni CA & Alster TS, Optimizing Treatment Parameters for Hair Removal Using a Topical Carbon-Based Solution and 1064-nm Q-Switched Neodymium: YAG Laser Energy, Archives of Dermatology 1997 Dec;133(12):1546-9.

¹³²*Tester v ThermoLase*, Calif Superior Court (S.F. County, case #995285).

¹³³See supra note 130.

liable under general product liability law based on the negligent design or manufacture of the laser; for breach of an express or implied warranty of safety and/or may be held strictly liable in tort¹³⁴.

A physician who performs laser treatment resulting in injury to a patient could also be subject to a malpractice suit brought by the injured patient based on the tort of negligence (where a technical or judgmental error has occurred) or based on a lack of informed consent (where a negative result or complication occurs through no fault or negligence of the doctor)¹³⁵.

F. Limits on Device Regulations: Pre-emption

Regulation of medical devices, particularly lasers, is arguably severely limited by the doctrine of ‘pre-emption’. The MDA of 1976 specifically preempts state laws that are different from, or in addition to, any federal requirement applicable to the device which relates to safety or effectiveness.

The possibility of device manufacturers avoiding state product liability claims on the basis that such claims are preempted by the FDCA¹³⁶ is one of the more controversial aspects of the 1976 MDA. While the result of this may not be so harmful in the case of a device that has undergone the PMA process, this is not the case where a device avoided the procedure by relying on the §510(k) substantial equivalence procedure. In such cases, manufacturers of medical devices would enjoy immunity from state tort claims. Without this fear of lawsuits, laser manufacturers have arguably less incentive to ensure their laser equipment is safe.

However, the scope of preemption under MDA is unclear following the Supreme Court’s decision in *Medtronic, Inc v Lohr*¹³⁷ where the court held that a 510(k) would not always preempt state tort claims. Justice Stevens stated that a finding of substantial equivalence under 510(k) was not a statement by the FDA regarding the safety and effectiveness of a device, but simply permission to market the device without going through the PMA process. Indeed the CDRH has agreed with this interpretation: “A finding of substantial equivalence does not represent, and should

¹³⁴For an elaboration of this, see John R. Irwin MD, Legal Aspects of Lasers, April 30, 1999 (available at <http://www.lawyerdoctor.com/lasers.htm>).

¹³⁵See id.

¹³⁶See Caleb Nelson, Preemption, 86 VA. L.Rev 225 (2000). See the preemption provision in 21 U.S.C. §360k(a).

¹³⁷518 U.S. 470 (1996).

not be construed as, a statement of a devices' safety and effectiveness.”¹³⁸ However, a majority of the court believed that the MDA could preempt state tort claims, but that Lohr's claims in the case were not preempted.

Unfortunately, the trend after *Lohr* in the circuit courts is to find that both a PMA and a §510(k) submission has preemptive effect¹³⁹. Indeed, in the recent case of *Kemp v. Medtronic Inc*¹⁴⁰, the Supreme Court denied an appeal by an Ohio woman seeking to overturn a lower court ruling that her state law tort claims were preempted by the MDA. The case involved an allegedly defective pacemaker, which the FDA had approved for sale pursuant to §510(k).

In the case of laser manufacturers, the benefits of preemption are clear but for consumers unable to sue under the common law of tort, preemption is an assault on the fundamental right of injured persons to legal redress. Proponents of federal preemption of state claims, such as the American Medical Association, argue that product liability claim have a negative impact on the development of new medical technologies such as lasers¹⁴¹. Nevertheless, as already mentioned, the threat of product liability suits may act to ensure that device manufacturers exercise a certain level of care when producing their devices. Indeed, device manufacturers gain a double benefit by avoiding the time, costs and investment needed for premarket research as to a laser's safety by using the substantial equivalence procedure, whilst gaining immunity from tort claims based on their devices being unsafe and defective.

¹³⁸See LESS THAN THE SUM OF ITS PARTS, supra note 82 at 8.

¹³⁹See also *Buckman Co v Plaintiffs' Legal Committee*, 121 S.Ct. 1012 (2001) where it was held that the MDA preempted state “fraud on the FDA” claims which attempt to recover for injuries suffered from devices which would not have obtained FDA approval if the device manufacturer had not defrauded the FDA during the premarket review process.

¹⁴⁰No. 00-1766, cert. denied (U.S., Oct. 1, 2001)

¹⁴¹AMA, Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies (1 June 1988).

III CRITICAL CONSIDERATIONS REGARDING LASERS AND THE LASER INDUSTRY

A. Side effects and other considerations of the treatment itself.

Patients are generally warned to avoid prolonged exposure to the sun for a few months after laser treatment. This is to protect the new layer of skin that is being formed as a result of laser resurfacing, and which is extremely sensitive¹⁴². Furthermore, patients experience bruising and swelling for between 7 and 10 days after treatment depending on the healing capacity of the individual¹⁴³. It should be further borne in mind that the results are not perfect – patients should see an improvement in the skin, but will not have perfect unlined and unscarred skin.

Unfortunately, darker skinned ethnic groups are not generally suitable candidates as the laser alters the skin color too unpredictably and dramatically¹⁴⁴.

As with all medical procedures, complications are possible with laser surgery, including a prolonged redness of the skin and pigmentary changes such as hyperpigmentation when the skin appears darker than normal¹⁴⁵. Other more serious risks include permanent hypopigmentation (lighting of the skin) in the area of the resurfacing, as well as scarring, burns, lesions and infections (especially if the surgeon removes more layers of skin than necessary or uses an excessively high settings¹⁴⁶). Indeed postoperative infections can be devastating. Herpes simplex virus infections can also occur resulting in severe scarring¹⁴⁷.

The more common problem with lasers, however, is the risk of burning. A recent newspaper report cited the case of a cosmetic surgeon in Florida who disfigured 5 women when a laser he used to remove wrinkles caused serious burns instead¹⁴⁸.

¹⁴²In other laser treatments aimed at removing skin discolorations, the skin is also very sensitive following treatment, necessitating the wearing of sun block for at least 6 months after treatment.

¹⁴³See supra note 78, CDRH, Laser Facts, May 2001.

¹⁴⁴See supra note 79.

¹⁴⁵See supra note 89, and Alexandra Greeley, FDA Consumer, May-June 2001.

¹⁴⁶See Dennis Jacobson MD & Lawrence S. Bass et al, Carbon Dioxide And ER:YAG Laser Resurfacing, Aesthetic Laser Surgery 27:2, p.241-250 (April 2000); Alexandra Greeley, FDA Consumer, May-June 2001; and Andrea James, Hairfacts: Lasers, at www.hairfacts.com/medpubs/lasermed.html

(“Skin discoloration which can last several months can occur in 1% to 10% of patients, with a higher likelihood in darker skin”).

¹⁴⁷This is why patients most at risk should receive a course of an antiviral prior to the laser treatment. See supra note 148.

¹⁴⁸See F. Schulte and J. Bergal, Member Quits Board Of Medicine in Protest, The South Florida Sun-Sentinel, June 7, 2001,

There have also been reports in the US of patients who have developed severe anaphylactic shock following laser treatment which indicates the necessity of having resuscitation equipment available in all establishments using lasers (especially for tattoo removal), and to have staff fully conversant with resuscitation techniques¹⁴⁹.

The following horror story, reported in the FDA Consumer Magazine¹⁵⁰, serves to illustrate some of the problems:

“Consider the case of Anne Jones (not her real name) in semi-rural Mississippi, a stay-at-home mom and a doctor’s wife. Wanting to remove some mild acne scars, she went to a well-respected local plastic surgeon, but after a five-month recovery period, Jones realized that something had gone very wrong. He had just burned my face, she says. It was red, with scar tissue all over, she adds.

Eventually, Jones went for help to an ophthalmologist who had extensive laser knowledge—many ophthalmologists use lasers for corrective eye surgery. He took one look at her and exclaimed, Oh, I am so sorry this has happened to you. He told her that the surgeon had been too aggressive and had not used the right settings, so that her skin had retained too much heat and had been severely burned. . .

. . . Two years after her procedure, [Jones] has spent nearly \$70,000 for both the initial surgery and subsequent consultations and corrective surgeries to remove the scarring. She says she has partially reclaimed her life. But she bitterly regrets undergoing the initial surgery. I will never look right, says Jones. I would never do this again.

B. Long-Term Effects.

Because laser resurfacing and laser hair removal are new methods, long-term data on safety and effectiveness have not yet been established. However, a number of studies on laser resurfacing using microscopic examination have shown that the physical changes that occur to laser-treated skin are essentially identical to those that occur with either dermabrasion or chemical peel¹⁵¹.

Furthermore, response rates to treatment have not been established; nor have regrowth rates (for hair

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¹⁴⁹Dr J A Cotterill BSc MD, The Management Of Tattoos With Lasers, Skinlaser Directory (produced by the Disfigurement Guidance Centre in the UK, available at:

<<http://www.skinlaserdirectory.org.uk/Tattoos.htm>>.)

¹⁵⁰See supra note 79.

¹⁵¹See Plastic Surgery Information Service at:

<http://www.plasticsurgery.org/surgery/lasersrg.htm>.

removal treatment) been accurately established and cannot be predicted due to a number of variables¹⁵². Indeed, results of laser treatment vary widely, and despite promotional claims by laser manufacturers, there is insufficient comparative data to determine if one type of laser is more effective and safer than another¹⁵³.

Results of resurfacing are also difficult to quantify. How do you measure improvement? Most studies have provided only subjective evaluation and no comparative objective data¹⁵⁴.

Accordingly, at present time, results can only be reviewed on a short-term basis, which includes evaluating such criteria as recovery, immediate cosmetic improvements, and complications. Gradually, over the years, results will need to be looked at on a long-term basis, which will include reviewing the longevity of the cosmetic improvements, and again, the complications¹⁵⁵.

Given that lasers have been rushed to the market without a full evaluation of their capabilities and limitations, it is important, if not vital, that researchers and practitioners publish their experiences and findings.

Fortunately, skin cooling and pain management techniques continue to be improved¹⁵⁶ although the risks of side effects have not been eliminated¹⁵⁷. Indeed, a consumer death was reported in 2001 due to a combination of pain medications prior to laser treatment¹⁵⁸.

C. Cultural Factors about our Society

As mentioned in the introduction, today, in our consumer-driven and time-demanding culture, for many, life is about finding the quickest and easiest way to do something. Lasers offer a 'quick-fix' enabling us to rejuvenate ourselves over a lunch break¹⁵⁹.

Demand and supply for laser treatment has been heavily influenced by the media. Among the public at

¹⁵²See Andrea James, Hairfacts: Lasers, at www.hairfacts.com/medpubs/lasermed.html and See supra note. Also, see id.

¹⁵³See Raulin C, Greve B, and Raulin S, Ethical Considerations Concerning Laser Medicine, *Lasers in Surgery and Medicine* 28:100-101 (2001).

¹⁵⁴See supra note 146.

¹⁵⁵See id.

¹⁵⁶See Haas AF, Use of a Unique Cooling Gel Applied Prior to Laser Hair Removal, *Surgery*. 2000 Nov;26(11):1045-6.

¹⁵⁷See supra note 130.

¹⁵⁸Jackman T, Man's Death After Visit to Clinic Spurs Suit, *Washington Post*, January 31, 2001, p.B1.

¹⁵⁹See Michael J.Ward, The History and Controversial Future of Refractive Surgery, SURE Program (1999) (available at http://www.sciencenet.emory.edu/undergrad/SURE/Articles/1999_art_ward.html).

large, the idea of laser treatment invokes ideas of painless, speedy treatment enabling us to attain beautiful unblemished skin with little effort. Indeed, thanks to the media, the laser has been given magical powers¹⁶⁰. Many people are convinced by the preliminary findings that these surgeries are safe and beneficial. Nevertheless, caution must be taken. As already mentioned, there is no long-term data on the effect of lasers. Nor are there comparable studies that would allow physicians to accurately predict what sort of effect these surgeries can have forty years from now¹⁶¹.

As one commentator notes:

*“the United States has a tendency to immerse itself in medicine that enhances life. Ironically, without proper testing and enough data, such life-enhancers can prove to be detrimental. Before anyone undertakes such a procedure whether it is for their eyes, their weight or their hair, they must realistically understand the implications of their undertaking.”*¹⁶²

Unfortunately, in today’s fast-paced society, most patients do not have the time or energy to do the necessary homework on the treatment they plan to undergo. As a result, the tendency is to trust the first laser physician a patient encounters. Objectivity is removed and the patient subjects him/herself to a limited perspective. An example is that of a physician who only uses one type of laser (and spent a great deal of money on it) who may neglect to inform the patient that another laser has been found to be more effective for the patient’s condition. Indeed, it is conceivable that some physicians may try to use the one laser they have so heavily invested in to treat a multitude of cosmetic complaints, which may not be in a patient’s best interests ¹⁶³.

D. Promotional Claims by Laser Manufacturers and the Need for Clinical Data

The massive public interest in lasers, and the patient’s demand for laser treatment have been fueled by the media, and more particularly, by effective advertising and marketing from the laser companies. As noted by laser researcher Christian Raulin, M.D.:

Laser companies, tattoo and cosmetic studios, as well as self-proclaimed laser institutes promote their work with full-page advertisements in newspapers and lifestyle magazines... It is not uncommon for the industry

¹⁶⁰For an interesting discussion on lasers and the media, see Raulin C, Greve B, and Raulin S, Ethical Considerations Concerning Laser Medicine, *Lasers in Surgery and Medicine* 28:100-101 (2001).

¹⁶¹Supra note 159.

¹⁶²See id.

¹⁶³See id.

*to advertise newly developed lasers for which the efficacy has not been determined by means of objective, randomized trials. When a laser is first marketed, there are thus no dependable data available from studies; instead, physicians must rely upon the often unfounded claims from the advertising literature.*¹⁶⁴

To many physicians, the rapid increase in demand for laser treatment offers a new source of income, as well as presenting a new pressure for them to buck the trend and to purchase a laser or risk losing out to competitors.

Unfortunately, however, promotional material from manufacturers and practitioners is often unreliable. It is common for the industry to advertise new lasers whose effectiveness has not been determined by objective clinical evidence. When a laser is first marketed, there is therefore no dependable data available and thus, physicians must rely on the unsubstantiated claims in the advertising material¹⁶⁵. Self-promotion is also common among laser practitioners, especially given that they have incurred significant expense for a new laser. The pressure to recoup such expense as well as an attempt to use the one laser for a number of treatments (when other lasers would be more effective) leads to a series of expensive, ineffective and, sometimes, unsafe treatments.

The laser industry is being driven by market forces, with minimum consideration being given to evidence-based medicine. There is little comparative data to allow physicians and their patients to make rational choices¹⁶⁶. This has led to the result whereby well-founded scientific studies are no longer the basis for the widespread use of lasers. Therefore, as noted by some commentators:

*“Careful clinical assessment cannot occur under such conditions, and the absolute opposite of the Hippocratic Oath to do no damage can easily be achieved.”*¹⁶⁷

Rox Anderson M.D., one of the pioneers in the field of laser dermatology, comments, that there is a big problem brewing:

¹⁶⁴Raulin C, Greve B, Raulin S., Ethical Considerations Concerning Laser Medicine. *Lasers in Surgery and Medicine* 28:100-101 (2001).

¹⁶⁵See *id.*

¹⁶⁶Laughlin SA, Dudley DK, Long-Term Hair Removal Using a 3-Millesecond Alexandrite Laser, *Journal of Cutaneous Medicine and Surgery* (2000) Apr;4(2):83-88. See Andrea James, Hairfacts: Lasers, at www.hairfacts.com/medpubs/lasermed.html.

¹⁶⁷See *supra* note 164.

“Unfortunately, there is relatively little good, hypothesis-driven research on lasers in dermatology. These studies are expensive and slow to perform, analyze, present, and publish. The laser companies are quick to promote their new devices and procedures, even before efficacy and safety are well established, and before a specific FDA clearance is given...

*But the problem lies mainly with us, the professionals. We should simply refuse to believe infomercials over peer-reviewed studies... Those industry salesmen who can't support their claims well, should be tolerated only as village idiots. In short, the patients are ours, and we should make better patient care the only real bottom line.”*¹⁶⁸

In a perfect world, the laser would be able to do what its makers claim it will do. However, as one commentator notes:

*“today laser salesmen tell you their lasers can do anything: figure out your taxes, improve your sex life, open your garage door. Don't buy this. Claims must be measured against proven performance”*¹⁶⁹.

The Federal Trade Commission and the Consumer Product Safety Commission, as well as a variety of other federal agencies, regulate the advertising of medical devices, including lasers, however, whether they can comprehensively regulate all the claims made by laser manufacturers is open to doubt.

Part of the reason why we have reached this position, is because of the ability of laser manufacturers to avoid the PMA process by using the substantial equivalence provision. This has led to unfortunate consequences in the medical laser industry with the majority of new lasers entering the market via this route to the detriment of the consumer given that in many cases, no clinical data has been submitted to the FDA as to the laser's safety and effectiveness. Indeed, focusing on substantial equivalence rather than absolute safety and effectiveness has led to laser manufacturers to design clinical and pre-clinical tests focusing on the question of substantial equivalence, rather than proving safety and effectiveness¹⁷⁰. Surely, efforts would be better spent researching absolute safety and effectiveness given that this is the main patient concern¹⁷¹.

In an interview with Dr Larry Bass¹⁷², he notes that most cosmetic lasers today have been marketed via

¹⁶⁸Rox Anderson, M.D., Lasers in Dermatology: A Critical Update, Journal of Surgery and Medicine. 2000 Nov;27 (11): 700-5; and Rox Anderson, M.D., Response to Letter to the Editor, Lasers in Surgery and Medicine 28:102 (2001).

¹⁶⁹See Barry A. S. Lycka, Shaping a New Image: The Practice of Cosmetic Surgery, Chapter 13 (1st ed. 1999).

¹⁷⁰Indeed, the FDAMA reinforces this focus by instructing the FDA to limit its clinical data submission requirements only to information related to substantial equivalence. See 21 U.S.C. §360c(i)(1)(D) and Richard Cooper etc, see supra note 63.

¹⁷¹See supra note 63, Richard Cooper etc.

¹⁷²Interview with Dr Lawrence Bass. M.D., F.A.C.S on 31 January 2002 at his New York clinic. Dr Bass is Co-Director of

the substantial equivalence procedure and not through the PMA process, with the result that no clinical testing has been done on lasers employing this procedure (laser manufacturers generally not being required to submit clinical data). Indeed, even on the relatively few occasions when clinical testing on a new laser is done, and when clinical data has been submitted to the FDA by a laser manufacturer, such data (including any test results) is generally not made available (either to the public or to practitioners). Larry Bass notes that most laser manufacturers do not like disclosing such test results for fear of competition.

As will be discussed later, most laser manufacturers are relatively small and specialized compared to other companies within the medical device industry. Many laser manufacturers obtain funding from venture capitalists who, as a condition of financing, oblige the manufacturer to either repay the loaned funds or generate minimum revenues within a short-time frame (between 2-5 years). Given such financial pressures, laser manufacturers have a strong incentive to market the device as quickly as possible and to avoid spending substantial time and incurring costs to engage in clinical studies that would require long-term follow-up (in any case, most laser companies due to their relatively small size do not have the finances to fund clinical research)¹⁷³. Indeed, as Larry Bass notes, another important consequence of the lack of clinical testing is that lasers are not optimized for human application when first placed on the market.

E. The Unregulated Use Of Lasers

As mentioned above, the FDA regulates medical devices on the basis of their manufacturing and distribution, and not on the basis of the use of such devices by physicians. The so-called “practice of medicine” doctrine¹⁷⁴, which provides that the FDA lacks authority to regulate treatment practices by licensed physicians, effectively allows licensed practitioners to use any legally marketed device for any indication, even if that indication is not approved specifically for that device – off-label use is thus allowed giving the physician a wide latitude in treatment options¹⁷⁵. Significantly, the FDA does not distinguish between the off-label use of drugs and devices¹⁷⁶.

the Center for Minimally Invasive Plastic Surgery at the Institute of Reconstructive Plastic Surgery at NYU Medical Center. He also currently sits on the Device and Technique Assessment Committee of the Plastic Surgery Educational Foundation and has served on the Board of Directors of the American Society for Lasers in Medicine and Surgery.

¹⁷³See *id.*

¹⁷⁴See *supra* note 56, John J. Smith, Physician Modification etc.

¹⁷⁵See *Buckman Co. v. Pls, Legal Comm.*, 121 S. Ct. 1012, 1018 (2001): “ ‘Off-label’ usage of medical devices . . . is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.”

¹⁷⁶See FDA., 1991 FDA COMPLIANCE MANUAL, No. 7292.900.

Indeed, the FDAMA explicitly recognized the practice of medicine doctrine by providing that:

*“Nothing in this Chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship”.*¹⁷⁷

As Dr. Smith, M.D, Assistant Radiologist at Massachusetts General Hospital, states:

*“The practice of medicine doctrine stands firmly for the proposition that regulatory efforts are directed primarily at device marketing by manufacturers, not device use by physicians. Under the doctrine, a licensed physician enjoys wide latitude in the treatment use of a physician-modified product . . .”*¹⁷⁸

This is particularly significant for lasers. Given the cost of lasers, and the fact that such lasers often become outdated given rapid developments in the area, physicians, only able to afford, one or two cosmetic lasers, have the incentive to use the lasers for a variety of patient conditions rather than go to the expense of purchasing a specific laser that would best treat the patient condition¹⁷⁹.

As the FDA does not regulate the practice of medicine, medical practice in the US is generally regulated at state level via state licensing of healthcare professionals¹⁸⁰.

States regulate who can use lasers for various therapeutic procedures. But Class 2 and 3 medical lasers are prescription devices available for sale only to “licensed practitioners”. It is therefore up to each state to determine who qualifies as a licensed practitioner, including what training, if any, should be required.

However, inconsistencies occur in the US given that each state’s medical licensing board determines who qualifies as a licensed practitioner in their state¹⁸¹. Physicians, electronologists, and beauticians have all claimed permission to use lasers, but its up to each state to decide¹⁸².

¹⁷⁷See 21 U.S.C. § 396.

¹⁷⁸See supra note 56, John J. Smith, Physician Modification etc.

¹⁷⁹A reported example of this is the use of lasers designated for the treatment of port-wine stains (red/pink birthmarks) to treat brown café-au-lait marks (which generally requires a more specific laser to remove the melanin produced by a café-au-lait mark).

¹⁸⁰See 37 Fed. Reg. 16,503 (1972) and the preamble to the Final Rule Regarding New Drug, Antibiotic, and Biologic Drug Regulations, 52 Fed. Reg. 8803 (1987); Stuart L. Nightingale, Unlabeled Uses of Approved Drugs, 26 Drug Info. J. 141 (1992). See more generally, supra note 56, John J. Smith, Physician Modification etc.

¹⁸¹See supra note 78, CDRH, Laser Facts, May 2001.

¹⁸²Crawley M.T. & Weatherburn H., Application of Regulations to Cosmetic Lasers in Private Practice, Journal of Radiological Protection. 2000 Sep;20(3): 315-9.

More significantly, Larry Bass notes that the requirement is only for the treatment to be ‘supervised’ by a licensed practitioner, and therefore the treatment itself can be performed by anyone without the licensed practitioner even being present ¹⁸³. According to reports, many places that offer laser treatment claim that it is done under the supervision of a physician; however, in some cases the physician may not be on site when a technician performs the procedure ¹⁸⁴.

One of the main areas of concern within the laser industry is the use of lasers by unregulated and unqualified ‘practitioners’. Indeed, unqualified people are flooding the cosmetic laser market which, in itself, presents a grave risk to consumers.

One commentator notes that as with x-ray use 100 years ago, “use of dermatological lasers is in danger of being rapidly debased into a cosmetic procedure”¹⁸⁵. Self-proclaimed “laserologists” have set up “training institutes” for beauticians and other non-physicians. Some even offering laser treatment to consumers without direct medical supervision¹⁸⁶. The increased availability of lasers to non-physicians will increase the likelihood of injury and quackery.

As noted by Christian Raulin, MD:

“Anyone, including healers, hair stylists, tattoo artists, and cosmeticians, can buy lasers and then advertise for their services. There are no legal requirements for training, no quality control measures, no official quality standards of guidelines . . . We must demand the extensive scientific evaluation of new and existing systems; objective and trustworthy marketing by laser manufacturers; well-founded training for laser operators; and legislation which restricts the use of lasers to physicians alone.” ¹⁸⁷

Indeed, given the investment involved by laser manufacturers in marketing a laser, they are so eager to sell their lasers that they stage one- or two-day training courses, which has led to the situation that now dentists, obstetricians, gynecologists, and family doctors are offering laser surgery¹⁸⁸.

Unlicensed practitioners cannot assess skin types, nor develop an understanding of how lasers affect the skin.

¹⁸³See supra note 172.

¹⁸⁴See Laura Meade Kirk, “First Razors, Now Lasers”, South Coast Today, 20 April 1999.

¹⁸⁵See supra note 130.

¹⁸⁶See id.

¹⁸⁷Raulin C, Greve B, and Raulin S, Ethical Considerations Concerning Laser Medicine, *Lasers in Surgery and Medicine* 28:100-101 (2001).

¹⁸⁸Tina Alster, M.D., director of the Washington Institute of Dermatological Laser Surgery. See supra note 79.

In the weekend courses offered by some laser manufacturers, very little practical training is given and no mention is made of potential complications and how to deal with them¹⁸⁹. Instead, as Raulin et al notes, “hands-on training is performed on apple and orange peels under the guidance of so-called ‘specialists’”¹⁹⁰.

According to Richard Felten, a senior reviewer in FDA’s Center for Devices and Radiological Health:

*“The person planning to do laser surgery must understand the basic physics of how laser energy is absorbed by tissue and how tissue responds. Then that person should go where the surgery is performed and watch a skilled surgeon use the equipment”*¹⁹¹.

Ideally, the best people to use lasers are the dermatologists and plastic surgeons who best understand skin and surgery of the skin.

Indeed, as Tina Alster¹⁹² notes:

*“sometimes people may choose the wrong laser, or a surgeon may believe more is better, which can lead to significant burning.”*¹⁹³

Without an understanding of the basic physics of how laser energy is absorbed by tissue and how tissue responds, as well as an understanding of dermatology generally, fatal mistakes can be made by an untrained or rogue laser users.

Accordingly, problems and complications do not generally happen with dermatologists and plastic surgeons, but occur with nurses, beauticians and other unqualified users who take crash weekend courses and rent laser equipment that they are not familiar with (especially where the rental equipment tends to be older and not tuned up)¹⁹⁴.

¹⁸⁹See id.

¹⁹⁰See id.

¹⁹¹See supra note 79.

¹⁹²See id.

¹⁹³See id.

¹⁹⁴See Rose Palazzolo, Do You Rent or Own, ABC News, April 18, 2001 (available at: http://abcnews.go.com/sections/living/DailyNews/laser_risks010418.html).

The American Society of Plastic Surgeons acknowledge a death rate of 1 patient per 57,000 surgeries (not limited to laser surgeries), and that 0.5% of patients develop serious complications. Some argue that as such treatment is optional (the patient not being ill or diseased), even this relatively low rate of death or injury is unacceptable¹⁹⁵.

As regards differing state regulation across the US, this also presents a problem, given that residents of different states receive different standards of care depending on their state's credentialing policy for laser practitioners. Rhode Island, for example, requires that all electrologists be licensed. To obtain a license they must go to school, serve an apprenticeship for 650 hours, and pass a national exam¹⁹⁶. But, like many states, Rhode Island has no such regulations or licensing requirements for people using lasers and laser-like devices for hair removal¹⁹⁷. In comparison, New Jersey provides that all laser treatments must be performed by an MD¹⁹⁸.

Nevertheless certain states have passed laws relating to the ownership, registration, and use of lasers¹⁹⁹. However, state law varies considerably in this area so that one would need to review the laws of their particular state.

Furthermore, as physicians must effectively police themselves, the doctor may need to discourage patients from treatment when such treatment would be detrimental no matter how much the patient wants it. If a patient has low self-esteem, they may never be happy no matter what you do – they may need counseling more than surgery²⁰⁰.

Despite the FDA regulating the marketing of lasers for the specific indications requested, the FDA can only recommend training needed to operate the lasers. Credentialing is a state function, since states are responsible for the licensing of doctors and nurses, and standards for laser training vary from state to state. To date, no national policy exists for credentialing those planning to practice laser surgery²⁰¹, nor is there any single agency or authority which provides laser certification or credentialing of physicians.

¹⁹⁵See Judith Gaines, Body Works, The Boston Globe Magazine, February 6, 2002.

¹⁹⁶Laura Meade Kirk, "First Razors, Now Lasers", South Coast Today, 20 April 1999.

¹⁹⁷See id.

¹⁹⁸See supra note 172.

¹⁹⁹See John R. Irwin MD, Legal Aspects of Lasers, April 30, 1999 (available at <http://www.lawyerdoctor.com/lasers.htm>).

²⁰⁰See Body Works, The Boston Globe Magazine, February 6, 2002.

²⁰¹See supra note 79.

Despite this, some positive developments have occurred. National Council on Laser Excellence has been formed to provide voluntary certification of laser service engineers, laser operators and laser safety offices (although this Council does not address the certification of physicians)²⁰².

The American National Standards Institute has promulgated a variety of standards with respect to medical devices. There are currently proposed standards relating to the medical use of lasers²⁰³ which, if adopted uniformly across America, will have significant effect on the industry.

A further problem that is unfortunately ignored in the laser industry is that very few clinics have the facilities to offer a comprehensive care program for patients undergoing laser treatment, including having staff qualified in administering general anesthesia or sedating the patient, as well as offering CPR. Nor do many clinics provide adequate post-operative care, especially to those patients who have extensively damaged skin due to laser treatment²⁰⁴. Resuscitation equipment should be available in all establishments using lasers, as well as having staff fully conversant with resuscitation techniques.

A recent story in the Washington Post reported the death of a 20-year old man who suffered an allergic reaction whilst undergoing treatment for laser hair removal. According to the report, at the moment of crisis, no suitably qualified doctors were around in the clinic to administer CPR or other lifesaving treatment that could have saved the patient ²⁰⁵. There have been other reports of severe anaphylactic shock following laser treatment.

The above story illustrates the dangers of inadequately staffed and ill-equipped clinics that provide laser treatment.

F. The Laser Industry Itself and Financial Pressures: Just Big Business?

Lasers are extremely expensive to own and operate, costing between \$30,000 to \$250,000 (vision correction lasers cost \$500,000!), and some doctors own several, with up to a million dollars invested in their equipment. The technology changes so rapidly that in a few short years the equipment becomes outmoded and has to

²⁰²See The Laser Training InstituteTM, About Credentialing (available at <http://www.lasertraining.org/about.htm>).

²⁰³See ANSI Z136.1. See also supra note 194, John R. Irwin MD, Legal Aspects of Lasers.

²⁰⁴See supra note 200.

²⁰⁵Tom Jackman, Man's Death After Visit To Clinic Spurs Suit, The Washington Post, January 31, 2001, p.B01.

be replaced.

The costs of buying and operating a laser are enormous. Furthermore, given this expense, most laser practitioners and clinics can only afford one laser, which necessitates them choosing the “right” laser from a wide selection of ever-increasing lasers. Unfortunately, there is no “universal laser” that will work for every condition²⁰⁶, yet once a laser has been purchased, practitioners have a financial incentive to use that laser as often as possible and to treat as many conditions as possible to the detriment of the consumer patient (especially where alternative treatments would be safer and more effective, as well as less costly)²⁰⁷.

Furthermore, like personal computers, lasers become outdated within a very short time with technical developments in the field taking place daily. As one commentator notes: “before the first payment has been made, there are already better, higher-performance alternatives which are often more expensive than the earlier models”²⁰⁸. Yet, very few practitioners or clinics have the funds to regularly expand their armory of lasers. Some clinics rent laser equipment giving them access to the lasers they need. However, this option is highly impractical. Careful planning and coordination is needed to manage patient appointments and visits. Further, to be economical, a laser clinic must ensure it has a minimum number of patients to be treated by a particular laser on the day it rents out that laser, which may encourage the liberal use of the laser for a variety of conditions outside the laser’s labeled indications²⁰⁹.

Furthermore, given that each laser is unique, those renting lasers will not always be able to attain the detailed knowledge and significant hands-on experience required for each laser. Indeed, being an intermittent laser surgeon, as one laser researcher puts it, “is like trying to be an electrician on the weekend after taking a crash course in the past”²¹⁰.

By way of an example, the cost for a LASIK laser is approximately \$2,500 per eye. LASIK is big business in the American corporate world. Lasers cost approximately \$500,000 and run about \$90,000 annually in maintenance costs. One company that produces such equipment called VISX has a market capitalization of \$3.5 billion dollars. This means that all of VISX’s stock is worth this dollar amount. In fact, the recent

²⁰⁶See supra note 159.

²⁰⁷See id.

²⁰⁸See id.

²⁰⁹See supra note 194, ABC News, April 18, 2001.

²¹⁰Dr. David Goldberg, Director of Laser Research at Mount Sinai School of Medicine (quoted in ABC News Report on April 18, 2001 – see id).

run-up in VISX's stock price over the past year combined with the lofty price-to-earnings ratio of 100 that it carries, suggests that shareholders expect this company to earn a lot of money. For investors to pay such an expensive price for a stock, indicates that people expect VISX to continue to make as much money in the future as they have in the past ²¹¹.

However, many laser companies are experiencing financial troubles. Premier Laser System (mentioned above) has been experiencing financial troubles necessitating it to petition for reorganization under Chapter 11 of the Bankruptcy Code in March 2000²¹². Similarly, American Dental Technologies is experiencing falling revenues and profits²¹³.

Indeed, according to EyeNet Magazine (an official journal published by the American Academy of Ophthalmology), the LASIK market is experiencing hard times. Large laser eye centers offering discount prices, like LASIK Vision and Icon Laser Centers, have been experiencing financial troubles and have been gradually reducing the price for laser vision correction, so that in some markets, it costs \$500 for treatment. Unfortunately, as a result of falling prices due to increased competition within the industry, profits for such companies and their competitors plummet²¹⁴. According to industry analysts, times are desperate for many laser centers²¹⁵. There are numerous reports of financial troubles in the laser industry²¹⁶.

The pressure to sell lasers has never been so great.

A good example serves to illustrate the problem. According to a report in the Business Journal of Tampa Bay²¹⁷, Sunshine Laser Centers Inc, which competed for business in the LASIK procedure, went bankrupt within a year of joining the market and has filed Chapter 11 bankruptcy protection in U.S. Bankruptcy Court, Middle District of Florida,

²¹¹See Michael J.Ward, The History and Controversial Future of Refractive Surgery, SURE Program (1999) (available at http://www.sciencenet.emory.edu/undergrad/SURE/Articles/1999_art_ward.html).

²¹²See Premier Laser System Press Release at: <http://www.premierlaser.com/pressreleases/bankruptcyannouncement.htm>.

²¹³See American Dental Technologies Quarterly Report for May 2001 at: <http://biz.yahoo.com/e/010515/adli.html>, and ADL's Income Statement as of September 30, 2001 at <http://biz.yahoo.com/fin/1/a/adli.html>.

²¹⁴See EyeNet Magazine, April 2001 at: http://www.aao.org/eyenet_mag/04_01/news.html.

²¹⁵per Al Kildani, a medical services and technology industry analyst at Pacific Growth Equities in San Francisco. See id, EyeNet Magazine..

²¹⁶See for example, LaserVision Centers Inc Press Release on April 4, 2001 at <http://ir.laservision.com/news/20010404-42903.cfm?t=n>; Investor's report on Pro-Laser at http://www.stockpole.com/Analyses/prolaser_4.htm; USA Today, 7 February 2001, at : <http://www.usatoday.com/community/chat/2001-06-29-sumers.htm>.

²¹⁷Sarah Fanous-Samaan, Business Journal of Tampa Bay, January 12, 2001. See: <http://tampabay.bizjournals.com/tampabay/stories/2001/01/15/story1.html>.

Tampa Division. Court records show that Sunshine estimated its debt between \$1 million and \$10 million. Sixty-five entities and potential creditors were served with notice on December 23²¹⁸.

Of significance, the Business Journal reports that:

*“The Chapter 11 filing spawned speculation that Sunshine succumbed to price competition that requires massive patient volume to sustain the high overhead of running a LASIK practice.”*²¹⁹

Dr. Byron E. Holley, who operated at Sunshine Laser as the chief surgeon and medical director, stated that:

*[Laser] businesses start up and . . . fail. When you see people willing to do it (the LASIK procedure) for \$499, you have to wonder. The business is very money-driven right now. The amount of competition in this area had to be a factor. We are saturated.*²²⁰

Fierce competition surrounds the laser industry. It is a crowded market, and a medical practice is a business. You have to be profitable to provide care. It is indeed a challenge for all medical practices in today’s environment. Sunshine’s bankruptcy filing mirrors situations of other health care providers in the business. Expensive equipment and high overheads (especially given the pre- and post-operative care that is required), not forgetting the costs of advertising and marketing the laser itself present severe financial obstacles to any company contemplating entering the laser industry. This, combined with the competitive nature of the industry which has driven down prices (as well as encouraging price slashing) to historically low levels, has led to increased emphasis on volume and ‘getting patients through the door’. Now consumers are bombarded with aggressive advertisements, from newspapers and over the airwaves, with claims of better prices and better surgeons²²¹.

Indeed, given the nature of laser treatment, which unlike other medicine, treats the patients’ subjective self-image and not objective symptoms of disease, doctors in the field wish to ensure the patient is subjectively happy. With laser treatment, it is not diseased skin which is treated, but rather it is healthy skin which is damaged on the patient’s request²²². As Dr. Christian Raulin MD et al notes:

²¹⁸See id.

²¹⁹See id.

²²⁰See id.

²²¹See id.

²²²See supra note 164, Raulin et al.

*“The inevitable conclusion is that the happiness of the patient, which is of course subjective, becomes the center of medical attention, as opposed to the goal of restoring and maintaining health in the Hippocratic sense.”*²²³

Furthermore, if the patient determines his/her treatment, the doctor arguable becomes a vendor in a business transaction motivated only by profit and the need to keep the patient happy, at the expense of the doctor’s fiduciary responsibility to the patient²²⁴.

Raulin et al pessimistically conclude that:

*“If financial pressure coerces physicians into treating patients using lasers against their better knowledge or judgment, they will sell their souls to cosmetics and commerce.”*²²⁵

CONCLUSION

Unfortunately, as there are no official statistics of adverse reactions from laser treatments or of surgeries that have actually gone wrong due to the fault of the practitioner, it is difficult to get a sense of how significant the problems of laser surgery are.

Certainly, one of this paper’s goals was to highlights the dangers inherent in the unregulated cosmetic laser industry, and although not specifically advocating a need for regulation both of the laser industry itself and of those qualified to use lasers, this is implicit throughout.

However, one must be careful not to castigate the industry without objective evidence. Properly-tested and approved lasers, in the right hands, are a fantastic tool to genuinely help both those suffering from cosmetic deformities, as well as those just wanting a little boost to their self-image. It is however, inevitable, that developing technologies should be subject to proper scrutiny from the FDA, and medical authorities, before

²²³See id.

²²⁴See id.

²²⁵See id.

they are allowed out into the market. The substantial equivalence procedure does not provide this adequate level of scrutiny.

There is an important need for scientific evaluation of lasers based on evidence collected from objective third-party clinical trials over a long-term period. This, together, with established training programs instigated by appropriate medical boards on a federal basis, and legislation restricting the use of lasers to appropriately qualified physicians, should help ensure that the laser becomes a justifiably popular and potent tool for the foreseeable future.

A concluding quote from an expert would be appropriate:

*“In good hands, lasers are among the safest, most effective, unique, useful tools we have for treating skin. When oversold or misused, lasers are just another way of courting disaster. . . . The sky is not falling (yet). But what can be done about the decrepit standards for quality of introducing new aesthetic laser applications? Somewhat tighter FDA regulation for the 510k process of clearing devices might help. . . . But the problem lies mainly with us, the professionals. We should simply refuse to believe infomercials over peer-reviewed studies. We don’t have to buy every latest gadget appearing in cosmetic magazines. Those industry salesmen who can’t support their claims well, should be tolerated only as village idiots . . .”*²²⁶.

²²⁶Dr Rox Anderson MD, Letter to the Editor, Lasers in Surgery and Medicine 28:102 (2001)