
The Medi-Spa: A Current Cosmetic Dermatology Public Safety Concern

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Abstract

Medi-spas (aka: medical spas) are currently under much crossfire due to many illegally operated facilities opening up all over the country and overseas. While there are many that operate legally under current law, there are others that continue to perform medical procedures without the supervision of physicians or other licensed providers, such as nurse practitioners and physician assistants. This constitutes a significant patient safety issue in the US and abroad. While there are no national standards for medi-spas, there is debate surrounding legislation in California, where lack of physician supervision is being addressed. However, this legislation is being met with much opposition. Implementation of this legislation will be met with great obstacles, such as, the sheer magnitude of the problem and financial limitations. With patient safety at its heart, this legislation is well worth the effort.

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INTRODUCTION

Since the advent of modernized dermatologic and cosmetic medical practice, licensed and non-licensed healthcare professionals have been vying for a piece of these lucrative “cash-cow” industries. Cosmetic dermatology, in particular, has generated enormous revenue as a result of every “Tom, Dick, and Harry” looking to cash in on the seemingly feverish thirst for eternal youth.

According to the American Society of Aesthetic Plastic Surgery, one of the Board Certified Plastic Surgeon Associations, the number of cosmetic procedures went from 1.1 million in 1997 to 11.5 million in 2007 (Rodeo Drive Plastic Surgery [RDPS], 2008).

This has resulted in the creation of the “medi-spa” concept and the trend of physicians, not board certified in dermatology, to open practices in cosmetic dermatology. This trend has not spawned without significant patient safety

concern.

Indeed, as a result of this infant industry taking off so quickly, there has been very little time for governmental laws and regulations that control the delivery of such care to catch up with demand. Moreover, many skilled and not so skilled technicians are essentially practicing medicine without a license, delivering potentially dangerous laser treatments and chemical peels, injecting non-FDA approved medicines, and making quasi-diagnoses all without physician supervision. Without state medical board oversight, results of this kind of practice have had disastrous outcomes. Take for example one 22-year-old college student who suffered a coma and died after applying a local anesthetic cream from a North Carolina laser clinic while preparing for her laser removal treatment (Fashionista, 2008).

Currently, there are only limited and nebulous governances regarding this kind of dermatologic practice. This leaves enormous potential for medical error and patient detriment.

According to The American Society for Aesthetic Plastic Surgery, “...there are no national standards for medi-spas, no recognized definition of what constitutes a medi-spa, and no oversight organizations that provide the information you

need to make an informed, safe choice for your medi-spa experience”(ASAPS, 2008).

California Assembly Bill 2398 has been the topic of much heated debate between California board-certified dermatologic physicians and medi-spa owner/operators (Nakanishi, 2008). This legislation is sponsored by the American Society for Dermatologic Surgery. AB 2398 would require that all medi-spas be medically supervised by physician staff. On one side of the argument stand physicians opposed to unregulated operation of medi-spas without direct, on-site medical doctor supervision. They argue further that the operation of such facilities is in direct violation of current laws that protect consumers from the unlawful practice of medicine. In opposition to this argument stand medi-spa owner/operators who feel that their livelihood is at stake should AB 2398 pass and they are forced to close their doors. Physicians in favor of AB 2398 proclaim that patient safety is at the heart of their push for such legislation. Medi-spa owners debunk this argument, proclaiming the motivation behind such sponsorship is politically driven; that they are only trying to corner a larger market share (Barson, 2008).

Not only are spa owners concerned about passage of such legislation, the Manufacturers of Equipment for Light-Based Aesthetics, a trade association of manufacturers of laser and intense pulse light devices for aesthetic skin care services, states that this bill is “broad and vague,” and believes that proper training for all users of light-based cosmetic devices is the key to ensure safety regardless of facility ownership (Nakanishi, 2008).

This ongoing debate only underscores the obvious importance of and need for a working oversight committee on patient safety regarding the delivery of such dermatologic services. Everyone involved in this industry needs a clearer understanding of scope of practice, more specifically, which procedures constitute the enlistment of physician staff and which procedures can be administered by technical staff, without need for specific diagnosis and physician supervision. Patient safety hangs in the balance, as lawsuits pile up in direct relation to lack of such understanding and control of daily business operations.

INTERNET LITERATURE REVIEW

Information abounds on the internet regarding patient safety and the medi-spa. While most of this information is anecdotal, sifting through the available resources brings to light certain key safety points. These key points will be

discussed later. Currently, there exists no evidence based, single source document which governs the operation of medi-spas. Furthermore, every state operates very differently from the others. In most states, any licensed physician can open a medi-spa, regardless of his or her residency training or board certification. This leaves room for huge disparity in how things are done clinically. As Florida physician, Dr Michael Sinclair points out, “a blind psychiatrist sleeping in the back of the medi-spa technically allows the medspa to do every procedure you can think of” (realself.com, 2008).

The American Society for Aesthetic Plastic Surgery (ASAPS) and The American Society of Plastic Surgeons (ASPS) have, perhaps, the most succinct standard by which consumers should conduct their research on how to find a relatively safe and effective medi-spa. Their website helps consumers ask the right questions before deciding on the right medi-spa. For example, is the spa located within a physician’s office? What are the credentials of the physician supervising your treatment at the spa?

Many internet forums exist where physicians, midlevel practitioners, and lay-persons can discuss current trends in medi-spa operations, laws, and trends. One such site is Medical Spa MD (MSMD). This forum is run by a community of physicians in cosmetic medicine. This author found MSMD to be the most comprehensive and medically sound forum available. MSMD has its hand on the pulse of the current state of affairs regarding regulation and oversight of medi-spas. One recent article covered the current California debate on AB 2398, as mentioned above. Within this very popular forum, the many varied opinions stated regarding this assembly bill are a good starting block from which legislators and law-makers can hear the voice of California.

The British are in the same predicament as the US. One useful website regarding the current state of medi-spa affairs in England is run by the British Association of Aesthetic Plastic Surgeons. Last year the BAAPS website ran an article educating and warning consumers to many of the same US concerns regarding medi-spa practice (BAAPS, 2007). The British are dealing with the same overwhelming rise of independently run and operated medi-spas proliferating across the country which may be found in spas, salons, and even retail outlets such as department stores (BAAPS, 2007). They are finding the same issues regarding medical treatments being rendered without proper physician supervision.

In response to the enormous and often over-indulged US appetite for cosmetic perfection, WebMD published an article in its Skin and Beauty section last year entitled, "How Much Is Too Much?" (Meredith, 2007) This very informative and entertaining article addressed the on-going trend of over-bleaching, tweezing, Botoxing, lasering, peeling, and filling the skin to the point of mask-like appearance. According to its author, "The craze in upkeep has women so hooked doctors and industry pros are now turning them away" (Meredith, 2007).

LITERATURE REVIEW

A survey conducted by University of Texas authors found that 55 percent of Texas physician respondents felt that laser procedures should be conducted by physicians only (Rohrich & Burns, 2002). An overwhelming 91 percent felt a patient should be seen by a physician before treatment to evaluate that patient for a specific laser treatment or procedure (Rohrich & Burns, 2002). While there are no accreditation standards for laser procedures in the state of Texas, this survey is being used in collaboration with the Texas Society of Plastic Surgeons and the Texas State Board of Medical Examiners to establish guidelines in this area (Rohrich & Burns, 2002).

Another example of non-plastic surgeons employing injectables in their practice was described by ophthalmologists John Mandeville and Peter Rubin (Mandeville & Rubin, 2004). According to the authors, "[these] experts in the upper half of the face will be involved in periocular rejuvenation and its complications" (Mandeville Rubin, 2004). This informative piece of literature was written specifically to educate ophthalmologists in the practice of applying injectables. This education is very detailed and includes knowledge in pharmacokinetics, pathophysiology of disease leading up to the necessity for such procedures, performance of the procedures, and managing complications resulting from rendering such procedures. This paper serves as a great example of what literature should exist for physicians across all sub-specialties who wish to break into the field of cosmetic dermatology.

There is current debate regarding what type of surgical training dermatologist should receive in order to conduct procedures such as hair replacement, tumescent liposuction, soft tissue augmentation, fat transplantation, wound closure techniques, grafts, and flaps. In New Orleans, a proposed yearlong postgraduate year (PGY) 5 fellowship in

dermatologic surgery for dermatologists has raised objections from the American College of Surgeons (ACS) (Lamberg, 2002). The residency review committee for dermatology seeks approval of the fellowship by the Accreditation Council for Graduate Medical Education (ACGME). ACGME accreditation would establish uniform educational quality standards across programs. The existence of such programs has caused a turf war with surgeons from other fields such as, otolaryngology and plastic surgery. These surgeons claim that one additional year of post residency training in surgery isn't enough time to make competent dermatologist/surgeons.

In a similar vein, England's National Health Service (NHS) has established the "General Practitioners with a Special Interest" program (GPSI) (Lawrence, 2003). This program rises from a lack of dermatologists in the country and increased wait times for patients to see dermatologists. Sometimes patients are forced to wait months to see a dermatologist. This paper summarizes the British Association of Dermatologists' (BAD) view on how GPSI services should be organized and training and supervision implemented. As in the American based PGY 5 fellowship for dermatologists, questions arise as to the scope and practice of GPSIs. In England, GPSIs will more likely work as assistants on dermatologic teams, rather than in solo practice settings (Lawrence 2003). This system is much akin to the US medical model wherein board certified dermatologists supervise physician assistants and nurse practitioners. Such a system augments the providing of patient safe services to large populations without increased medical costs.

Australians are also facing the same concerns. A shortage of dermatology trained specialists has opened the possibility of general practitioners to practice in the field of dermatology. In Australia the emergence of "Skin Cancer Clinics" has caused debate regarding the level of expertise necessary to run such clinics (Wilkenson, Bourne, Dixon, & Kitchener, 2006). As in England and the US, there are no set standards for credentialing these physicians who practice in this area of medicine. As a result of this on-going debate and national need, the University of Queensland, School of Medicine has developed a masters degree in skincare medicine to help elevate the credentials standard necessary to provide this kind of care. As in England and the US, there is serious concern on the part of board certified specialists in the fields of dermatology and plastic surgery regarding issues of encroachment on their domains of practice (Wilkenson,

Bourne, Dixon, & Kitchener, 2006).

PRESENT STATUS OF PATIENT SAFETY PRACTICE

As stated above, there currently is no one oversight committee or doctrine governing the practice of medical aesthetics in the US. Currently any licensed physician or surgeon can perform surgical or non-surgical cosmetic procedures whether or not they have had the proper specific training associated with certain techniques, machinery, medicines, and devices. This glaring hole in the infrastructure of modern medicine is placing patient safety in jeopardy. Until this trend is carefully examined and rectified, more patients will succumb to medical mishap and poor patient outcomes. This unfortunate set of facts, coupled with lack of technician supervision, is recipe for disaster.

EXPLORATION OF THE PATIENT SAFETY LANDSCAPE

Implementation of a national, comprehensive, and legally binding patient safety act regarding the operation of medi-spas is an enormous undertaking. Just when a national legislative body thinks they have the answer that will satisfy everyone involved, new local, ethical, or cultural issues will arise, thus further stirring the debate and slowing the process of moving toward consolidated agreement on standards. Moreover, techniques and technology race forward at a pace faster than any governing body geared to regulate their implementation and use. For this and many other reasons, this author believes that standards can only be realized at the state level. For now, this seems the only reasonable approach, given the complexity and ever changing landscape of the issue. As evidenced by the on-going debate in California on AB 2398 it appears that the state level is where these issues must first be worked out before any national consensus can be met. After all, each state has its unique set of issues and needs surrounding the dilemma.

THE MEDI-SPA DEFINED

It is important to describe certain common characteristics among medi-spas. This understanding will be important when conceptualizing an improved system of care. Although no concrete definition exists of what constitutes a medi-spa, the term medi-spa (short for “medical spa”) could loosely be defined as an establishment in which patients may undergo certain therapeutic treatments under the supervision of a licensed health care professional, such as a medical doctor or mid-level practitioner. Services in these facilities may commonly include the following: laser and intense pulsed

light procedures, medical microdermabrasions, photo-facials, Botox and Restylane injections, and medical peels (Wikipedia, n.d.).

The term medi-spa needs to be distinguished from “day spa.” The terms do not mean the same thing, but are often misused synonymously. A “day spa” is different from a medi-spa in that medical services requiring medical supervision may not be rendered. Services commonly performed in the “day spa” setting are: facials, massage; waxing, body treatments such as body wraps, aromatherapy, salt scrubs, and skin exfoliation—including chemical peels and non-medical microdermabrasion (Wikipedia, n.d.).

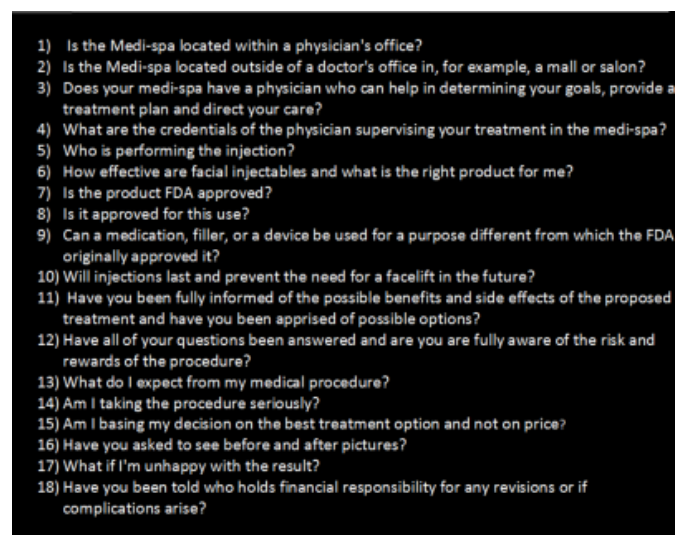
CONSUMER EDUCATION

Of course, there are many spas that have characteristics of both. This is where laws and regulations governing these facilities are either intentionally or unintentionally broken. ASAPS has provided protection guidelines that consumers should follow when searching for legitimate medi-spas. They have created a comprehensive list of questions to ask when researching medi-spas.

These questions are found in Table 1.

Figure 1

Table 1: Patient Safety Advisory on Medi-spas. Adapted from The American Society for Aesthetic Plastic Surgery (2008). From <http://www.surgery.org/public/consumer/tips/medispas>

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- 1) Is the Medi-spa located within a physician's office?
 - 2) Is the Medi-spa located outside of a doctor's office in, for example, a mall or salon?
 - 3) Does your medi-spa have a physician who can help in determining your goals, provide a treatment plan and direct your care?
 - 4) What are the credentials of the physician supervising your treatment in the medi-spa?
 - 5) Who is performing the injection?
 - 6) How effective are facial injectables and what is the right product for me?
 - 7) Is the product FDA approved?
 - 8) Is it approved for this use?
 - 9) Can a medication, filler, or a device be used for a purpose different from which the FDA originally approved it?
 - 10) Will injections last and prevent the need for a facelift in the future?
 - 11) Have you been fully informed of the possible benefits and side effects of the proposed treatment and have you been apprised of possible options?
 - 12) Have all of your questions been answered and are you are fully aware of the risk and rewards of the procedure?
 - 13) What do I expect from my medical procedure?
 - 14) Am I taking the procedure seriously?
 - 15) Am I basing my decision on the best treatment option and not on price?
 - 16) Have you asked to see before and after pictures?
 - 17) What if I'm unhappy with the result?
 - 18) Have you been told who holds financial responsibility for any revisions or if complications arise?

ANSWERS AND OBSTACLES

While these questions are helpful in protecting the consumer, they exist as a result of poorly defined laws and no enforcement of existing laws governing the operation of medi-spas. This author proposes some possible solutions to

this dilemma. First, beginning at the state level, the passage of California AB 2398 is essential to set a precedent. If it is passed in California, many other states may follow suit. AB 2398 is an important bill in favor of consumer/patient protection. Once in place, this bill will give greater authority to prosecutors when going after law breakers. Regarding the practice of medicine without appropriate licensure, California law prohibits corporations and other artificial legal entities from having any medical professional rights, privileges, or powers. This concept is known as the “prohibition against the corporate practice of medicine” (Nakanishi, 2008). AB 2398 will require the following of all medi-spas:

[AB 2398] specifies that the review conducted by the MBC [Medical Board of California], the BRN [Board of Registered Nursing] and the PAC [Physician Assistant Committee] shall include the appropriate level of physician supervision needed; the appropriate level of training to ensure competency; guidelines for standardized procedures and protocols that address patient selection, education, instruction and informed consent, use of topical agents; and procedures to be followed in the event of complications or side effects from treatment and procedures for governing emergency and urgent care situations (Nakanishi, 2008).

Those who choose to break the law will deal with severe consequences. Under AB 2398 those consequences could be as stiff as imprisonment in the state prison for two, three, or five years, or by a fine not to exceed \$50,000. Many of those in opposition of this bill are currently in violation of current state law and the passage of this bill may certainly shut them down or force them into compliance. That’s the whole point, shut them down or force compliance. At the end of the day, patient safety must be priority, not the self-interest of non-compliant spas. AB 2398 has enormous backing by professional medical entities in the state, such as, the American Society for Dermatologic Surgery Association, California Academy of Eye Physicians & Surgeons, California Medical Association, California Society of Dermatology and Dermatologic Surgery, California Society of Plastic Surgeons, Medical Board of California, and the Osteopathic Physicians & Surgeons of California (Nakanishi, 2008). California is often referred to as the “Maverick State”, and as such, she holds a great deal of responsibility regarding this issue. That responsibility is toward her citizens in advocating patient safety in the market place.

There are many obstacles to enforcing the above measures if

they are passed. First, the magnitude of the problem will make it fiscally difficult, if not impossible, for states to enforce. As popular and inexpensive as these illegally run facilities are, there will be very few whistle blowers willing to come forward--including workers and patients. So long as no one is seriously injured in these facilities they will remain in business, but under the radar, of course. Given the sheer number of facilities there is simply not enough investigators to go around to every facility and inspect. The cost of hiring more investigators will financially burden each state as they attempt to protect the consumer. Regardless of these obstacles, it is important to move forward and balance these issues as they come up.

Another obstacle to improving this situation is lack of patient education regarding what should be the standard. When patients and clients are enjoying results from these procedures, they are satisfied despite who performed the procedure. This is especially true if they are receiving the services at a reduced rate. Most lay persons are unaware of what constitutes a “medically supervised procedure.” They are also often unaware of what complications can arise during these procedures. These are all deterrents to exposing the illegalities of such facilities. Therefore, once California has AB 2398 in place there should be a large media campaign educating the public regarding what to look for in a medi-spa. The Medical Board of California could place ads on television, in print, and on the internet.

Pressures in the market place will make it difficult for legitimate companies to compete. Where licensed medical personnel are employed, prices for such services will be high enough to pay these professionals. In other words, it is expensive to operated legitimate facilities. When patients are led astray to less than ethical facilities for financial reasons, physicians feel slighted. This, aside from patient safety and medical legal issues, is a major bone of contention with physicians who operate legitimate services. Those who oppose AB 2398 see this stance as the impetus for creation of AB 2398, but this is certainly not the case. This can be said because the above California medical boards and associations have no direct financial ties to the outcome of AB 2398’s passage. This would constitute a gross conflict of interest.

CONCLUSION

Cosmetic dermatology and the concept of the “medi-spa” are currently at the forefront of much debate. This controversy surrounds what procedures are deemed medically

complicated enough to require physician supervision. This debate is not unique to the US, but has found its way to countries such as Brittan and Australia. This controversy exists for many reasons. The speed at which this burgeoning industry has flourished in connection with the slow pace, at which governmental regulation has lagged behind, set this debate in motion. The public is at risk while non-licensed providers continue to render services outside the scope of their training. California may set a new standard in care with its passage of AB 2398, but many complications exist which may hinder its passage and implementation. The stakes are high and the likelihood of change is daunting, but the cause is certainly worth the fight. If patient safety is of any concern to the majority of Americans, then it's only a matter of time and much sweat on the part of legislators to bring medi-spas under more consistent and trustworthy medical regulation.

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