

THE RISE OF THE REGULATORS



BY ALEX R. THIERSCH, JD

Alex R. Thiersch, JD, is a Chicago healthcare attorney who represents medical spas, plastic surgeons, and aesthetic medical professionals. He is the founder and director of the American Med Spa Association (AmSpa), which was created for the express purpose of providing comprehensive, relevant, and timely legal and business resources for medical spas and medical aesthetic physicians throughout the United States. For more information about becoming a member or to learn about AmSpa's upcoming events, log on to www.americanmedspa.org. Alex can be contacted at alex@americanmedspa.org.

In recent years, the medical aesthetics industry has experienced explosive growth. According to the American Society of Plastic Surgeons (ASPS), 15.9 million surgical and minimally invasive cosmetic procedures were performed in the United States in 2015, a 115 percent increase over the number performed in 2000. Additionally, the American Society for Aesthetic Plastic Surgery (ASAPS) reports that consumers spent more than \$13.87 billion on aesthetic procedures in 2015—an all-time high.

These numbers are certainly good news for medical aesthetics practice; however, such robust growth and visible success has caused regulators on both the state and federal levels to begin taking a closer look at the industry. What these regulators are finding are areas in which legalities are poorly defined, enforcement is lax, and punishment is viewed as insufficient. State regulatory agencies have traditionally been underfunded and undermanned, but they are beginning to take action to rectify these perceived oversights.

This increased scrutiny could potentially be very bad news for owners and operators of non-compliant medical aesthetics practices. Laws are changing, enforcement is increasing, and punishments are becoming more severe, so it is important that medical aesthetic professionals learn about the areas in which regulators are beginning to crack down and correct any shortcomings their practices may have as soon as possible.

A CASE IN POINT

The case of microneedling is an example of the ways in which regulations are evolving. Microneedling—also known as collagen induction therapy (CIT)—is a skin

treatment in which small needles penetrate the skin in order to create superficial wounds that stimulate the production of collagen and other growth factors. It produces visible results with little chance of complications, and it has become popular with both patients and professionals because it is simple, fast, and lucrative.

However, microneedling is not without controversy. The primary issue surrounding this procedure revolves around whether or not it is medical in nature. Typically, any treatment that breaks the outer layer of the patient's skin is considered to be medical. It stands to reason that any procedure involving a needle also involves breaking the skin, but determining whether or not the skin is actually being broken is very difficult when you are dealing with tiny needles that can be only fractions of a millimeter long. Other factors that affect this judgment include the part of the body being treated and the amount of pressure being applied.

Because these distinctions are typically not codified in state rules and regulations, the owners and operators of some medical aesthetic practices have allowed these procedures to be performed by unlicensed personnel, such as aestheticians, and have administered these treatments without a physician first conducting an exam, as is required prior to a medical procedure. These shortcuts allow practices to see more patients and use licensed medical professionals less often, both of which positively affect their bottom lines.

However, in recent months, regulatory bodies in both California and Illinois have asserted that microneedling is an invasive procedure and, thus, medical in nature, regardless of depth. According to these agencies, aestheticians

are absolutely prohibited from administering this treatment, and a face-to-face exam by a physician or mid-level practitioner is always required prior to the procedure. This proves that regulators have their eyes on this issue and, as these two states go, it is likely that so too will go much of the industry. Because of this, this former grey area may quickly become much more black and white.

Another example is Colorado, in which the state medical board is in the process of reviewing its regulations to more clearly specify which procedures should be viewed as medical and which should be viewed as non-medical. Notably, these revisions indicate that state regulators will take stricter views of certain treatments—the use of Class I lasers, for example, is designated non-medical, but the use of Class II and above lasers is classified as being medical in nature.

There are a number of these “in-between” types of procedures—laser treatments, dermaplaning, ultrasound and other body-sculpting treatments, for instance—that tend to be viewed with suspicion by state regulators. If an unconventional or new technology appears to them to be under-regulated, the state will likely err on the side of issuing sanctions, regardless of whether specific statutes actually govern the administration of these treatments. This trend indicates regulators will tend to view the majority of procedures offered by medical aesthetic facilities as medical in nature. Therefore, practices should get used to the idea that they will need to provide initial physician exams (or exams by mid-levels) for more of their patients and that licensed medical professionals will need to perform many of these procedures. This will almost certainly take a bite out of the bottom lines of most medical aesthetic practices, as it costs more to employ medically licensed personnel to do work that was formerly performed by non-medically licensed individuals; however, if a practice wishes to stay compliant, it will likely have no choice but to make this change.

IMPORTATION RULING THE NATION

As you no doubt are well aware, botulinum toxin treatments—primarily Botox, but also including competitors such as Dysport and Xeomin—are among the most popular procedures in the medical aesthetic industry. According to the ASAPS, more than 4.25 million of these treatments were administered in the United States in 2015, for a total expenditure of more than \$1.35 billion—the most of any cosmetic procedure, surgical or otherwise. At an average of \$317 per treatment, botulinum toxin is affordable for patients, yet still quite profitable for practices. But some want more, and they are beginning to put themselves in danger in the pursuit of larger profits.

One of the ways in which practices are attempting to

do this is by buying cheap, usually counterfeit botulinum toxin from other countries, most prominently China. These drugs are not particularly difficult to procure on the Internet if you know where to look and, to some medical aesthetic practices, this represents a way to avoid paying the name-brand premium that legitimate botulinum toxin carries, such as Botox.

While this is shady at best, and dangerous to patients at worst, historically it tended to be fairly easy to get away with. Recently, however, the U.S. Food and Drug Administration (FDA) has stepped up the enforcement of its statutes (fake botulinum toxin is not FDA approved, of course), seizing these drugs at the border and handing down criminal charges against those in the United States who are complicit in their importation, such as the practices that order it.

This enforcement effort has proven to be extremely controversial. “It’s caused quite a bit of angst,” said Michael Byrd, partner for ByrdAdatto, a national business and healthcare law firm based in Dallas. “There’s a lot of unhappiness, even within the governmental agency [FDA]—they refer to themselves in a derogatory manner as the ‘Botox police’ or the ‘Allergan police.’”

FDA agents may feel like their strings are being pulled by a corporation, but this is also unquestionably a matter of maintaining the health of the botulinum toxin-using public.

“Those who are against it say that it’s really just action on behalf of Allergan for Allergan to keep their prices [high],” says Byrd. “Those who are for it, as you might suspect, point to patient welfare.”

Regardless, enforcement has increased, and the charges a medical aesthetic practice can incur as a result of being caught with counterfeit botulinum toxin are very serious. If a medical aesthetic practice owners or operators is found guilty of them, they could theoretically serve jail time in addition to facing heavy fines and the suspension of their medical licenses.

Medical aesthetic practices have also attempted to purchase less expensive botulinum toxin treatments by engaging in a practice called “parallel importation,” whereby a licensed foreign entity purchases legitimate US-produced drugs at a lower rate than US-based distributors (due to local price controls) and then resell them to US-based practices for far less than it would typically cost for the practices to procure them from domestic sources. The US Supreme Court broadly upheld the legality of this practice in the case of *Kirtsaeng vs. John Wiley & Sons, Inc.* (2013), although that particular case related to textbooks, not prescription drugs. As such, there are still some grey areas involving FDA compliance that make this practice risky, despite the fact that every step of the process seems to

respect the laws of both the country in which the outlet is located and the United States.

“Enforcement typically stems from an employee, patient, or American industry representative reporting a foreign label on the product. Because the labeling is different on legitimate US products purchased by a foreign entity, practices engaging in parallel importation are also being reported,” explains Byrd. “When I counsel my medical spa or cosmetic practice clients, [I tell them] you have to recognize the risk that comes with any effort to utilize parallel importation. Even if a client is ultimately not found guilty of wrongdoing, an enormous business cost comes with losing inventory in a raid, legal costs to defend the action, and the business disruption that comes with an enforcement action. There is, of course, also risk regarding the legality of the use of parallel importation for prescription drugs. And so, my counsel would be that if you do anything other than buy an FDA-approved and US-distributed product, you have to recognize both of these risks.”

For now, it is probably best not to engage in parallel importation, but it is entirely possible that in the near future, it will be a viable way to purchase FDA-approved products.

AN OSHA OF PROBLEMS

The US Occupational Safety and Health Administration (OSHA) is a government agency that is dedicated to ensuring workplace safety. Its enforcement efforts have become noticeably more aggressive recently, and potential penalties for non-compliance have increased tremendously, making non-compliance very dangerous for small businesses, such as medical aesthetic practices.

“For the first time in 15 to 18 years, they increased their penalty amounts, and it was such a substantial increase that it just knocked everybody’s socks off,” explains Steve Wilder, president of Sorensen, Wilder & Associates (SWA), a safety and security risk management consulting group specializing in healthcare. “This past August, they had a 78 percent increase in the minimum penalties they can assess. Previously, they could start penalties at a maximum of \$7,500; that amount has now gone to about \$12,500. For repeat offenses or ‘willful and wanton’ offenses—meaning ‘we knew we had an unsafe work environment for our employees but we looked the other way instead of correcting it’—they raised the maximum penalty from \$75,000 to \$125,000.”

Keep in mind that this is the maximum penalty—OSHA will not necessarily issue penalties this large, but it can.

“Over the last couple of years, I have seen from client experiences that [OSHA] seem to have a propensity to start [penalties] higher, and force the employer who is

receiving the penalty to contest them and challenge them, which can still end up costing them just as much,” Wilder says. “I had one client who got a penalty for \$6,000 and wanted to appeal it during the informal process, and by the time they finished the appeal, OSHA dropped the cost from \$6,000 down to \$3,000, but the client ended up spending \$3,000 on legal and consulting fees, so they still ended up spending \$6,000. So it’s still a very expensive proposition.”

And if a medical aesthetic practice finds itself on the receiving end of an OSHA citation, it will definitely end up costing the practice money.

“There’s no insurance for this,” Wilder says. “If they give you a penalty, you’re writing a check. It’s coming off the same bottom line as your payroll, the same bottom line as your equipment, supplies, profits, everything. It’s an out-of-pocket operating expense, so it can put a small medical spa [or medical aesthetic practice] out of business.”

If you suspect your medical aesthetic facility is not OSHA-compliant, you owe it to yourself to bring it up to code, in the interest of both the safety of your employees and your practice’s financial health. If you do not know how to get started, consult a healthcare attorney with expertise in this field or log on to www.americanmedspa.org and access the American Med Spa Association and SWA’s OSHA Self-Assessment Checklist. Ignorance is no excuse, and it will never get you out of trouble with OSHA.

ADVERTISING IN ADVERSITY

Regulators are also likely to begin taking a closer look at the ways medical aesthetic practices get the word out about their services. Medical aesthetic practices and traditional spas that offer medical treatments tend to utilize marketing techniques such as websites, social media, and advertising. To the younger generation of more tech-savvy professionals, this is the way to get spread the word about their products and services. And as the medical aesthetic industry continues to expand, more people from outside the industry are going to be entering it—it would not be particularly unusual to see a medical spa hire a marketer who has previously only worked in the auto industry, for example.

Medical boards are watching this, however, and some are not at all happy about the way this is trending. They see this new wave of digital marketing as having an adverse affect on the industry, as it commodifies health care and risks patient privacy. Traditionally, health care has been something people need, not something they want, so traditional thinking has suggested that it is unseemly for medical practices to advertise.

The medical aesthetic space is unquestionably different from the traditional medical space, primarily in the sense that all medical aesthetic treatments are elective. Therefore, it makes a certain amount of sense that medical aesthetic practices would have a different way of getting the word out about their offerings than traditional medical practices. However, judging by the way the rest of the industry is trending, these businesses should expect more regulation as it pertains to their publicity, not less.

Medical advertising statutes maintain that practices must specify who is performing treatments and what their qualifications are, present their pricing in a simple manner, and refrain from making comparisons to competitors. Officers of state regulatory agencies—which are almost always short of funding and staff—will often spend much of their time looking at the websites of medical aesthetic facilities and medical spas to determine which ones should be investigated. If a practice is advertising online in an improper manner, it is much more likely to find itself the

subject of a state investigation than if it respects advertising guidelines.

Given the current trend toward increased regulation, it seems likely that state agencies will increase their efforts to find such offenders.

KEEP YOUR HEAD UP

If you are the owner or operator of a medical aesthetic practice, it can sometimes seem as though the deck is stacked against you. However, the key to avoiding the pitfalls described above is learning more about them. Consulting with a healthcare attorney is a good first step toward finding out what you need to do to keep your practice in the law's good graces. (Author's note: The American Med Spa Association (AmSpa) provides a variety of legal and regulatory resources for medical aesthetic practices and medical spas to help you stay legal and compliant. Become a member at www.americanmedspa.org.) What you do not know definitely can hurt you. ■