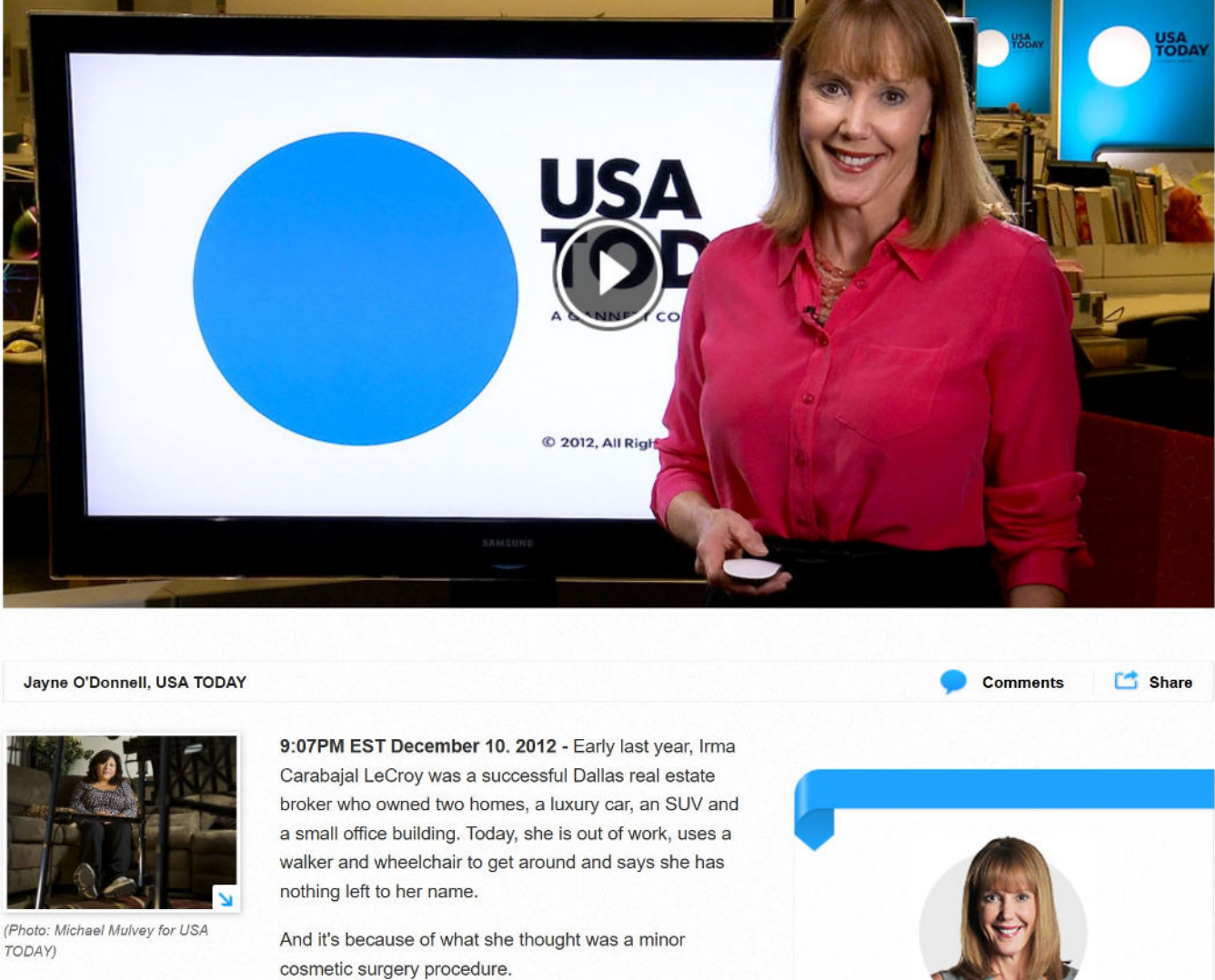


Cosmetic surgery laws often aren't enough



Jayne O'Donnell, USA TODAY

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9:07PM EST December 10, 2012 - Early last year, Irma Carabajal LeCroy was a successful Dallas real estate broker who owned two homes, a luxury car, an SUV and a small office building. Today, she is out of work, uses a walker and wheelchair to get around and says she has nothing left to her name.

And it's because of what she thought was a minor cosmetic surgery procedure.

LeCroy is one of a growing number of women who have had liposuction, sometimes combined with fat-transfer surgery, in doctors' offices or med spas — salon-like medical facilities that have doctors on the premises and offer skin care treatments, such as Botox injections, facials and laser resurfacing.

Some patients have found themselves disfigured or disabled. Others have died. Critics say the victims may not know that the rules that govern hospitals do not necessarily apply to the medical offices or spas popping up across the country. That's where a new breed of cosmetic surgeon now practices, often down the hall from where they do routine physicals, perform gynecological exams or pull wisdom teeth, according to state regulators, lawyers and plastic surgeons.

USA TODAY reported last year that only half of states require licensing or accreditation of medical offices where surgery is performed. But even when there are office-based surgery rules or laws in place, they often aren't enough, critics say. For example, most accreditation or licensing rules cover surgeries only if the patient is fully anesthetized. Some rules apply only if private insurance or Medicare is billed, which typically isn't the case in cosmetic procedures.

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There are now about 4,500 med spas in the United States, up from about 800 five years ago, says Allan Share, executive director of the International Medical Spa Association.

The growth of med spas has states scrambling to figure out how much legal oversight is needed. The Federation of State Medical Boards recently hosted a workshop for medical board attorneys that covered the regulatory oversight of med spas and office-based cosmetic surgery.

State medical boards and the laws regulating the practice of medicine were "created 100 years ago when cosmetic procedures or surgeries weren't anything that anyone had contemplated," says Mari Robinson, executive director of the Texas Medical Board. "It was about treating illness and disease — not this idea of people personally pursuing medical procedures solely based on improving their appearance."

In September, Maryland's health department shut down the Monarch Medspa in Timonium after three women contracted Group A Streptococcus infections during liposuction and one died. The department cited "deviations from standard infection control practices."

The Group A Streptococci bacteria, which can cause strep throat, are often found in the throat and on the skin and are spread through direct contact with mucus from infected people or contaminated surfaces, according to the health department. Most of these infections are relatively mild, such as with strep throat, but they can cause serious and even life-threatening complications.

Protecting consumers

Joshua Sharfstein, Maryland's secretary of Health and a pediatrician, sent a letter to three committee chairmen in the Maryland legislature last month asking them to tighten laws governing outpatient surgery. The existing law doesn't apply to outpatient surgery centers unless insurance companies are involved, according to a department press release.

Health insurance typically covers only medically necessary or reconstructive plastic surgery after cancer. He also asked that the state Board of Physicians database include information on whether doctors perform cosmetic surgery and whether their facility is accredited.

"We asked ourselves if more needs to be done to protect consumers from unsafe cosmetic surgery," says Sharfstein. "There are some protections that exist for bigger surgical centers, but gaps in regulation might put consumers at risk" because smaller operations, including med spas, can take advantage of loopholes.

In Texas, doctors with office-based surgery centers or med spas that aren't accredited by one of three outside entities or licensed as ambulatory surgery centers, can register them for any level of anesthesia used that is above local anesthesia.

It wasn't the anesthesia that harmed LeCroy, however. It was the surgery itself, according to a lawsuit filed on her behalf against internal medicine doctor Hector Molina and the company that sold him the liposuction machine. The suit charges that Sound Surgical Technologies should have known of the risks of a non-surgeon who was not adequately trained in liposuction using the machine. In its response to the suit, Sound Surgical denied the allegations and says it was not to blame for any of LeCroy's injuries. In a statement provided to USA TODAY, the company said LeCroy's attorneys aren't suggesting the liposuction machine was defective, so it "is confident that it will be dismissed from this lawsuit either before or during trial." LeCroy's attorney, Jim Mitchell, says it wasn't that the machine was defective, it was that "Dr. Molina simply didn't know how to use the system."

LAWSUIT: [Irma LeCroy vs. Hector Molina, MD, and Sound Surgical Technologies](#)

RESPONSE: [Hector Molina's response to LeCroy lawsuit](#)

RESPONSE: [Sound Surgical Technologies response to LeCroy lawsuit](#)

When they prohibited Molina from performing cosmetic surgery in April, a Texas Medical Board disciplinary panel found his "entire knowledge" of the procedure he performed on LeCroy (who it did not name) "consisted of reading a book provided by the manufacturer of the liposuction equipment, completing an online program over two weeks, passing an online exam and completing one procedure under the direct supervision of another surgeon."

DISCIPLINARY ORDER: [Texas Medical Board's order against Hector Oscar Molina, MD](#)

Texas-size problems

LeCroy was left permanently disabled by Molina due to problems including massive infection and the nerve and muscle condition known as "compartment syndrome," which causes body tissue to die, according to her lawsuit and an expert witness report by Miami plastic surgeon Alberto Gallerani. Molina denied the allegations in an answer to the lawsuit, and his lawyer declined to comment.

EXPERT WITNESS TESTIMONY: [Affidavit of Dr. Alberto Gallerani](#)

After LeCroy's more-than-nine-hour liposuction and fat-transfer surgery, Molina and a doctor assisting him abandoned her in his office "without any medical supervision or monitoring," according to Gallerani's report. Her friend, Marilyn Walker, found her "short of breath, unable to stand" and in severe pain in her legs and feet, the report said. She was rushed to the emergency room and transferred to a trauma center. So much fat was injected into the muscles in her buttocks, it caused the compartment syndrome, which Molina failed to diagnose, according to Gallerani's report. LeCroy needed 27 more surgeries to treat the compartment syndrome and related complications, according to Gallerani's statement. She spent a month and a half in the hospital.

LeCroy, 49, now has a home health aide coming to her house three times a week. The money she earned selling real estate, which she did starting at age 25, went to pay medical bills, because complications from cosmetic surgery aren't covered by insurance. She says she is unable to walk without a walker and needs a wheelchair for long distances. "I have nothing," says LeCroy. "I'm down to \$698 a month in disability benefits."

Harlan Pollock, a Dallas plastic surgeon and past president of the American Association for Accreditation of Ambulatory Surgery Facilities, says Texas' law doesn't go far enough to protect patients.

When offices register with the state of Texas, certain requirements kick in for the safe administration of anesthesia, according to Texas Medical Board spokeswoman Leigh Hopper. These include the presence of a doctor and another person certified in treating cardiac arrest and a "crash cart" containing life-saving equipment. But Pollock says these requirements apply only to anesthesia and have little to do with the safety of the surgery itself. Accreditation, on the other hand, would require sterile procedures, physical requirements for the operating room, safety equipment and thorough record-keeping procedures, Pollock says. Sterile procedures are key for infection control, which was what Maryland officials found lacking at Monarch Medspa, medical experts say.

This kind of "an out," in Pollock's words, means "The public has no real assurance that the facility is an adequate facility, and that is disturbing and a real concern," he says.

On Nov. 30, the Texas Medical Board barred Molina from ever performing surgery or dispensing controlled substances, a category that includes some pain medications, such as those with codeine. But Texas has done little to crack down on the offices and med spas where doctors like Molina practice cosmetic surgery, say plaintiff attorneys and plastic surgeons.

Hopper emphasizes that Texas' medical board "rigorously screens" doctors who apply for medical licenses. And once they have these licenses, doctors are required to meet what's known as the generally accepted standard of care no matter what area they practice in, she says.

Still, if Texas' state Legislature wanted to address office-based surgery, Robinson says, the board would "be happy" to implement any new rules.

LeCroy isn't the only Texas patient to suffer after cosmetic surgery in a doctor's office or med spa. The Texas Medical Board also found OB/GYN Barbara Marino didn't meet the "standard of care," have emergency procedures in place or maintain a sterile operative facility during liposuction on patients at Medspa 21 in Houston. One died two days after his liposuction, and an autopsy report said the cause of death was "acute toxicity" from the combined effects of four medications, including a patch for the pain medication Fentanyl, according to the medical board's records. Another patient had excessive levels of pain medicine, the board said.

DISCIPLINARY ORDER: [Texas Medical Board's order against Barbara Doyle Marino, MD](#)

Late last month, Marino was ordered to observe at least 30 hours of cosmetic surgery by a board-certified plastic surgeon and document other procedures for treating at-risk patients and dealing with emergencies. She did not respond to calls seeking comment.

In November 2011, Laura Bennack, an emergency room doctor who owns Radiance MedSpa in San Antonio, had her practice put under the supervision of another physician by the Texas Medical Board. It had investigated the treatment of 10 cosmetic surgery patients and found she didn't meet what it considers the appropriate "standard of care" or keep adequate surgery records. According to the board's disciplinary order, Bennack performs tummy tucks, liposuction and breast augmentation while patients are awake. The board said in an order in February 2010 that Bennack acknowledged her medical recordkeeping was "sparse at best." Bennack did not respond to calls seeking comment.

Little regulation

Med spas typically offer only procedures without anesthesia or under local anesthesia, which isn't regulated in Texas or many other states. "There is absolutely no regulation of med spas," Pollock says. "That's something that to me is very frightening."

Some doctors, including Marino and Molina, register their facilities for higher levels of anesthesia. Several states require accreditation for offices intending to use deep sedation or general anesthesia, since it is the type used for the most serious procedures, says Tampa anesthesiologist Hector Vila. But doctors can get around the law by registering for a lower level of anesthesia or using large volumes of local anesthesia, says Vila.

Vila says existing laws need to be more strictly enforced to ensure people don't continue to skirt them. Performing surprise inspections and more frequent inspections could be one way to accomplish this, he says.

Some of the toughest laws:

Florida. The state changed its law early this year to authorize the state to inspect any facility, including med spas, that remove more than 1,000 cc's of fat during liposuction. That would cover all but the most minor procedures, says Democratic state Sen. Eleanor Sobel, who introduced the bill. Previously, the inspection authority existed only for facilities that accepted Medicare or other insurance. The law was passed after two women died of an overdose of lidocaine, a local anesthetic similar to novocaine, after liposuction.

California. Under a law passed in January, California's medical board keeps a list of accredited outpatient surgery settings. The board approved four accreditation agencies that inspect and accredit outpatient surgery settings, including medical offices and spas. These agencies can reject, revoke, or otherwise restrict a facility's accreditation. If that happens, the medical board is notified and alerts the public on its website.

New York. Any office-based surgery facility that removes more than 500 cc's of fat during liposuction or uses anything more than minimal sedation must be accredited. Still, even though New York has some of the most stringent regulation of office-based surgery, any licensed physician can perform cosmetic surgery under a local anesthetic in an unaccredited facility, says Manhattan plastic surgeon Adam Schaffner. "My hope is that they will require that physicians who perform such procedures perform them in accredited facilities (and) that they have hospital privileges for any procedure they perform outside the hospital," says Schaffner.

The issue of med-spa regulation is "absolutely rising to a national level ... everyone is really looking at it right now," says Robinson.

"Every single person needs to pay attention to the training of the person who's doing the procedure and the status of the facility — whether it's accredited or not," says Sharfstein. "What you find out can make the difference between life and death."

Contributing: Yasmeen Abutaleb, Sarah Meehan.

Steps to take if considering cosmetic surgery:

• Find out if your doctor is board certified in plastic surgery
www.certificationmatters.org/

• Find out if your doctor is licensed and has any in-state disciplinary actions
http://www.fsmb.org/directory_smb.html

Order full physician profile and disciplinary history report
<https://s1.fsmb.org/docinfo/>

• Search for AAAASF-accredited surgery facilities
<http://www.aaaasf.org/consumers.php>

• Search for AAAHC accredited organizations
<http://www.aaahc.org/>

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