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Special report: Silicone implants

Silicone is back, but surgeons still have some work to do

Doctors must submit to more oversight and requirements if using silicone again

The long-awaited return of silicone breast implants is being hailed as great news for both plastic surgeons and their patients, but federal approval of the products for general use comes with some strings attached. Surgeons who wish to return to using silicone in a general patient population—or those younger surgeons using them for the first time—will have to abide by certain rules aimed at ensuring that the doctor is well trained and the patient is followed long after recovery.

Although more work than surgeons might typically encounter with a surgical implant, the requirements

should not be overly burdensome, say leading surgeons. Even better is the prediction that there is little risk of a return to the lawsuit craze of the 1990s that resulted in the severe restriction—almost an outright ban—of this type of implant for 14 years.

Until the recent approval, silicone implants were only available in the United States to women seeking breast reconstruction and revision surgery through clinical studies. The approval means that women in the United States now have the same augmentation options that women in more than 60 countries have had for the last 25 years.

After rigorous scientific review, the U.S. Food and Drug Administration (FDA) recently approved the marketing of silicone gel-filled breast implants made by two companies for breast reconstruction in women of all ages and breast augmentation in women aged 22 and older. The products are manufactured by Allergan Corporation (formerly Inamed Corp.) in Irvine, CA, and Mentor Corporation in Santa Barbara, CA.

Daniel Schultz, MD, director of the FDA's Center for Devices and Radiological Health in Washington, DC, says the decision came after extensive study of the claims that silicone implants caused a number of serious health problems.

"The FDA has reviewed an extensive amount of data from clinical trials of women studied for up to four years, as well as a wealth of other information to determine the benefits and risks of these products," Schultz says. "The extensive body of scientific evidence provides reasonable assurance of the benefits and risks of these devices. This information is available in the product labeling and will enable women and their physicians to make informed decisions."

FDA to continue monitoring

Now that the products have been determined to be

Inside This Month...

Special report: Silicone implants

- *Lawsuits still possible but not like in 1990s*135
- *Silicone implants safer than ever, research shows*137
- *Makers offer online education, resources*138
- *What about latest concerns over platinum in implants?*139
- *Web site educates patients interested in silicone*139
- *Avoid ethical mistakes when advertising your practice*140
- *Association seeks to promote ethical conduct in plastic surgery*140
- *Society bylaws restrict some methods of advertising*141
- *Enzyme injections show promise for cellulite*143
- *Breast asymmetry, treatment can have big effect on women*143
- *ASAPS cautions against lipoplasty for children*143

In future issues

- *Irregular office hours: Are they worth the trouble?*
- *Finding a good marketing professional*
- *Pros and cons of presurgery sedatives*

continued on p. 134

Silicone

continued from p. 133

safe and effective, the FDA will continue to monitor them by requiring each company to conduct a large postapproval study following about 40,000 women for 10 years after they receive breast implants. The FDA often requires postmarket studies to answer questions that can only be answered once a product is in broader use, such as the incidence of rare adverse events.

The FDA's decision to approve the implants was based on a thorough review of each company's clinical (core) and preclinical studies, a review of studies by independent scientific bodies, and deliberations by advisory panels of outside experts that heard public comment from hundreds of stakeholders. In addition, the FDA conducted inspections of each company's manufacturing facilities to determine whether they comply with the FDA's Good Manufacturing Practices.

Some of the complications reported in the core studies included hardening of the area around the implant, breast pain, change in nipple sensation, implant rupture, and the need for additional surgery. The majority of women reported being satisfied with their implants.

In the past decade, a number of independent studies have examined whether silicone gel-filled breast implants are associated with connective tissue disease or cancer. Schultz notes that the studies, including a report by the Institute of Medicine, have concluded that there is no convincing evidence that breast implants are associated with either of these diseases. However, these issues will be addressed further in the postapproval studies conducted by the companies.

"The silicone breast implant is one of the most extensively studied medical devices," he says. "We now have a good understanding of what complications can occur and at what rates. We also know that women who get these devices will probably need to have additional breast implant surgery at least once. This is valuable information for women who may be considering these products."

Approximately 300,000 women chose breast augmentation and 58,00 had breast reconstruction in 2005, according to the American Society for Aesthetic Plastic Surgery (ASAPS) and the American Society of

Plastic Surgeons' (ASPS) statistics.

Patient labeling provides details

Full information about the risks and benefits of the devices can be found in the package and patient labeling mandated by the FDA. The patient labeling outlines important factors that women should consider when deciding whether to get silicone gel-filled breast implants, such as the following:

- Breast implants are not lifetime devices and a woman will likely need additional surgeries on her breast at least once over her lifetime
- Many of the changes to a woman's breast following implantation are irreversible
- Rupture of a silicone gel-filled breast implant is most often silent, which means that usually neither the woman nor her surgeon will know that her implants have ruptured
- A woman will need regular screening magnetic resonance imaging (MRI) examinations over her lifetime to determine whether silent rupture has occurred

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—Daniel Schultz, MD

The device labeling states that a woman should have her first MRI three years after her initial implant surgery then every two years thereafter. This significant expense should be explained to the patient during the informed consent process: The cost of MRI screening over a woman's lifetime may exceed the cost of her initial surgery and may not be covered by medical insurance. The labeling also states that if an MRI indicates an implant rupture, the implant should be removed and replaced, if needed.

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In addition to the large postapproval study, the FDA approved the silicone gel-filled breast implants with a number of other conditions, including requiring each company to continue its core study through 10 years; conduct a focus group study of the patient labeling; continue laboratory studies to further characterize types of device failure; and track each implant in the event that health professionals and patients need to be notified of updated product information.

Schultz says the postapproval studies will continue to gather information about the safety and effectiveness of the implants. Information will be collected about rates of local complications, connective tissue disease and its signs and symptoms, neurological disease and its signs and symptoms, cancer, and suicide, potential effects on offspring of women with breast implants, reproduction, and lactation, and potential interference of breast implants with mammography, MRI compliance, and rupture rates.

The postapproval studies will be closely monitored by the FDA. Schultz says the FDA anticipates that data from the studies will provide important information for patients and physicians, and may lead to improvements in device labeling.

Surgeons welcome return of silicone

The FDA approval was cheered by plastic surgery professional organizations, which had encouraged the government to fully study the alleged risks and bring the products back to market. The ASAPS and the ASPS both applauded the decision as a positive move for surgeons and patients alike. ASPS President **Roxanne Guy, MD**, a surgeon in Melbourne, FL, says it was clear that the FDA had taken the time to carefully evaluate the risks.

"This is a great day for American women and the plastic surgeons who care for them," Guy says. "Silicone breast implants have been scrutinized more than any medical device, and we applaud the FDA for making its well-thought-out decision and allowing American women to make informed choices about their healthcare."

The FDA decision followed a lengthy process in which the agency sent "approvable with conditions" letters to the two silicone breast implant manufacturers in the second half of 2005. The approvable letter stipulated a number of conditions that the manufacturers needed to satisfy in order to receive FDA final approval to market and sell silicone breast implants in the United States. These letters came after an FDA

continued on p. 136

Special report: Silicone implants lawsuit frenzy not likely again, but still reason for caution

Plastic surgeons eager to offer patients silicone breast implants don't have to worry that they will be swallowed up in another lawsuit craze such as the one in the 1990s that led to the 14-year ban, but at the same time, some caution is necessary.

When it comes to lawsuits, any patient can sue any surgeon at any time, regardless of whether there is any scientific merit to the case, says **Al Bixler, JD**, an attorney with the law firm of Eckert Seamans Cherin & Mellott in Philadelphia. You may win the lawsuit in the end, but you still will go through the hassle, legal expense, and stress of being sued, he says.

In fact, most experts would say that was what happened with the lawsuits of the 1990s. Time has proven that there was little or no scientific basis for the claims of patient injury, so does that mean that surgeons are better protected now? Not necessarily.

"Even though the FDA has now approved silicone implants and even though the science behind the previous claims has been largely debunked, those two facts alone will not immunize a surgeon from potential claims," Bixler says. "You can see examples all the time of FDA-approved devices and pharmaceuticals that give rise to litigation."

So patients can still sue over silicone implants, and Bixler says it is virtually certain that some patient will try to bring a

new claim that she was harmed by the silicone implant. But the key question is how common such claims might be.

"I would say the odds of a big landslide of litigation are not very high. I would be stunned if that happened," he says. "Since these cases were first brought, the science has changed so much for the better, and the FDA position has changed. I don't see the plaintiff's bar being eager to take on a difficult case where the science is against them, because they are in business to make money like the rest of us, and that is just not good business sense."

Bixler suggests that it would be prudent to ensure that patients are well educated about not only the current scientific data regarding the safety of silicone implants, but also their controversial history. The informed consent process should include some discussion of how silicone implants were the subject of numerous lawsuits alleging patient harm, and the FDA's decision to restrict their use for many years, he says.

"You can't expect the patient to evaluate the epidemiology and the long scientific history, but you can be certain that the patient is aware of the history of this device," he says. "Full disclosure is always best in the informed consent process. You don't want someone claiming that she had no idea silicone implants were once criticized so harshly."

Silicone

continued from p. 135

advisory panel hearing in April 2005, in which the panel heard more than 20 hours of data presentations from the manufacturers and public comment.

Doctors encouraged to follow patients

Guy notes that, in addition to certification in the two silicone implant products, surgeons must abide by the FDA's requirement that patients be adequately informed about the potential risks.

"The informed consent documents have to be given to the patient well in advance of the surgery, and, in the case of Mentor, have to be signed by both the patient and the surgeon in advance of the surgery," she says.

The requirements may seem like a hassle to surgeons who have been using exclusively saline implants in recent years, but they actually represent an improvement over the strict criteria that allowed the use of silicone implants for certain patients, notes **Robert Schulz, MD**, a plastic surgeon in Honolulu, who is familiar with the history of silicone implants and has testified for both plaintiffs and defendants in implant-related lawsuits.

The use of silicone implants was restricted mostly to women undergoing breast reconstruction or those who had previously had implants, and the procedure usually required extensive approval and oversight from the hospital as a research project. Follow-up and data collection requirements were far more stringent when the procedure was classified as investigatory, Schulz says.

Schulz points out that, unlike 10 or 15 years ago, there are now plenty of surgeons who have little or no experience with silicone implants. Surgeons must obtain education from the FDA and the manufacturers before they can use the products, and Schulz says physicians should not take that step lightly.

"One big difference is that you have to have a bigger incision to put them through," Schulz says. "You can roll a saline implant up and put it just about anywhere, but to get the silicone implant in, you have to have an incision that is big enough to slide the whole thing in."

Schulz also cautions that patients must be well educated about silicone implants because there is still a lingering stigma associated with them. Many patients have thoroughly researched the issue on their own and will have a good understanding of the facts, but a few will cling to the idea that silicone implants make people sick.

"There are a lot of people in between who know the latest research showing the implants are safe but who still wonder in the back of their minds about the risk," Schulz says. "We have to make sure that we address their concerns before moving forward."

Some market analysts have predicted a big upsurge in breast augmentations now that silicone is back, but Schulz disagrees. Silicone implants may attract more women who are interested in above-the-muscle augmentation because they can give a better result than saline, he says.

"That small segment of the population may come and say they're now interested in getting the augmentation, but I don't expect an avalanche of new patients," he says.

"There are a lot of people in between who know the latest research showing the implants are safe but who still wonder in the back of their minds about the risk. We have to make sure that we address their concerns before moving forward."

—Robert Schulz, MD

Data needed to ensure continued use

Postmarket surveillance is another important issue for surgeons, Guy says. Although participation in the postmarket surveillance of women with silicone breast implants is not mandatory for individual surgeons or their patients, Guy urges plastic surgeons to cooperate.

"We don't want to end up in the same situation 10 years from now with allegations and without the requisite data to refute them," she says. "Some of this might be a little bit burdensome, but we are doing everything we can to encourage compliance so that we get really robust data on silicone implants."

The number of MRIs requested by the FDA is somewhat controversial, Guy says, with some surgeons saying it is unrealistic to expect patients to go for MRIs when they are asymptomatic and happy with the results of an augmentation performed years earlier. If a patient seems unlikely to participate in follow-up MRIs, Guy suggests that should factor into the surgeon's decision about whether silicone implants are the right choice for her.

The follow-up data are necessary not because there is still serious doubt about the safety of the implants, Guy says, but rather because the medical community should be committed to ongoing research that proves the FDA made the right decision. Following all of the guidelines and participating in long term surveillance is the price that the plastic surgery community must pay, Guy says.

"We wanted silicone implants and now we have to pay the piper," she says. "We have to really roll up our sleeves and get the data." ●

Silicone makers say implants safer than ever, no need for worry

The makers of silicone breast implants had to wait many years for the U.S. Food and Drug Administration (FDA) to finally agree that their products were safe for general use, but now they can point to that lengthy process as proof that there is no need for surgeons or their patients to worry.

David E.I. Pyott, chair of the board and CEO at Allergan in Irvine, CA, says the FDA has recognized the vast body of scientific evidence supporting the performance of these devices. Allergan's product is the Inamed Silicone-Filled Breast Implant.

"Our ability to offer surgeons in the United States a comprehensive portfolio of saline-filled and silicone gel-filled breast implants results in greater options for women considering breast augmentation, reconstruction, or revision surgery," he says.

Joshua H. Levine, president and CEO of Mentor Corporation in Santa Barbara, CA, says the plastic surgeons who participated in ongoing research over the past decade deserve thanks.

"At this historic moment for Mentor, we would like to recognize with gratitude the dedication of the patients, nurses, and surgeons who have participated in the studies that provided the clinical and scientific support for this approval," Levine says. "Over the past 14 years we have remained devoted to returning MemoryGel implants to the U.S. market, and we are pleased to be able to provide women seeking breast augmentation and reconstruction with important new options."

Pyott says silicone gel-filled breast implants are now among the most studied medical devices in existence, with thousands of peer-reviewed and published reports on studies, including robust epidemiological studies supporting their safe use. He says the safety of Inamed Silicone-Filled Breast Implants is supported by the company's extensive preclinical device testing, their use in approximately one million women worldwide, and nearly a decade of U.S. clinical experience involving more than 80,000 women.

Patients have more options

Silicone is used safely in the body in many medical devices and products, including pacemakers, heart valves, artificial joints, and baby pacifiers, notes **Scott L. Spear, MD, FACS**, chair of the Department of Plastic Surgery at Georgetown University School of Medicine in Washington, DC.

"The FDA's decision confirms what we in the plas-

tic surgery community have known for some time: Silicone gel-filled breast implants are a safe and effective option for women seeking breast implant surgery," Spear says. "For decades, I have had the ability to offer silicone gel-filled breast implants to my breast reconstruction patients. Now [with FDA approval] I am able to offer a broader range of options to all of my patients, many of whom are seeking breast augmentation surgery following significant life events such as child bearing."

"The FDA's decision confirms what we in the plastic surgery community have known for some time: Silicone gel-filled breast implants are a safe and effective option for women seeking breast implant surgery."

—Scott L. Spear, MD, FACS

Spear points out that, like many other medical devices on the market today, silicone implants have evolved over the last two decades. Today's implants have an advanced technology and enhanced safety profile due to several refinements in product design and manufacturing, including a more cohesive silicone gel. The Inamed product, for example, now has a thicker shell, which contains an additional barrier layer that is distinct from earlier breast implant devices and is designed to withstand more than 25 times the force of a normal mammogram without failure.

The FDA's approval of Inamed Silicone-Filled Breast Implants follows its review of, among other data, four-year data from 715 women involved in the maker's Core Clinical Study, which is an ongoing, 10-year prospective, multicenter safety study of women who have undergone breast augmentation, reconstruction, or revision surgery. In the Core Clinical Study, less than 1% of implants had a reported rupture at four years. All study participants received regular exams to detect rupture, and approximately 33% also received an MRI. Patient follow-up occurred at zero to four weeks and six months after surgery and will continue annually for up to 10 years.

Thousands of patients to be followed

Patricia Walker, MD, executive vice president for regulatory affairs, research, and development at Allergan Medical, a division of Allergan, explains that the company will initiate a 10-year prospective study

continued on p. 138

Silicone makers

continued from p. 137

referred to as the Breast Implant Follow-up Studies (BIFS) program to further validate the long-term safety and effectiveness of Inamed implants. In addition to the postmarket surveillance, the FDA also requires Allergan to distribute the Allergan Breast Surgery Patient Planner to physicians and patients to ensure that a patient has obtained the labeling within sufficient time prior to surgery and fully understands the risks associated with breast implant surgery.

Upon FDA approval, the BIFS program will enroll tens of thousands of patients, Walker says. A large patient base will allow Allergan to monitor potential statistical trends and further validate earlier conclusions based on worldwide clinical experience and scientific evidence, which show no association between silicone gel-filled breast implants and diseases or adverse events (e.g., connective tissue diseases, neurological disorders, etc.) that are rare among the general and studied patient populations.

Walker says Allergan is committed to the rapid

“We are confident in having developed a robust, surgeon-friendly study design and protocol that meets our high standards of scientific excellence and will encourage patients to enroll in the study for its full duration.”

—Patricia Walker, MD

and successful enrollment of patients in the BIFS program, which will be voluntary for plastic surgeons and their patients to facilitate long-term compliance in the study.

“We are confident in having developed a robust, surgeon-friendly study design and protocol that meets our high standards of scientific excellence and will encourage patients to enroll in the study for its full duration,” Walker says.

Also, Allergan has initiated a device tracking program for its silicone implants, according to federal regulation. Device tracking is intended to facilitate prompt notification to patients of new safety information regarding their breast implants. ●

Special report: Silicone implants

Surgeons must take online course to use silicone implants

Before surgeons are allowed to use the newly available silicone breast implants with the general population, they must participate in special educational courses about implants' proper use and safety. Both makers of the devices—Allergan and Mentor—have established simple ways for surgeons to obtain certification.

Allergan, maker of the Inamed Silicone-Filled Breast Implant, has established the Allergan Academy at www.allerganacademy.com. The site provides surgeons with education programs as well as a forum for peer-to-peer discussion and a comprehensive curriculum. With pending approval from the U.S. Food and Drug Administration (FDA), the Allergan Academy education programs will facilitate the Allergan Physician Certification Program. Upon completion of the Allergan Physician Certification Program, surgeons will gain access to an array of implant options designed to enable them to match the appropriate implant to each patient's body type and surgical goals.

Mentor, maker of the MemoryGel silicone breast

Web sites for required silicon implant courses:

www.allerganacademy.com

www.memorygel.com

implant, is providing physician education and certification through the Web at www.memorygel.com. Because silicone certification requires significant education, the Mentor Web site has three modules. Module 1 is a Labeling Education Module, which includes the Product Data Insert Sheet, the Augmentation Patient Brochure, and the Reconstruction Patient Brochure. Module 2 is a surgical observation video and Module 3 covers tracking requirements. The Mentor site notes that even if you already took a silicone gel training course, you still have to complete the FDA-required training for general use of the Allergan and Mentor products.

The online training courses are company-specific and related to labeling, device tracking, and patient education—not surgical technique. “These topics are mandated by the FDA and have not been covered in the same detail or with the same content in the live courses on silicone gels,” Mentor explains. ●

But what about reports of platinum in silicone implants?

Even with the extensive research showing that silicone breast implants are generally safe, new concerns keep popping up. Don't be surprised if your patients show up with questions about the latest criticism: platinum in silicone breast implants.

The manufacturers and the U.S. Food and Drug Administration (FDA) all say there is no need to worry. But it behooves surgeons to familiarize themselves with the topic before a patient asks a question that you can't answer.

Concerns about platinum are not new, but the issue has received renewed attention recently. Platinum is a metal used as a catalyst in the manufacture of the shell and gel components of silicone breast implants.

Because small amounts of platinum remain in the product following manufacturing, concerns have been raised that platinum may enter the body, either by diffusing through the intact shell or through an implant rupture, and cause adverse effects.

A 1997 study suggested that that platinum leaked from breast implants.¹ The experiments were carried out by exposing three intact, explanted silicone gel-filled implants to 10% soy oil in a water-based mixture or to soy oil alone for 24 hours at body temperature. A 2005 study reported on the presence of platinum in blood and other samples from 18 women who had breast implants (16 with silicone gel-filled breast implants and two with saline implants).² Some of the

silicone gel-filled implants were older generations for which gel bleed rates may differ from currently manufactured implants.

The FDA reviewed the research as part of its process for approving silicone implants and concluded there was little or no reason to worry.

"Some studies have shown that small quantities of platinum may bleed through an intact implant shell and be present in trace amounts (parts per billion) in surrounding tissue. However, these results need to be confirmed using a larger number of subjects. Other studies have serious scientific flaws that raise concerns about the validity of their results and conclusions," according to a June FDA statement. "Based on the existing literature, the FDA believes that the platinum contained in breast implants is in the zero oxidation state, which would pose the lowest risk, and thus that the small amounts of platinum that leak through the shell do not represent a significant risk to women with silicone breast implants."

The complete FDA background report on platinum is available at www.memorygel.com/PDF/Platinum-Safety.pdf. ●

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¹ Lykissa ED, Kala SV, Hurley JB, et al. Release of low molecular weight silicones and platinum from silicone breast implants. *Anal Chem* 1997; 69:4,912-4,916.

² Lykissa ED, Maharaj SVM. Total platinum concentration and platinum oxidation states in body fluids, tissue, and explants from women exposed to silicone and saline breast implants by IC-ICPMS. *Anal Chem* 2006; 78:2,925-2,933.

Web site offers information for patients on silicone implants

Patients may arrive in your office already fully educated about the silicone implants, or they may be curious about the many questions surrounding this augmentation option. In addition to the one-on-one counseling from a physician, many patients appreciate being able to study the topic online at their convenience.

A Web site is available for exactly that purpose. The American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons offer a site called www.breastimplantsafety.org.

The site offers objective and medically grounded information from the leading plastic surgery societies on breast augmentation, breast lifts, breast reconstruction,

and implants, including updates and comparative information on new devices and procedures. Information is available both for women seeking breast surgery for the first time and for those with existing implants that may need revision or replacement.

The Web site contains a photo gallery as well as detailed descriptions of the safety, risks, benefits, and costs of all of the major breast reconstruction and augmentation options. It also has features such as "Find a Surgeon," "Ask a Surgeon," and a "Woman to Woman" forum in which women can submit testimonials about their experiences and tips on selecting and consulting a plastic surgeon.

The site is updated on a regular basis to include the latest research and advances in breast augmentation and reconstruction. ●

Avoid ethical mistakes when advertising your practice

Many plastic surgery practices advertise these days, but the question of exactly what is and isn't acceptable is sometimes difficult to answer. For most surgeons, it comes down to a smell test, says **Barry Lycka, MD**, a plastic surgeon in Edmonton, Alberta, Canada, and founder of the Ethical Cosmetic Surgery Association (ECSA), based in Tallahassee, FL.

ECSA is dedicated to promoting the responsible practice of medicine and avoiding some of the more questionable practices that can creep into plastic surgery marketing. (See p. xx for more information about ECSA.) If the advertising makes you uneasy or you wonder whether you have crossed the line, chances are good that you have, he says.

"Advertising is something that plastic surgeons generally need to do, whether it is wide scale or just the small tasteful ad once in a while to keep your name out there," Lycka says. "There is nothing wrong with advertising as long as it is done properly."

Lycka says the best approach for advertising plastic surgery is to be conservative and attempt to educate, rather than advertise. ECSA encourages the use of seminars and Web sites that educate patients about procedures and plastic surgery in general, rather than direct appeals to book surgery.

Educating consumers about plastic surgery, as opposed to a hard sell that tries to get them in your office, is not just a good and honorable thing to do, Lycka says. It also can help narrow your office visits down to the people who are the best candidates for surgery. Casting too wide a net will be a waste of time

when it turns out that many who visit your office after seeing your ad are not suitable candidates or not seriously interested.

"You can waste a huge amount of advertising dollars by having everyone come to your office, where you're going to have to educate them anyway," he says. "Time is money, so get the right patients to come in, not just anyone."

"You can undermine plastic surgery, and even medicine in general, by appealing to people's baser instincts instead of taking the high road. One of the worst things we can do in advertising is to give false hope to people, to make people think we can fix every problem and make their lives wonderful."

—Barry Lycka, MD

Getting the right people's attention can be challenging, but Lycka cautions that trying too hard can lead your advertising campaign into dangerous territory. Advertising can go wrong in several ways, Lycka says. It can brag about the surgeon's talents so much that it promises results that no surgeon can guarantee. Or it can exploit patients' worst insecurities by trying to convince viewers that common imperfections are serious problems needing surgical correction.

"You can undermine plastic surgery, and even medicine in general, by appealing to people's baser instincts instead of taking the high road," Lycka says. "One of the worst things we can do in advertising is to

ECSA works to improve ethics in plastic surgery

The Ethical Cosmetic Surgery Association (ECSA), based in Tallahassee, FL, aims to provide practice management support for plastic surgeons who are interested in maintaining high levels of integrity and ethical behavior.

The association's Web site is www.ecsaonline.org. (Note that the site is ".org." The same ".com" site is aimed at consumers.)

This is the ECSA Code of Ethics:

1. Understand and advise patients of the inherent risks of cosmetic surgery procedures
2. Provide patients with reasonable outcome expectations
3. Take responsibility for surgery techniques and verify competency that knowledge to an experienced surgeons
4. Maintain our surgery techniques and improve our skills with a continuing education curriculum
5. Always honor commitments made to patients
6. Practice in a safe atmosphere at all times
7. Always employ the highest skilled cosmetic surgery team in the cosmetic surgery field
8. Maintain all equipment in keeping with proper safety standards and to observe all laws and safety regulations established to ensure the safety of our patients
9. Observe all applicable laws or regulations of state, federal, and other governmental bodies and to conduct only such operations as we can perform with competence
10. Participate in only fair and honest advertising of products and services

Source: The Ethical Cosmetic Surgery Association. Adapted with permission.

give false hope to people, to make people think we can fix every problem and make their lives wonderful.”

Avoid ‘bait and switch’ advertising

Lycka advises surgeons to avoid advertising prices at all. Even though many patients shop for the best price on a procedure, advertising your prices can be misleading because the cost varies—and trying to post the lowest price cheapens your image, he says. Further, price-based advertising can lead to a slippery “bait and switch” slope, in which you advertise a low price for Botox or Restylane injections or a “per area” price for liposuction, for example, knowing full well that the

patient likely will end up paying a higher amount once you evaluate his or her particular needs.

“Bait and switch is a terrible thing to do. It’s unethical and once people realize you did that to them, you’ve created ill will with that patient,” he says.

And no matter who creates your advertising, it is your responsibility to ensure that it is tasteful and ethical, says **Z. Paul Lorenc, MD**, clinical professor at New York University School of Medicine’s Institute of Plastic & Reconstructive Surgery. It is common practice to hire advertising and marketing experts to develop and place advertising, but don’t try to duck responsibility for a bad

continued on p. 142

Society bylaws restrict how practices can advertise services

Professional societies can provide guidance about what is and is not acceptable in advertising your plastic surgery practice. Surgeons will want to check with organizations to which they belong, but the Code of Ethics of the American Society of Plastic Surgeons (ASPS) provides a good starting point.

The entire ASPS Code of Ethics can be found online at www.plasticsurgery.org. Select “About” and then choose the Code of Ethics. The following excerpt pertains to advertising:

XI. To assist the public in obtaining medical services, physicians are permitted to make known their services through advertising. Advertising, however, entails the risk that the physician may employ practices that are false, fraudulent, deceptive, or misleading. Regulation is, therefore, necessary and in the public interest. Subsection II of the Specific Principles permits public dissemination of truthful information about medical services, while prohibiting false, fraudulent, deceptive or misleading communications, and restricting direct solicitation.

II. Advertising

A. Subject to the limitations of Section 2, I, G, a member may advertise through public communications media such as professional announcements, telephone and medical directories, computer bulletin boards, Internet Web pages, and broadcast and electronic media. The following are examples of the types of useful information that could be included in ethical advertising. The list is illustrative and should not be interpreted as excluding other relevant information consistent with the ethical guidelines established herein.

1. A statement of regular e-mail or Web site addresses and telephone numbers of the member’s office(s)
2. A statement of office hours regularly maintained by the member
3. A statement of language, other than English, fluently spoken by the physician or a person in the physician’s office
4. A statement as to specialty board certification or a statement that the physician’s practice is limited to specific fields

5. A statement that the member provides services under specified private or public insurance plans or health care plans
 6. A statement of names of schools and postgraduate clinical training programs from which the member has graduated together with the degrees received
 7. A listing of the member’s publications in educational journals
 8. A statement of teaching positions currently or formerly held by the member together with pertinent dates.
 9. A statement of the member’s affiliations with hospitals or clinics
 10. A statement that the member regularly accepts installment payments of fees, credit cards, other available financing options
- B.** A member shall not compensate or give anything of value directly or indirectly to a representative of the press, radio, television, or other communication medium in anticipation of or return for recommending the member’s services or for professional publicity. A member may pay the reasonable cost of advertising permitted by this Code. A member shall approve all advertisements before dissemination or transmission, and shall retain a copy or record of all such advertisements in their entirety for one year after its dissemination. A member shall be held personally responsible for any violation of the Code of Ethics incurred by a public relations, advertising, or similar firm which he or she retains, or any entity that advertises on the member’s behalf.
- C.** A member may use photographs of models in his or her advertisements. If photographs of models who have not received the services advertised are displayed in a manner that would suggest the model received the services advertised, the advertisement shall clearly and noticeably state that the model has not received the advertised services.

Source: The American Society of Plastic Surgeons. Adapted with permission.

Advertising

continued from p. 141

ad campaign by saying your ad agency ran amok.

"That's a very, very common excuse, but it doesn't hold water," Lorenc says. "It's your practice, your ad, and your money paying for it, so you have to take responsibility for what goes out to the public. You have to personally approve every ad for your practice and you shouldn't take that lightly when you're asked to sign off on something that might not be okay."

Lorenc also cautions plastic surgeons not to claim that they are the best in town or better than their competitors. Terms such as "best face lift in town" or "come see the best plastic surgeons in town" are misleading and may invite a letter from your professional organization's ethics board. (Lorenc advises checking with your society's Code of Ethics. See p. xx for more information.)

"Never forget that your competitors also are reading every word in your advertising. If you say something that disparages them by comparison, you may have to answer for that," Lorenc says. "You have to stick to the factual, always."

It is acceptable to state your experience and credentials in the advertising, but be careful not to embellish, says Lorenc, who once taught a resident who spent a couple of weeks at the institute and later advertised that he had had a full fellowship.

"We got feedback from the town he went back to, saying they thought he was overstating his experience here. Of course his excuse was that his [public relations] people put that together and he didn't have any control over it," Lorenc says. "We had another case in which a young plastic surgeon went out and said he devised some new face lifting techniques, which was hard to believe when he had only finished his studies a few weeks earlier. It discounts you when you make unrealistic claims and get caught."

Lorenc always warns his students to never make any guarantee in advertising, or any statement that could even remotely be construed as a guarantee. Doing so could encourage patients to sue if they are unhappy with the results, he says.

Consider placement of ads

The content of the advertising is not the only matter to consider. The placement also can be problematic.

"I was in Las Vegas recently and saw a taxi cab with an advertising placard on the top, and one side had a plastic surgery practice. The other side had an ad for one of those nude reviews," Lycka recalls. The surgeon's ad denigrated the image of the surgeon and the profession, Lycka says.

"Never forget that your competitors also are reading every word in your advertising. If you say something that disparages them by comparison, you may have to answer for that. You have to stick to the factual, always."

—Z. Paul Lorenc, MD

Lycka also remembers seeing an ad in a glossy magazine that depicted an attractive woman standing next to an equally attractive Ferrari sports car. The caption said "Car by Ferrari, Body by" the plastic surgeon. Soon after the ad was published, it became known that the doctor actually had not performed any surgery on the model in the ad.

"She hadn't had any work. She was a natural," Lycka says. "It became a scandal for this doctor and it could have very easily been avoided by doing a better ad. That sort of thing throws a lot of ill repute on our whole profession." ●

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Enzyme injections may help women fight cellulite, study shows

Women may have a fighting chance to diminish the appearance of cellulite through collagenase enzyme injections, according to preliminary clinical trial study results presented recently during the American Society of Plastic Surgeons Plastic Surgery 2006 conference in San Francisco.

The results were presented by **Alexander Dagum, MD**, chief of plastic surgery at Stony Brook (NY) University Medical Center (SBUMC).

"One of the biggest and most frustrating problem areas for women are their thighs; even healthy weight women often have cellulite in this area," Dagum says. "Our initial findings suggest that women may one day be able to safely and effectively reduce that cottage-cheese appearance with a visit to their plastic surgeon's office."

In the study, authored by Dagum and **Marie Badalamente, PhD**, professor of orthopedics at SBUMC, 10 female patients received collagenase injections in their thighs. Subjective measurements of the cellulite and photographs were taken before and after the procedure. Within one day, patients had a 77% decrease in the appearance of cellulite. After six months, results

remained noticeable, with patients experiencing a 76% decrease in the appearance of cellulite since the treatment began. There was no significant change in the patients' body mass index or thigh measurements.

At six months, all patients said they were either very or completely satisfied with their results. The only side effects, which lasted one to two weeks, were soreness, mild swelling, and bruising.

Collagenase, an enzyme naturally found in the body, helps break down fibrous tissue by dissolving collagen. Removing these anchoring fibers and breaking up enlarged fat cells seems to release the outer tissue, causing the skin to appear smoother, Dagum explains.

"Before starting this study, I was highly skeptical that collagenase injections would help smooth out the appearance of cellulite," Dagum says. "However, I've really been impressed by the results, as have my patients. Initial results show that this procedure may quickly reduce cellulite with minimal, if any, side effects."

Although the study "Collagenase in the Treatment of Cellulite" is no longer active, it may continue at a future date. Recruitment will likely be for women or men aged 18 years or older. Dagum says surgeons interested in being contacted if and when the study is reinstated should call Stony Brook University Medical Center HealthConnect at 631/444-4000. ●

Breast asymmetry causes significant problems for some

Breast asymmetry is a relatively common condition that is often not discussed. However, new research confirms that the resulting embarrassment can affect women's daily lives, sexuality, and confidence. For those with significant asymmetry, breast surgery can considerably elevate quality of life and self-esteem, according to the research presented recently during the American Society of Plastic Surgeons (ASPS) Plastic Surgery 2006 conference in San Francisco.

Walter Erhardt, MD, a surgeon in Albany, GA, and chair of the ASPS Public Education Committee, says surgeons should remember that this is a problem women often have difficulty bringing up on their own.

"All women have some degree of breast asymmetry,

but for those with a noticeable difference, the embarrassment often keeps them from seeking help," he says. "Even if breasts differ by less than a half-cup size it can be very noticeable. The condition is talked about so infrequently that many are unaware that there are surgeries that can correct the problem."

In the study, the authors measured how breast asymmetry surgery affected quality of life and self-esteem in 35 patients. Six months after undergoing surgery to correct the problem, all patients had statistically significant improvement in vitality, mental health, and self-esteem.

"Breast asymmetry can be emotionally devastating for women," Erhardt says. "Women need to know that this condition is extremely common, and there is nothing to be ashamed of in getting help that will improve their quality of life and self-esteem." ●

ASAPS cautions against use of lipoplasty for children

In a stern warning to surgeons and parents, the American Society for Aesthetic Plastic Surgery (ASAPS) announced recently that there is "no scientific evidence to

support the safety or efficacy of large-volume lipoplasty (liposuction) for weight loss in obese children." Further, the society noted that liposuction is not an effective treatment for obesity in any patient—adult or child.

continued on p. 144

Lipoplasty

continued from p. 143

The statement was issued in response to recent media reports of an obese 12-year old female who underwent large-volume lipoplasty. The ASAPS reported that clinical studies have demonstrated that lipoplasty does not have the same health benefits (e.g., reduced risk of heart disease/diabetes or benefits to metabolism) as diet and exercise. The child was Brooke Bates, of Austin, TX, who made media appearances after the surgery and explained that she has struggled with her weight since early childhood. By age 11, Brooke weighed 180 pounds; a year later, at 5-foot-5, she rose to 220 pounds, and her doctors classified her as morbidly obese. She and her family considered gastric bypass surgery but feared it was too risky. A plastic surgeon in Austin removed 35 pounds of fat and fluid from her body. After other lifestyle changes, Brooke now weighs 153 pounds.

Peter Rubin, MD, a member of the society's Body Contouring Committee and assistant professor of plastic surgery at the University of Pittsburgh, says surgeons must remember that lipoplasty does not address the important lifestyle and diet issues necessary for long-term weight loss. Lipoplasty in children "sends a dangerous message to our young people that plastic surgery is a cure for being overweight. That is simply not the case," Rubin says. "I would question the ability of a 12-year-old girl to fully appreciate the scope of possible complications and make a reasonable decision about an elective cosmetic procedure."

The point is underscored by **David Sarwer**, associate professor of psychology at the University of Pennsylvania's Center for Human Appearance and director of clinical services at the Center for Weight and Eating Disorders, both in Philadelphia. He is a noted expert on body image and plastic surgery.

"Childhood obesity is one of our nation's growing health problems, and there are a number of widely accepted treatments for children and adolescents who struggle with their weight. Liposuction and abdominoplasty are not among them," he says. "There is no evidence to suggest that these procedures lead to improvements in health conditions affected by obesity. Hopefully, the media attention surrounding this story does not lead other adolescents and their families to think that liposuction and abdominoplasty are accepted treatments for obesity."

James Stuzin, MD, president of ASAPS, says surgeons should refuse to perform lipoplasty on children. "The use of large-volume lipoplasty without the data to support its safety and efficacy in childhood obesity goes against our mission," he says. ●

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