PLASTIC SURGERY NEWS

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Plastic Surgery NEWS

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FDA decision on silicone breast implants called a 'disappointment'

BY LOUSANNE LOFGREN, CAE

The FDA's Jan. 9 decision on Inamed Corp.'s pre-market approval application for silicone gel filled breast implants set off a firestorm of media headlines such as "FDA raises breast implants" and "FDA says 'no' to silicone gel implants." A more accurate interpretation of the decision might be, "FDA delays on silicone implants."

The "not-approvable letter" sent by the FDA to Inamed represents yet another step in the long regulatory process for breast implants that has been characterized by highs and lows over more than three decades. The highs have come from study after study that failed to find systemic disease related to implants, while the lows have been the ongoing drumbeat of litigation and the sometimes FDA decisions come with all-encompassing.

In a definitive sense, the FDA's action prevents silicone gel breast implants from re-entering the marketplace until additional data are gathered by the manufacturer and evaluated by the agency. The decision, however, continues to allow access to the device for women who have had mastectomies and those enrolled in clinical studies.

A rarity

The agency's decision marked one of the rare instances in which the FDA did not follow the recommendation of its advisory panel. In October, the agency's General and Plastic Surgery Device Panel in a 9-6 vote recommended approval of the application for marketing, allowing widespread use in the United States. The recommendation included "conditions" the company would need to meet in exchange for PMA approval, including an implant registry, physician education, patient education, informed consent, patient follow-up and additional research.

While the FDA generally follows its advisory panels' recommendations, many will recall the FDA silicone implant panel hearings in the early 1990s and the agency's decision that also did not reflect the panel's recommendation.

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U.S. plastic surgeons gear up for new generation of fillers

BY JIM LEONARDO

The FDA's December approval of a hyaluronic acid filler poses new questions for plastic surgeons – how to become properly trained in its use and how to market it. Plastic surgeons who choose to incorporate the filler, known by its brand name Restylane®, into their practices must be thoroughly educated in its proper administration before offering it to patients. Good results through proper application is the most effective marketing technique available, according to ASPS President Rod Rohrich, MD, Dallas.

Due to its nature, hyaluronic acid injections require techniques unlike those for any other injectable filler, a factor that demands per-use training, he says. Dr. Rohrich maintains that the society will do its part to educate its members about Restylane's safe and effective use.

Help is coming

"Proper training is the key to this hyaluronic acid filler," Dr. Rohrich says. "Restylane requires different injection skills than, for instance, collagen, so plastic surgeons need to learn how to use it correctly."

One difference between this and other fillers is that "there's a little more discomfort" with the injection itself – thus mandating a dental block of the lips – and precision in depth of the injection, he says.

To provide the required knowledge, ASPS/PSEF, in conjunction with ASAPS, will sponsor courses on the hyaluronic acid filler during the Plastic Surgery 2004 annual meeting in Philadelphia and at the ASAPS annual meeting in Vancouver. This is in addition to other Educational Foundation-sponsored courses, as occurred last year with botulinum toxin type A. The University of Texas Southwestern in Dallas will hold a course March 27.

"These courses will address how to inject Restylane, on whom to use it and live demonstrations," he says, as well as discussions on patient expectations and informed consent.

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patients and helped with my development of its use," Dr. Born notes.

He wholeheartedly agrees with Drs. Rohrich's and Lorenc's training recommendations and warns against rushing to build a Restylane-related patient base. "It will build itself if you're careful and do quality work, it will come. Definitely."

Your best marketing

Dr. Rohrich says hyaluronic acid can be best marketed through good results. "Your best marketing tool is learning how to properly administer hyaluronic acid, and your best advertisements are your patients," he says.

Restylane experienced ASPS members in Canada can offer marketing advice based on their years' experience with the filler.

Gregory Wasden, MD, Calgary, Alberta, Canada, ventures into his community to inform potential patients of the benefits of facial rejuvenation, including Restylane. It is a necessary part of building his practice, he says.

"The most important thing I've learned in my 20 years of practice," he says, "is that you must want to establish a practice by this or that efficient kind is speaking directly with patients, not Dr. Wasden welcomes the opportunity to reach out to those not yet initiated to a procedure.

He holds educational seminars for potential patients. "I place an ad in our local newspaper announcing a free seminar to offer some information on plastic surgery procedures," he says. The ads contain a phone number to call for a reservation.

Dr. Wasden has held three seminars thus far, began each by explaining or describing all of plastic surgery, including skin facelifts and injectables, accompanied by a Powerpoint presentation and followed by a question- and answer session that averaged 30 minutes. Attendees received brochures outlining Dr. Wasden's education, experience, training and skills.

"Each of the three has been well attended – 20-25 each on three different evenings," Dr. Wasden says.

Big dividends will come with paying attention to aesthetician, hairdressers and spa specialists in general, Dr. Wasden notes. "These are people who need to know what plastic surgeons do. They are a very knowledgeable group, and once we have a chance to educate them, they're willing converts" who will regularly send clients to board certified plastic surgeons, he says.

Dr. Born was working with a public relations firm when Restylane received its approval. The firm focused on media attention rather than patient attraction, distributing press releases through a news wire and calling specific journalists with whom the P.R. firm had a relationship. "Whether they would follow-up on the news release was out of our hands, but it is important to build a relationship with media," Dr. Born says.

Dr. Rohrich sees a patient base built upon internal control. "Rather than external attempts on developing their techniques and continuing with their patients through e-mail, their Web sites and their practice newsletters," he says. "These patients will be the source accepting of any potential learning curve from brand new patients as whom you're marketing yourself as an expert."

According to Dr. Lorenc, the most effective marketing tool is an Restylane's "process education that's the terms I would use over and over. I use it in the office [injectable filler] exit diary."

Scheduling key

Those who have used hyaluronic acid fillers have learned quick lessons on scheduling.

"We learned that when scheduling patients calling for a consultation and injection, we need to create or reserve a bigger block of time," Dr. Born says. "The main thing we learned: We must be very specific in keeping the patient 'on topic' when she or he is on the phone, or else they voice on to different topics, ask additional questions about unrelated procedures and consume more time.

"When a patient comes for a filler, my nurse discusses their options, and I'll visit with him or her for a final assessment, and either go ahead with the injection or prepare for another day if I need more time for the injection," he says.

Dr. Rohrich's observations of hyaluronic acid lead him to concur. "I have separate office hours for Restylane because I take 15-20 minutes for each injection," he says. "I do a regional block and come back. It takes a bit more time."

A positive impact

Dr. Wasden says injectables have had "a very complementary effect" on his practice. "I feel I'm providing a more well-rounded practice. There's no question that it offers me another area for patient referrals, either directly for injectables or for other things: It's not uncommon for someone to come in for an injectable and pick up a brochure for a facelift to give to a friend or relative.

"It would be difficult to maintain a high quality aesthetic practice without injectables," Dr. Wasden says. "On a daily basis 15-20 patients of my patients are there for injectables, and they generate other patients. That's what makes me busy."

Dr. Lorenc says Restylane will be a boon to plastic surgeons for a reason perhaps overlooked by many: the ease by which its workings can be explained to – and understood by – the public.

"Patients' eyes light up when they hear that Restylane is composed of naturally derived sugars they have in their bodies, and that it's not animal- or human-derived; as a result, they don't have to be skin-tested. These are great selling points to patients," he notes.

For more information or to purchase the "Injectable Fillers Soft Tissue Augmentation" brochure, call ASPS Member Service at 1-800-766-4955, press 7, or go to www.plasticsurgery.org/psf, click on "Practice Tools," and choose "Product Catalogue."

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Shop online today (that is, whenever it's convenient for you)! Visit PSF® at www.plasticsurgery.org/psf and enter your username and password. For login assistance call 1-800-766-4955, press 6.

How they work

Hyaluronic acid is merely the newest addition to the line of fillers mainly used as an adjunct for facial rejuvenation. Restylane joins Botox®, collagen and others approved by the FDA for use in the United States. Hylaform®, a bioharmonic acid filler extracted from rooster combs, and Artecoll®, which combines collagen with tiny, non-silicone carbon-based polymers, are currently under FDA consideration.

Injected into the skin as a gel, hyaluronic acid – a main component of which is glucuronic acid and N-acetyl glucosamine, or sugars – absorbs water and binds subcutaneous tissue as it slowly degrades, causing facial lines and grooves to fade. The effective period of hyaluronic acid is approximately nine years and it is gradually absorbed by the body.

Collagen, a naturally occurring protein that supports joints and other body parts, can be injected as a filler. Its cosmetic effects result from, literally, the filling of facial lines from below. The effects of injections can last up to two years. Like hyaluronic acid, collagen is gradually absorbed by the body.

Indications for other injectable fillers can be obtained by going to www.plasticsurgery.org, clicking on "News Room," and looking under "Press Kits."

ARTICLE HIGHLIGHTS

> Unlike the impending U.S. education effort, Canadian plastic surgeons, whose government approved Restylane in 1998, received little training beyond the manufacturer's brief introduction. "A lot of my experience is self-taught," says Trevor Born, MD, Toronto, Ontario, Canada.

Therefore, his familiarity with Restylane progressed slowly. "I started very conservatively and took a lot of time explaining it to patients. My results were good and my patients were satisfied with the results, which greatly increased the number of subsequent patients and helped with my development of the use," Dr. Born notes.

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