ASPS and FDA partner to answer lingering breast implant questions

BY JIM LEONARDO

A unique and long-anticipated partnership grounded in patient safety has the FDA and ASPS working together to develop a national breast implant registry to track breast implants. This new registry will serve as a critical piece of the infrastructure for ongoing breast implant surveillance. It's anticipated that the partnership between ASPS and FDA will inform both existing and new regulatory requirements associated with these devices.

It's a "meeting of the minds" that gained steam when the FDA in 2009 released its findings of an association between anaplastic large-cell lymphoma (ALCL) and breast implants. ASPS has worked closely with the FDA to identify new cases and develop key questions for further investigation of the possible association between breast implants and ALCL.

The fruits of the ASPS and FDA collaboration can already be seen in the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) study – a working data repository – and the National Breast Implant Registry (NBIR), which is under construction.

Have you seen a case of ALCL?
All plastic surgeons are strongly encouraged to contact ASPS to report confirmed or suspected cases of ALCL. This can be done by sending an e-mail to *ALCL@plasticsurgery.org* or by contacting the ASPS Executive Office at (847) 981-9900.

A Cooperative Research and Development Agreement (CRADA) – executed between ASPS and the FDA in June 2011 to build the PROFILE study – was amended in June 2012 to include construction of the NBIR, with device manufacturers and other industry representatives invited to provide relevant perspective.

Since then, the work of ASPS and the FDA has gained momentum – and in mid-October, stakeholder representatives (industry, ASPS and the FDA) met in Washington, D.C., to solidify their roles and further hash-out how each would contribute to the development of the NBIR.

Plastic surgeons involved in breast implant surgery will always seek the very best devices available worldwide, says ASPS member Andrea Pusic, MD, MHS, the principle investigator acting on behalf of The PSF and plastic surgery to develop the registries. Therefore, it makes perfect sense that plastic surgery would grasp this opportunity to collaborate with the FDA.

"Doing so will allow us to have quicker and more efficacious access to these devices to offer them to our patients," says Dr. Pusic, a plastic surgeon at Memorial Sloan-Kettering Cancer Center and noted authority on outcomes registries and related data.

"Plastic surgeons who belong to ASPS put a premium on safety, but we're also about being on the cutting-edge," she adds. "So PROFILE and the NBIR will provide the infrastructure that will satisfy what the Agency seeks for regulatory requirements – while streamlining the process by which these products come safely and efficiently into the U.S. market."

Data registries unlike any other

The Society and the Agency are developing a data collection infrastructure unlike any repositories seen by ASPS members.

"We're applying modern statistical methods and modern study design to these registries, and what plastic surgeons will encounter will be very lean and clean data-gathering machines," Dr. Pusic says. "We understand that in order for a registry to be successful, it must incorporate a design that is input-friendly and not interfere with the flow of a busy surgical practice. We're developing a completely different approach with these."

The registries will be "far less onerous to patients and providers than anything that we've seen in the past," Dr. Pusic says. "Whereas the current post-market breast implant surveillance system is very paper-intensive, and often difficult to manage for participating physicians and patients, what we're designing will be intuitive and simple."

Drilling-down for efficiency

One critical question highlighted by the stakeholders involved in developing the registries is: How can its developers ensure that the information to be collected is truly clinically relevant? That issue will be a matter of intense focus for the study design team, Dr. Pusic notes.

The efficacy of the PROFILE and NBIR registries will rely on the consolidation and codification of everything the Society has learned about registries – and create the "leaner, cleaner" registries anticipated by all stakeholders, she says.

"We're looking hard at what clinical questions the NBIR should address. We must answer questions that are clinically relevant to plastic surgeons and our patients," she says. "This will involve a deconstruction that will include a review of current evidence involving rare conditions possibly associated with breast implants. As we develop the registry, we have no intention of chasing the same things we were chasing 10-15 years ago just because they were 'on the list.' A key question that I will continue to ask: Is the information that's going to be collected truly and clinically relevant? If not relevant, we don't intend to collect it."

The finished – but relentlessly "work-in-progress" – registries will provide clinically relevant outcomes data that will inform patients and clinicians, Dr. Pusic says. "We anticipate that this new infrastructure will assist our industry partners by furnishing a reliable mechanism with which they can potentially take their R&D and bring it into the U.S. market with increased efficiency," she says. "This way, all of us can utilize the best available devices."

Reducing trouble's footprint

The FDA in January 2011 announced that it had conducted a thorough review of scientific literature published from January 1997 through May 2010 – and had identified 34 unique cases worldwide of ALCL in women with breast implants. The announcement spurred ASPS into action. The PROFILE and NBIR studies are currently the most significant and visible vehicles under development through joint efforts of the FDA and ASPS.

According to the FDA's ALCL webpage (go to *fda.gov*, and enter "ALCL" into the search field), "The number of identified cases is small compared to the estimated 5 million-10 million women who have received breast implants worldwide. But based on these data, the FDA believes that women with breast implants may have a very small but increased risk of ALCL."

An FDA executive summary noted: "Because the risk of ALCL appears very small, FDA believes that the totality of evidence continues to support a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled."

The PROFILE study saw its beginnings at an ALCL panel held in 2011 at Plastic Surgery The Meeting in Denver. Then-ASPS President Phil Haeck, MD, implored all ASPS members to contribute to future data repositories, to help address vexing issues that will forever linger without new data.

Dr. Haeck's remarks shed early light on the priority the Society and the FDA were placing on breast implant data repositories. Are they all (ALCL cases) associated with silicone implants? We don't know," he told the Denver audience.

"The problem with the data we have now is that when you're going back to do retrospective reviews on cases that are 10-15 years old, it's almost impossible to know what type the implant was," he said. "There may be an operative report and some findings written within, but the implant will be long gone – and it may or may not have gone to a pathologist. Right now, it's pretty clear that we're going to have some saline, some silicone and some may have been textured. That's all we're going to know about it. (Registries) will give us a lot more information."

Respect

The expanding relationship between the Society and the Agency forecasts future collaborations that will help both add to their respective requirements of patient safety – and to the collegiality that will allow one to draw increasingly on the other's expertise, Dr. Pusic notes.

"The FDA respects us as a professional society," she says. "They've asked for our clinical expertise, as we've asked for their expertise and guidance. We have the same goal – working to offer the highest level of patient safety and the best outcomes for patients – so this pairing of the two groups provides a great chance for each organization to meet these critical goals.

"My impression of the FDA is that their leadership is very forward thinking and really wants to work with us," she adds. "The FDA would like to move device approvals through faster without compromising safety and provide more efficient surveillance of devices once they are on the market. And they're relying on us to give them the guidance on what's clinically relevant and what's important in designing pre- and post-market studies.

"Establishing the CRADA around the PROFILE study opened our eyes and the eyes of the Agency," Dr. Pusic says. "Each side in this collaboration is saying, 'These are people we can really work with.' " PSN

Input from ASPS members gives new MOC-PS exam study guide greater value – for less cost

Credit ASPS members for the newest version of the MOC-PS® Exam Study Guide. Input and suggestions from plastic surgeons over the last few years have driven the redesign of the study guide's presentation – from a single overarching guide to four individual guides in 2013, each one available as a separate study tool with its own CME credits.

A second change driven by membership is the new discount offered in conjunction with another, related testing product – the Comprehensive Self-Assessment Tool (CSAT), where residents can gain savings totaling $100 or $150. The CSAT is an excellent, online reference tool aimed at residents and younger surgeons to provide an overall review of plastic surgery content that could be used for exam preparation – including study for the ABPS Board exams and the ASPS In-Service Examination.

Youth is served

The improvements have been implemented to better serve young surgeons and others who called for a more streamlined and cost-effective way to achieve their study goals, according to ASPS Vice President of Education Keith Brandt, MD.

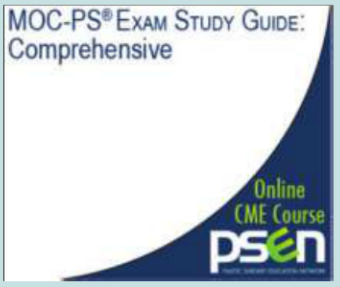
"Based on usage patterns, the MOC-PS study guide has been disassembled from a single 'block' of a study guide and repackaged into four, individual study guides based on subspecialty," Dr. Brandt says.

"In the past, the subspecialty modules were included in one block. While members had the potential to earn 20 CME credits for completing all of them, most plastic surgeons merely claimed the six or eight *AMA PRA Category 1 Credits*™ from studying a single subspecialty," he adds. "Starting with the 2013 exam, plastic surgeons will earn more than double the Category 1 credits they generally had under the old format and similar guides – the new division of subjects presents an overall increase in available credits."

Break it down

The four targeted guides that will be offered in 2013 are **Comprehensive, Cosmetic, Craniomaxillofacial** and **Hand**. This year, plastic surgeons can earn CME credits totaling 20 hours from Comprehensive; 16 hours from Cosmetic; 16 hours from Craniomaxillofacial; and 16 hours from Hand. (Each module's total includes four hours of credit for **Core** learning.)

The CSAT has been repriced for younger



surgeons. For individual residents, the cost of the self-assessment tool is $149; however, if three or more residents from the same training program combine for this offer, the price drops to $99 for each resident. Young plastic surgeons who've finished residency and have entered private practice will see the cost remain at $249.

"The Society is always on the lookout for way to better serve its members – particularly residents and young surgeons who are still finding their footing," Dr. Brandt says. "Hopefully, the changes in the study guide modules, as well as the self-assessment, will give them a significant boost in the development of their skill sets for this specialty." PSN