BY JIM LEONARDO

The desire to provide the FDA with information for its deliberations on facial soft-tissue fillers led to the need to assemble primary stakeholders for intensive discussion relating to the medical device provided the impetus for the Face Soft Tissue Fillers Senate Conference held Dec. 6-7 in Washington, D.C.

Plastic surgeons, dermatologists, ophthalmologists, researchers, device manufacturers and other stakeholders met at a joint conference called by ASPS and the American Academy of Dermatology (AAD) and co-chaired by ASPS past President Rod Rohrich, MD, and AAD past President C. William Harke.

In addition to ASPS and AAD, the conference was held in cooperation with the American Society for Aesthetic Plastic and Reconstructive Surgery; American Academy of Ophthalmology; American Academy of Otology/Neurology-Head and Neck Surgery; American Society for Artistic and Reconstructive Surgery and American Society of Dermatologic Surgery. Other physicians also were in attendance, although they did not officially represent the organizations to which they belong.

Among the stated objectives tackled by the approximately 60 attendees were patient safety, efficacy and cost-effectiveness in relation to approved and off-label use of soft-tissue fillers and candid information exchange as well as the spirit of cooperation among the participants. In addition, the conference composed of professionals who are very experienced, knowledgeable, forthright and collegial,” Dr. McGuire says. “Not only did agreement result. Both this synergy and good-harmony among the core specialties as well as the sub-specialties. From the perspective of meeting official and unofficial goals, it was a great success.”

And after two days of lively debating and consulting with AAD President David Pariser, MD, we departed not only as colleagues, but as friends.”

On the elements that came together in the unprecedented conference elevated the discourse and resulted in tangible gains, “It was truly the first time all the disciplines of cosmetic medicine – plastic surgery, dermatology, facial plastic surgery, ophthalmology and industry – met in a unique setting that focused specifically upon professional groups point by the FDA,” he says. “We talked about what hasn’t worked, what’s worked and what’s needed to make it work better. The focus rightfully was on safety – and of course on our patients, and how we can improve these.”

The core organization initially wanted the FDA involved in this conference, but due to its internal organization, instead became a preliminary conference in anticipation of a subsequent one that would adhere tightly to regulations that would allow the FDA to participate.

The agency is limited by its governmental process in how it can participate in meetings, and the format of this meeting was not in line with their guidelines – so their representatives were unable to participate in this particular meeting,” Dr. McGuire says. “Nevertheless, we agree that a greater dialogue with the FDA is desirable from both sides.”

The ASPS president adds that the unprecedented combination of the conference was among the elements that pointed to a bright future for the discussion of, and action relating to, facial soft-tissue fillers. “Never before had all these groups gathered in one room to discuss a common area of interest and concern, and to share education with each other,” Dr. McGuire adds. “In the long run, that might be the most important outcome of this meeting.”

Six sessions over two days

The conference was broken down into six sessions that addressed:

- Tools for predicting and assessing fillers’ efficacy, effectiveness and/or safety
- Adverse-event labeling, and related communication with providers and patients
- Current and future research needs
- The synthesis of state-of-the-art findings and implications

Through her Dec. 7 presentation, “Deriving Meaningful Data from Subjective Study Endpoints and Quality of Life Data,” Dr. Pariser provided a systematic review of existing data collection methods, as well as ways to design additional studies to collect data on product effectiveness based on subjective study endpoints – including, the FACE-Q. “The overall message was that understanding patients’ perceptions of outcomes is clearly important with regard to facial fillers, but we didn’t fully know how to capture that information in a way that was reliable and valid,” she says.

“While photo analysis and complications collected by clinicians are still very important, we also can tap into other measurement tools to add to that knowledge base. These won’t replace other analyses – they will flesh those out.”

One of these is the FACE-Q, which will soon be ready to incorporate the collection of patient-reported outcomes data on fillers into studies.

“It’s also very positive that we’ve begun to embrace a common language,” she says. “If we all report with the same outcomes measure, we can directly compare different populations and different studies, as long as you think about it, effective action anywhere begins when participants in that action fully understand one another.”

Next steps

The proceedings and related information will be published in the PRS journal, an effort that will include a systematic review of facial soft-tissue fillers, Dr. Rohrich says.

“In addition to providing our printed analysis, I’m hopeful that future meetings of these core specialties will lead to a more streamlined process for the safe approval of fillers – and a more open process in which we can report outcomes, safety and adverse events with more quick and historically available,” Dr. Rohrich adds.

“This conference laid the groundwork for additional meetings with the same goals,” Dr. McGuire says. “The more our organizations get together and recognize how much we have in common, the greater will be the benefit for all of us. The sooner this can happen, the better for our patients. Ultimately, they’re the ones we serve. We need to ensure their safety – and be able to prove to them through rigorous data that they are, in fact, in good hands.”

BY MICHAEL MCGUIRE, MD

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A SP S/PSSF and ASAPS/ASEF are convening an advisory council of experts from plastic surgery, dermatology, pathology, oncology and the FDA to further study anecdotal case reports of an abnormality that has been found in a small number of patients with saline and silicone gel breast implants. The impetus for convening this panel came from recent reports by Gary Brody, MD, professor emeritus at the University of Southern California, who has sought to identify any common factors and gain a greater understanding of the cases. Dr. Brody will be presenting his most current data in March at the meeting of the American Association of Plastic Surgeons in San Antonio, Texas. The draft for his presentation is available on the ASPS website at asps192.org/abstracts/2010/04/e7.

In recent weeks, the leadership of ASPS/PSSF and ASAPS/ASEF became aware of several additional cases and undertook a thorough analysis of the currently available data by meeting with Dr. Brody and his research team, and by consulting with additional epidemiologists, oncologists and pathologists with expertise in this area. What is known is that in more than half the cases reported, the lymphocytes have been found in seroma fluid or capsular tissue adjacent to the breast implants. Several of the cases have been confirmed as primary implant infections. In the joint lymphocytes have been found in seroma fluid or capsular tissue adjacent to the breast implants. Several of the cases have been confirmed by pathologists. In the joint lymphocytoma (ALCL) of the breast; however, the clinical outcome in the cases to date has not been typical of primary ALCL of the breast in women without implants – with most cases appearing to have a benign course.

Many of the known cases were in patients with implants textured using the now-debunked manufacturing process. It is important to note that the accurate pathologic diagnosis of the observed abnormality cannot be limited to cytologic or histologic only, and require a more specialized (immuno-)histochemical testing by a pathologist specializing in this field. Most importantly, it must be emphasized that currently, there is no currently available data, the clinical significance and incidence is unknown.

In addition to convening the advisory council of experts, the PSSF through funds from the National Endowment for Plastic Surgery – which was specifically created to fund research on topics of immediate relevance to the practice of plastic surgery – will support continued research by Dr. Brody and his team. Further, ASPS/ASAPS and PSSF/ASEF have received unqualified support from the three major implant manufacturers for additional research to be determined by the advisory council.

Based on what we know today and given that additional information is being evaluated, we are not making recommendations to change current clinical practice. As additional information is evaluated, this could be considered if appropriate. Additional data would be needed to determine the depth of this effort in a careful, expeditious and transparent manner to yield the needed and valid scientific data. For additional information and action, please visit the “Members Only” section of plasticurgery.org and click on “The New Breast Implant Research Link.”

BY JIM LEONARDO

New CME recording process offers greater ease – and speed

In a continuing effort to more efficiently post CME credits and avoid unnecessary delays, ASPS members may now submit the following information online through the “CME Center” on the ASPS website at plasticsurgery.org:

- All Category 2 credits
- Category 1 credits from non-ASPS activities, unless special arrangements have been made with other organizations (including ASPS, California Society of Plastic Surgeons, Texas Society of Plastic Surgeons and the Florida Society of Plastic Surgeons)

To access the CME submission form – or view your CME report – simply log-in to the ASPS website at plasticsurgery.org and click on “CME Center” in the upper-right-hand corner on the homepage.

The practice of faxing or mailing the above-listed CME credit forms to ASPS is being discontinued. To answer questions and to assist you and your staff during this important transition, ASPS Member Services Center representatives are available at (800) 766-4955.