COMING

CLARITY ON THE BREAST IMPLANT/ANAPLASTIC LARGE CELL LYMPHOMA (ALCL) LINK

Silicone-filled breast implants have certainly garnered their fair share of headlines over the years, and they are back in the news due to reports of a small but increased risk of anaplastic large cell lymphoma (ALCL) seen in the scar capsule adjacent to textured implants. ALCL is a rare and treatable type of T-cell lymphoma. Many of us vividly recall the 14-year ban on silicone-filled breast implants that ended in 2006, and this is starting to feel like déjà vu all over again. Is the link concerning? Yes. Do we know enough to say how concerning? Not yet.

We should have some clarity soon, thanks to the American Society of Plastic Surgeons (ASPS)/FDA PROFILE Registry, which is tracking and confirming cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). PROFILE has received 183 reports of unique cases of BIA-ALCL in the US as of December 1, 2017. Worldwide, approximately 500 unique cases have been reported, including 17 disease-related deaths. The ASPS and the American Society for Aesthetic Plastic Surgery (ASAPS) BIA-ALCL task force is also on the case. As experts investigate the risks, we must remain informed, prudent, and vigilant and be ready to have open conversations with patients. In addition, the FDA recommends that any suspected or confirmed cases of BIA–ALCL be reported to the PROFILE registry (thepsf.org/PROFILE), the MAUDE database (Accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm), and the device manufacturer.

GOING

STEM CELL INSANITY

The FDA is cracking down on stem cell claims in big, bold ways. And don't test them; they mean business. The Administration announced a plan to regulate stem cell procedures and is focusing enforcement efforts on "bad actors" that inject stem cells into the bloodstream, nervous system, or eyes for a variety of diseases, including multiple sclerosis and Alzheimer's. Going forward, such providers must receive FDA permission before offering experimental stem cell therapies. What's more, the watchdog group is also turning the heat up on practices and practitioners who enhance fat by adding stromal vascular fraction or platelet-rich plasma. It's not all bark, either. The FDA warned American CryoStem Corporation of Monmouth Junction, NJ and its Chairman/Chief Executive Officer, John S. Arnone, about their practices, including receiving and processing adipose tissue into a product called Atcell and then marketing such product without the required FDA approval.

As much as they are reining in bad actors, the FDA is also also working to foster progress and the technology to take us there. To that end, the Mayo Clinic received FDA approval for a platform that can manufacture stem cells by the billions in just days, in contrast to previous methods of making stem cells that took months. What does this new regulatory landscape mean for aesthetic doctors? It's a moving target for sure. We must be careful about the procedures we promote. Using terminology like stem cell facelift or stem cell cure may land us in hot water. We should focus on the techniques and technologies that are FDA-approved and have a proven track record. ■