May 6, 2019

Dear Valued Plastic Surgeon Partner,

As the FDA announced last Thursday, **all breast implant options remain safe and effective and will continue to be available in the U.S.** I wanted to take this opportunity to reiterate that Sientra fully supports the FDA and will maintain our leadership position in breast implant safety.

The FDA's Advisory Committee Meeting in March fostered a thoughtful and scientific dialogue around topics such as BIA-ALCL. And following a comprehensive review of post-approval study data, medical device reports, scientific literature and breast implant expert and public testimonies, the FDA stated: *"At this time, the FDA does not believe that, on the basis of all available data and information, the device meets the banning standard set forth in the Federal Food, Drug and Cosmetic Act."*

Importantly panel experts recognized that **Board-Certified Plastic Surgeons (BCPS)** are the most highly trained to consult, treat and follow-up with breast implant patients. This is why Sientra has always been the only silicone gel implant manufacturer who sells exclusively to BCPS.

The full FDA statement regarding the next steps to ensure all patients and healthcare providers have accurate safety information around implants, can be found here. Among other items, the Agency is considering the following actions:

- Updating the device labeling which may include a boxed warning and a patient decision checklist in order to ensure patients are fully informed of potential benefits and risks;
- Educating the pathology community further about testing for BIA-ALCL;
- Continuing updates about global medical device reports for BIA-ALCL;
- Communicating information the agency receives about systemic symptoms experienced by patients with breast implants;
- Researching the broad array of systemic symptoms that have been mentioned as potentially associated with breast implants;
- Updating summary reporting for breast implant manufacturers to submit individual medical device reports that will be publicly available in Manufacturer and User Facility Device Experience (MAUDE); and
- Partnering with registries that collect real world data on breast implants, and encouraging stakeholders to expand participation.

Again, we fully support the efforts detailed in the FDA's May 2nd announcement and will continue to work closely with regulators, patients and you, the BCPS community, to ensure women have the information they need to make informed decisions around breast implants. We look forward to our continued coordination with the FDA and you to help patients feel confident in themselves and their Sientra OPUS® breast implants.

Consistent with this recent announcement, the FDA has approved Sientra's Xtra High Profile implants in both smooth and textured surfaces, which will provide you and your patients with additional options in the near future. We continue to be proud of the **Sientra Difference** including our broad portfolio of innovative surgical options that meet or exceed the highest standards for quality and safety.

We encourage you and your patients to visit our Commitment to Safety page. As always, please do not hesitate to reach out to me or my team with any questions or ideas on how we can work together to improve the information available to women considering breast implants.

Respectfully,

Jeffrey Nugent
Chairman and Chief Executive Officer
Sientra, Inc.