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December 20, 2019

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: FDA-2019-D-4467

Breast Implants - Certain Labeling Recommendations to Improve Patient Communication
Draft Guidance for Industry and Food and Drug Administration Staff

To Whom It May Concern:

Thank you for the opportunity to submit comments on behalf of FORCE, the only national nonprofit organization devoted to people and families affected by hereditary cancers. Our organization has been providing support, advocacy, education, and research to this community for over 20 years.

A large portion of our community is affected by a significantly increased risk of breast cancer due to inherited genetic mutations. Tens of thousands of our constituents have undergone mastectomies due to cancer diagnoses or high risk of the disease. While lumpectomy or unilateral mastectomy are options for many women, our community members are urged to have a double mastectomy due to the risk of another primary cancer.

Breast reconstruction is considered a choice, but for many women reconstruction after mastectomy is an attempt to feel whole again. While many opt for autologous reconstruction, it is not a viable choice for all. Millions of women have benefitted from implant reconstruction.

We applaud the FDA's efforts to provide direction on breast implant safety, labeling, and informed consent. As noted, the FDA is issuing this draft guidance "to help ensure that a patient receives and understands the benefits and risks of these devices. The recommendations are being made based on concerns that some patients are not receiving and/or understanding information regarding the benefits and risks of these devices."

Our comments at the March 2019 Advisory Panel meeting encouraged the FDA to take a measured approach based on sound science. We indicated that the community needed better information for informed decision-making, including:



- balanced information on breast reconstruction safety,
- access to well-tested devices,
- best practices, consensus guidelines, and insurance coverage for implant monitoring,
- comprehensive, high-quality research, and
- an easy path to report adverse events.

Following that meeting, the Panel gave recommendations that the FDA:

- require a boxed warning in breast implant labeling and a standardized checklist as part of the informed consent process,
- revise the MRI screening recommendations for silent ruptures of silicone gel-filled breast implants,
- provide greater transparency regarding materials present in breast implants, and
- emphasize the role of the patient device card in providing important information about the patient's breast implant(s).

Boxed Warning

The FDA proposes that, “a boxed warning should be part of physician and patient labeling materials for breast implants.” While not opposed to a boxed warning, we question the value and efficacy of such a warning. Patients rarely, if ever, see the box that their implants come in. As such, only the surgeon and his team will see the warning. Ultimately, this will fail to “ensure that patients receive and understand information regarding the benefits and risks of these devices.” A boxed warning is more symbolic than functional in this situation. If the agency insists on use of a boxed warning, we urge the FDA to elucidate the connection between smooth implants and BIA-ALCL as the data supporting a link in the U.S. market is questionable. A boxed warning should have concise, consistent, evidence-based messaging.

Patient Decision Checklist

The FDA suggests that manufacturers include, “a patient decision checklist highlighting key information regarding risks...at the end of the patient information booklet/brochure.” A checklist may serve as a useful tool in the informed consent process but it is not the only improvement that should be made to better communication of important information to potential breast implant recipients. We recommend that device manufacturers collaborate with professional societies such as the American Society of Plastic Surgeons and patient advocacy organizations to develop alternative informed consent tools including interactive web-based resources, video, and/or more engaging print materials. Informed consent is a process, not a booklet or sheet of paper. A checklist should be only one of multiple components in this process.

The proposed/sample checklist needs revision and reorganization to be effective. Requiring a signature at the bottom of the page or the end of the checklist is no better than the status quo. Patients should initial each paragraph or declaration to confirm that the information was discussed and understood. In addition, comingling information about breast implants for augmentation vs. reconstruction leads to confusion. Unique benefit/risk



data for these two communities should be broken out in the checklist. Even better, completely separate materials and checklists might be developed for these different populations. This would facilitate the tailoring of information for the specific patient population in question, addressing issues that may be more pertinent to them.

Additional Labeling Recommendations

The Advisory Panel recommended revision of the FDA's MRI screening guidelines for breast implant ruptures, suggesting that screenings begin 5-6 years post surgery, and occur every 2-3 years after that. Additionally, the draft guidance suggests that ultrasound is an acceptable alternative for screening asymptomatic patients. These updated recommendations may reduce the screening burden and cost for patients. However, we urge surgeons, device manufacturers, and the FDA to closely monitor the utility of these new recommendations to ensure that patient safety is the highest priority. Additionally, while ultrasound is generally less expensive than MRI, the cost may still be prohibitive for many women. Amending the Women's Health and Cancer Rights Act (WHCRA) to include implant monitoring for those who undergo breast reconstruction would benefit many women. Device monitoring should be part of the law's scope.

Patient Device Card and More

The patient device card is a useful tool and its importance should be emphasized to every implant patient. This card, however, is not sufficient. Notification and recall in the event a device presents a serious health risk is only one factor among many reasons to communicate with patients. Given our lack of quality research and evidence-based information about breast implant risks, every patient should be required to register her device(s) so that she can be contacted and queried over the lifetime of the device. Device manufacturers could be administer this registry in collaboration with surgical societies and researchers, with oversight by the FDA.

Community Collaboration

The Breast Device Collaborative Community (BDCC) coordinated by William Adams, MD is a balanced, multi-stakeholder group that has put a great deal of thought into devising a user-friendly decision checklist and improved boxed warning language. A member of our staff serves on this workgroup. We urge the FDA to consider the recommendations of the BDCC before finalizing this guidance. Further, device manufacturers are encouraged to consult with this group on improved materials for implant products.

In conclusion, we believe this guidance will be a positive step toward ensuring that women are adequately informed about the benefits and risks of breast implants. As we have stated, however, more should be done to facilitate improved patient education and the informed consent process—and more robust research on these devices.

Sincerely,

Lisa Schlager
Vice President, Public Policy

