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FDA Announces Updates to Two Guidance Documents Concerning Breast Implant Safety and Transparency

Maintaining its focus on breast implant safety, on September 28, 2020, FDA announced the issuance of the final guidance, "Breast Implants—Certain Labeling Recommendations to Improve Patient Communication," (the "2020 Final Guidance"), which updated and replaced the 2019 draft version of this document.[1] For consistency with these labeling recommendations, FDA also announced an update to the guidance, "Saline, Silicone Gel, and Alternative Breast Implants"[2] and issued a bulletin signaling its intention to provide a more comprehensive update to this guidance in the future.[3]

As discussed in previous client alerts,[4] FDA has put a spotlight on breast implant safety since 2018, when safety concerns associated with breast implants reemerged and the agency committed to being "first in the world" in identifying and acting upon safety signals related to medical devices, particularly devices impacting women.[5] Toward that end, FDA held a breast implant Advisory Committee Meeting on March 25-26, 2019, to gather data that informed FDA's new labeling recommendations.[6]

Below, we provide an overview of FDA's new labeling recommendations for breast implants and "key takeaways" for industry stakeholders.

I. OVERVIEW OF FDA'S NEW LABELING RECOMMENDATIONS

The 2020 Final Guidance revised the recommendations set forth in 2019 draft guidance with respect to the boxed warning, patient decision checklist, and rupture screening recommendations. Additionally, the 2020 Final Guidance added two new sets of recommendations with respect to materials/device descriptions and the patient device card. For consistency, these new labeling recommendations are now referenced and reflected in FDA's "Saline, Silicone Gel, and Alternative Breast Implants" guidance, as well.[7]

A. Boxed Warning

FDA's 2019 draft guidance, titled "Breast Implants – Certain Labeling Recommendations to Improve Patient Communications Guidance," released on October 24, 2019, initially recommended a black box warning for physician and patient labeling materials for breast implants. FDA specifically recommended that the black box warning inform patients:

- Breast implants are not considered lifetime devices;
- The chance of developing complications increases overtime;
- Some complications will require more surgery; and
- Breast implants have been associated with the risk of developing BIA-ALCL and may be associated with systemic symptoms.[8]

According to FDA, given new information collected since that time (as reflected in FDA's MDR Analysis Update),[9] the 2020 Final Guidance, adds the following warning:

- BIA-ALCL occurs more commonly in patients with textured breast implants than smooth implants, and deaths have occurred from BIA-ALCL.[10]

FDA provides examples of black box warnings that follow these recommendations in Appendix A to the 2020 Final Guidance.[11]

B. Patient Decision Checklist

The 2019 draft guidance also recommended that a patient decision checklist highlighting key information regarding risks be included at the end of the patient information booklet/brochure, to ensure that patients are fully informed about potential risks. The following key considerations for inclusion in the patient decision checklist remain unchanged in the 2020 Final Guidance:

- Situations in which the device should not be implanted;
- Considerations for a successful breast implant candidate;
- Risks of undergoing breast implant surgery;
- Importance of appropriate physician education, training and experience;
- Risk of BIA-ALCL and systemic symptoms; and
- Discussion of options other than breast implants, as appropriate.

However, the 2020 Final Guidance specifically recommends that the rates of BIA-ALCL included in the patient decision checklist reflect current information based on estimated incidence rates, which should include overall incidence rates of BIA-ALCL, as well as rates for the manufacturer's specific breast implant based on published literature, registries, and medical device reports.[12] It is also suggested that manufacturers explain the methodology used for determining the incidence rates of BIA-ALCL.[13] FDA provides examples of decision checklists that follow these recommendations in Appendix B of the 2020 Final Guidance.[14]

C. Rupture Screening Recommendations

The 2020 Final Guidance maintains the 2019 draft guidance's updated recommendations for breast implant rupture screening—i.e. that magnetic resonance imaging (MRI) screening should begin between 5 and 6 years post-surgery, occurring every 2-3 years afterwards, with ultrasound being an acceptable alternative to MRI for asymptomatic

patients.[15] But the 2020 Final Guidance emphasizes that "for symptomatic patients or patients with equivocal ultrasound results for rupture at any time postoperatively, an MRI is recommended."[16]

D. Materials/Device Descriptions

A new recommendation included in the 2020 Final Guidance is that the patient information booklet/brochure include a detailed device description of the materials of construction of the breast implant shell and filling in a format that is understandable to the patient.[17] Specifically, FDA recommends that the patient information booklet/brochure "include tables listing breast implant materials, chemicals that might be released from breast implants, and heavy metals present in breast implants."[18] Additionally, the final guidance recommends that booklet/brochure provide context to the levels of risk/exposure of the chemicals and heavy metals listed in the tables.[19] FDA also recommends that the patient should be "informed that most of these chemicals stay inside the shell of the implant but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking."[20] The 2020 Final Guidance provides examples of materials/device descriptions that follow these recommendations in Appendix C.[21]

E. Patient Device Card

Another new recommendation in the 2020 Final Guidance suggests that the patient device card, which is intended to provide patients with specific information about their device (and may be useful, for example, in the event of a recall), be clearly labeled so that "the physician can easily find it and provide it to the patient immediately following surgery."[22] Additionally, FDA recommends that the device card include, at a minimum, the following information:

- A statement that "This card belongs to the patient. Please give it to the patient";
- Device's serial or lot number;
- Device's style and size;
- Unique Device Identifier (UDI);
- Web link to access most current patient decision checklist, boxed warning, and labeling for the specific implant that the patient received;
- A statement that "There is a boxed warning for breast implants, see web link; and
- Toll-free phone number to communicate with the breast implant manufacturer.[23]

II. KEY TAKEAWAYS

As new data on breast implant safety becomes available, FDA is increasingly requiring breast implant manufacturers to make related disclosures, to ensure that patients considering breast augmentation or reconstruction are fully informed about potential risks. The new labeling recommendations set forth in the 2020 Final Guidance, and the examples provided in the appendices should help manufacturers conform to FDA's new labeling expectations. Given that FDA has already issued a bulleting signaling its intention to provide a more comprehensive update to the "Saline, Silicone Gel, and Alternative Breast Implants" guidance, industry stakeholders should continue to monitor agency activity in this space closely.

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[1] FDA, FDA News Release—FDA Issues Final Guidance for Certain Labeling Recommendations for Breast Implants (Sept. 28, 2020), https://www.fda.gov/news-events/press-announcements/fda-issues-final-guidance-certain-labeling-recommendations-breast-implants; see also 85 Fed. Reg. 61001 (Sept. 29, 2020), https://www.govinfo.gov/content/pkg/FR-2020-09-29/pdf/2020-21453.pdf.
[2] FDA, FDA News Release—FDA Issues Final Guidance for Certain Labeling Recommendations for Breast Implants (Sept. 28, 2020), https://www.fda.gov/news-events/press-announcements/fda-issues-final-guidance-certain-labeling-recommendations-breast-implants.
[3] FDA, FDA Bulletin—FDA Issues Final Guidance for Labeling Recommendations for Breast Implants (Sept. 29, 2020), https://content.govdelivery.com/accounts/USFDA/bulletins/2a28b45.
[4] *See* King and Spalding, FDA Continues its Focus on Breast Implant Safety and Transparency with an Eye Toward Improving Regulatory Decision-Making (Sept. 1, 2020), https://www.kslaw.com/attachments/000/008/168/original/ca090120.pdf?1598906535; King and Spalding, FDA's Focus on Devices Impacting Women's Health is Fully Underway: Breast Implant Advisory Set for March 25-26 (Feb. 21, 2019), https://www.kslaw.com/attachments/000/006/737/original/ca022119b.pdf?1550770770.
[5] FDA, Statement from FDA Commissioner Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on FDA's Updates to Medical Device Safety Action Plan to Enhance Post-Market Safety (Nov. 20, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and-2.
[6] *See* FDA, General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, Notice of Meeting ("Breast Implant Advisory Committee Meeting Notice"), 84 Fed. Reg. 4476, 4476 (Feb. 15, 2019); *see also* FDA, 24 Hour Summary—General and Plastic Surgery Devices, Advisory Committee Meeting, March 25 & 26, 2019, https://www.fda.gov/media/122960/download.
[7] See FDA, Saline, Silicone Gel and Alternative Breast Implants (updated Sept. 29, 2020) at 37-40, https://www.fda.gov/media/71081/download.
[8] King and Spalding, FDA Continues its Focus on Breast Implant Safety and Transparency with an Eye Toward Improving Regulatory Decision-Making (Sept. 1, 2020), https://www.kslaw.com/attachments/000/008/168/original/ca090120.pdf?1598906535.
[9] See FDA, FDA Updates Analysis of Medical Device Reports of Breast Implant Illness and Breast Implant-Associated Lymphoma; Agency Also Announces Qualification of a Medical Device Development Tool to Aid in the Effectiveness Assessment of Devices Used in Breast Reconstruction (Aug. 20, 2020) ("FDA Press Release—FDAS Updates Analysis of MDRs for BII and BIA-ALCL"), https://www.fda.gov/newsevents/press-announcements/fda-updates-analysis-medical-device-reports-breast-implant-illness-and-breast-implant-associated.
[10] FDA, Breast Implants – Certain Labeling Recommendations to Improve Patient Communication (Sept. 29, 2020) at 5, https://www.fda.gov/media/131885/download.
[11] *Id*. at 9.
[12] *Id*. at 5.
[13] *Id*.
[14] *Id*. at 10.
[15] *Id*. at 7.
[16] *Id*. at 6.
[17] *Id*. at 7.
[18] *Id*.
[19] *Id*.
[20] *Id*.
[21] *Id*. at 17.
[22] *Id*. at 8.
[23] *Id*.