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## FDA Continues its Focus on Breast Implant Safety and Transparency with an Eye Toward Improving Regulatory Decision-Making

In an August 20, 2020, [press release](#), the Food and Drug Administration (FDA) provided an update on the medical device reports (MDRs) received by the agency relating to breast implants, including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), and systemic signs and symptoms sometimes reported and referred to by patients as “breast implant illness” (BII).<sup>1</sup> In the same press release, FDA also announced its qualification of a Medical Device Development Tool (MDDT)—the Breast Q Reconstruction Module—to aid in the assessment of certain devices used in breast reconstruction, including breast implants.<sup>2</sup>

These announcements are in keeping with FDA’s November 2018 [commitment](#) to being “first in the world” in identifying and acting upon safety signals related to medical devices, particularly devices impacting women.<sup>3</sup>

As discussed in our previous [client alert](#) announcing FDA’s breast implant Advisory Committee Meeting, which was held March 25-26, 2019, this uptick in FDA’s attention to devices impacting women is unsurprising against the backdrop of a surge in media attention around the processes the agency uses to approve drugs and devices, and the reemergence of safety concerns associated with breast implants.<sup>4</sup>

Below, we provide an overview of actions FDA has taken since the 2019 Advisory Committee Meeting to improve transparency and regulatory decision-making concerning breast implants and breast implant safety—including the agency’s updated analysis of MDRs and its new qualification tool for breast reconstruction devices. Additionally, we provide “key takeaways” for industry stakeholders.



## I. OVERVIEW OF RECENT FDA ACTIONS TO IMPROVE TRANSPARENCY AND REGULATORY DECISION-MAKING CONCERNING BREAST IMPLANTS AND BREAST IMPLANT SAFETY

Following the March 2019 Advisory Committee Meeting, FDA has taken several steps to improve transparency and regulatory decision-making concerning breast implants and breast implant safety. Those steps include: (1) issuance of an agency guidance setting forth new labeling recommendations consistent with the Committee's recommendations, (2) changes to MDR reporting to improve the quality of the information contained in those reports, (3) updating the agency's analysis of MDRs associated with BIA-ALCL and BII, as well as making that information accessible through the FDA website, and (4) qualifying a medical device development tool to assess outcomes of breast reconstruction surgery among women.

### A. FDA Guidance

Following the March 2019 Advisory Committee Meeting, on October 24, 2019, FDA issued a draft guidance titled "Breast Implants – Certain Labeling Recommendations to Improve Patient Communications" (Guidance). This Guidance implements several of the Committee's recommendations.<sup>5</sup> First, the Guidance recommends including a boxed warning for physician and patient labeling and materials for breast implants. FDA recommends that the boxed 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.<sup>6</sup>

Additionally, the Guidance recommends that a patient decision checklist highlighting key information regarding risks should be included at the end of the patient information booklet/brochure.<sup>7</sup> FDA recommends that the body of this checklist include the following:

- Situations in which the device should not be used or 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.<sup>8</sup>

The Guidance also revises breast implant rupture screening recommendations. As such, it is now recommended that magnetic resonance imaging (MRI) screening begin between 5 and 6 years post-surgery, occurring every 2-3 years after that. Additionally, ultrasound is recommended as an acceptable alternative to MRI for asymptomatic patients.<sup>9</sup>

### B. Changes to MDR Reporting

With an eye toward improving transparency, on May 2, 2019, FDA announced an important change in the way important adverse information concerning breast implants is reported in MDRs.<sup>10</sup> More specifically, FDA ended all summary reporting of breast implant medical device reports as part of a broader agency effort to end all alternative summary reporting programs for medical devices. Summary reporting began in 1997 as a means of improving efficiency



in the review of adverse events for well-established risks,<sup>11</sup> although it was never permitted for patient deaths and unusual, unique, or uncommon adverse events.<sup>12</sup>

### C. MDR Analysis Update

FDA's MDR Analysis Update on August 20, 2020, updates the agency's last public report on breast implant MDRs to include information from July 7, 2019 – January 5, 2020.<sup>13</sup> With this update, the table on FDA's BIA-ALCL webpage now shows a total of 733 unique cases and 36 deaths globally.<sup>14</sup> As such, the August 20, 2020, update reflects an increase of 160 new reports of cases and 3 deaths since the early-July 2019 update.<sup>15</sup> These new data include 733 cases of BIA-ALCL, 496 of which involved patients with textured implants.<sup>16</sup> Additionally, of the 36 deaths reported, 16 cases involved textured implants, while the remaining 19 reports did not contain information on the implant surface.<sup>17</sup>

FDA also updated its MDR analysis to include reports of BII that the agency has received between January 1, 2008 – October 31, 2019.<sup>18</sup> A new table on FDA's website shows that between January 1, 2008 and October 31, 2019, FDA received 3,577 MDRs containing symptoms consistent with BII.<sup>19</sup> These symptoms include fatigue, brain fog, joint pain, anxiety, hair loss, depression, rash, autoimmune diseases, inflammation and/or weight problems.<sup>20</sup>

The data show that 2,497 MDRs indicating cases of BII were reported within the last year of the covered time period (i.e. November 2018 - October 2019).<sup>21</sup> By comparison, only 1,080 BII cases were reported from January 2008 – October 2018.<sup>22</sup> FDA suspects that this jump in reported BII cases is due to increased awareness among patients and providers stemming from press, social media, and FDA's Advisory Committee Meeting held in March of 2019.<sup>23</sup> Significantly, FDA concedes that “[the agency] doesn't have definitive evidence demonstrating breast implants cause [the symptoms consistent with BII],” but the agency also alleges that “current evidence supports that some patients experience systemic symptoms that may resolve when their breast implants are removed.”<sup>24</sup>

### D. BREAST Q-Reconstruction Module

In the August 20, 2020, press release, FDA also announced the qualification of a validated, self-administered questionnaire—the BREAST-Q Reconstruction Module—through the agency's Medical Device Development Tools (MDDT) program.<sup>25</sup> The module, which is available in paper and electronic formats, uses four scales to evaluate different aspects of a woman's quality of life and satisfaction with breast reconstruction surgery: (1) psycho-social well-being (2) sexual well-being, (3) physical well-being (chest), and (4) satisfaction with breasts.<sup>26</sup> FDA's announcement states that these scales may be used by medical device sponsors and sponsor-investigators in feasibility, pivotal, and post-approval studies to support the effectiveness of breast reconstruction-related medical devices, such as an implant or mesh, befitting the clinical meaningfulness of the scale to support the proposed indication.<sup>27</sup>

As an example, FDA's MDDT summary of the qualification decision for BREAST-Q Reconstruction Module provides that “satisfaction with breasts” scale may be used as a primary effectiveness endpoint in clinical studies evaluating women undergoing breast reconstruction with a medical device, whether the proposed indication directly relates to the patients satisfaction with breast reconstruction.<sup>28</sup> FDA further explains that the “psychological well-being” and “physical well-being (chest)” scales may be used individually or together as secondary effectiveness endpoints for such studies.<sup>29</sup> Ultimately, the four scales in the BREAST-Q Reconstruction Module can be used to facilitate development and regulatory evaluation of devices involved in breast reconstruction to include the patient's perspective.<sup>30</sup> Sponsors are encouraged to engage FDA to determine the applicability MDDT to their clinical studies.<sup>31</sup>



## II. KEY TAKEAWAYS

Since the reemergence of safety concerns associated with breast implants in 2018, FDA has continued to use transparency as a tool to fuel continued scrutiny of breast implants by the media and others—when the scientific data falls short of warranting agency action. FDA's qualification of the BREAST-Q Reconstruction Module, however, may be a bright spot to the extent that it may give proponents of breast implants an opportunity to quantify the quality of life benefits of breast implants moving forward. The ability to quantify the impact of breast implants on women's "psychological well-being," as well as their "physical well-being," is critical to ensuring that women who need breast implants can access them.

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<sup>1</sup> See U.S. Food & Drug Admin., 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/news-events/press-announcements/fda-updates-analysis-medical-device-reports-breast-implant-illness-and-breast-implant-associated>.

<sup>2</sup> *Id.*

<sup>3</sup> See U.S. Food & Drug Admin., Statement from FDA Commissioner Scott 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/NewsEvents/Newsroom/PressAnnouncements/ucm626286.htm>.

<sup>4</sup> See King & Spalding LLP, Client Alert: FDA's Focus on Devices Impacting Women's Health is Fully Underway: Breast Implant Advisory Set for March 25-26, <https://www.kslaw.com/attachments/000/006/737/original/ca022119b.pdf?1550770770>.

<sup>5</sup> See FDA, 24 Hour Summary—General and Plastic Surgery Devices, Advisory Committee Meeting, March 25 & 26, 2019, <https://www.fda.gov/media/122960/download>.

<sup>6</sup> FDA, Breast Implants – Certain Labeling Recommendations to Improve Patient Communication (Draft Guidance), <https://www.fda.gov/media/131885/download>.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> FDA, Statement from FDA Principal Deputy Commissioner Amy Abernathy and CDRH Director Jeff Shuren on FDA's new efforts to protect women's health and help ensure the safety of breast implants (May 2, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-principal-deputy-commissioner-amy-abernathy-md-phd-and-jeff-shuren-md-jd-director-fdas>.



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<sup>11</sup> *Id.*  
<sup>12</sup> *Id.*  
<sup>13</sup> See FDA Press Release—FDA Updates Analysis of MDRs for BII and BIA-ALCL.  
<sup>14</sup> See FDA, Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma, <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma>.  
<sup>15</sup> See FDA Press Release—FDA Updates Analysis of MDRs for BII and BIA-ALCL  
<sup>16</sup> *Id.*  
<sup>17</sup> *Id.*  
<sup>18</sup> *Id.*  
<sup>19</sup> FDA, Medical Device Reports for Systemic Symptoms in Women with Breast Implants, <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants>.  
<sup>20</sup> *Id.*  
<sup>21</sup> FDA Press Release—FDA Updates Analysis of MDRs for BII and BIA-ALCL  
<sup>22</sup> *Id.*  
<sup>23</sup> *Id.*  
<sup>24</sup> *Id.*  
<sup>25</sup> *Id.*  
<sup>26</sup> *Id.*  
<sup>27</sup> *Id.*  
<sup>28</sup> FDA, MDDT Summary of Evidence and Basis of Qualification Decision for BREAST-Q Reconstruction Module, <https://www.fda.gov/media/141349/download>.  
<sup>29</sup> *Id.*  
<sup>30</sup> *Id.*  
<sup>31</sup> *Id.*