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## FDA's Focus on Devices Impacting Women's Health is Fully Underway: Breast Implant Advisory Set for March 25-26

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Late last year, the Food and Drug Administration's (FDA's) Device Center announced a new objective when it comes to devices – “ensuring that the FDA is consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices.”<sup>1</sup> With that objective in mind, FDA stated that it would focus on devices that impact women's health.<sup>2</sup> It appears that this focus is already underway. FDA held an advisory committee meeting February 12, 2019, concerning the safety and effectiveness of surgical mesh placed transvaginally in the anterior vaginal compartment to treat pelvic organ prolapse.<sup>3</sup> In addition, on February 15, 2019, FDA formally announced that it will hold an advisory committee meeting to address potential risks associated with breast implants on March 25 and 26, 2019.<sup>4</sup>

FDA's recent attention to device products impacting women comes amidst a surge of media attention around the process by which the agency approves drugs and medical devices. For example, a report by the International Consortium of Investigative Journalists (ICIJ), the *Implant Files*, released last fall, devoted an entire segment to uncovering serious adverse events and suspected risks associated with breast implants—including an increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), an emerging type of lymphatic cancer.<sup>5</sup>

The focus on women's health issues is unsurprising, if not overdue, given the growing national awareness of the need for more attention, research, and understanding, with regard to the unique health concerns of women. Indeed, recent data suggest the United States is well behind other western nations when it comes to overall women's health, and the gap is growing.<sup>6</sup>



Below, we provide an overview of the focus and the genesis of the upcoming breast implant advisory committee meeting on March 25-26, as well as “key takeaways” regarding what FDA’s new focus on device safety and women’s health means for industry stakeholders.

## I. OVERVIEW OF RE-EMERGING SAFETY CONCERNS ASSOCIATED WITH BREAST IMPLANTS AND UPCOMING ADVISORY COMMITTEE MEETING

Breaking protocol, on January 28, 2019, FDA Commissioner Gottlieb announced via Tweet that FDA would hold an advisory committee meeting on safety issues associated with breast implants.<sup>7</sup> The advisory committee meeting will be held on March 25-26, 2019. Since Commissioner Gottlieb’s Tweet, FDA has issued a formal notice regarding the upcoming meeting, pursuant to the usual protocol, in the Federal Register. The Federal Register notice provides that the advisory committee will focus on discussing and making recommendations regarding the benefits and risks of breast implants indicated for breast augmentation and reconstruction concerning the following topics: (1) BIA-ALCL, (2) systemic symptoms reported in patients receiving breast implants, (3) the use of registries for breast implant surveillance, (4) magnetic resonance imaging screening for silent rupture of silicone gel-filled breast implants, (5) the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy, (6) the use of real-world data and patient perspectives in regulatory decision making, and (7) best practices for informed consent discussions between patients and clinicians.<sup>8</sup>

FDA first signaled its intention to hold this advisory committee meeting in a September 14, 2018, press release issued by Dr. Binita Ashar, Director of Surgical Devices in FDA’s Center for Devices and Radiological Health, on behalf of the agency.<sup>9</sup> The press release expressed disagreement with a study published by MD Anderson, which purported to be the largest study of breast implant outcomes to date.<sup>10</sup> The study concluded that silicone implants are associated with an increased risk of systemic harms, including cancers, connective tissue diseases, autoimmune diseases, and reproductive issues.<sup>11</sup>

More specifically, the MD Anderson study analyzed data generated by large post-approval studies (LPAS) that were required by FDA, after the agency approved silicone gel-filled implants sponsored by two manufacturers— Allergan and Mentor Corp.— in 2006.<sup>12</sup> Prior to those approvals, there had been a moratorium on the use of silicone-filled breast implants in the United States since 1992, after concerns emerged about their use and the incidence of cancer, connective tissue disease, and autoimmune disease.<sup>13</sup> The moratorium was eventually lifted after the Institute of Medicine determined that there was no evidence to support an association between breast implants and systemic diseases.<sup>14</sup>

In FDA’s press release, Dr. Ashar urged the public and the healthcare community to view the study’s conclusions with caution due to “significant shortcomings with the study’s methodology.”<sup>15</sup> In an editorial that Dr. Ashar released, accompanying the press release, Dr. Ashar was more specific— stating that the MD Anderson study failed to account for “methodological differences between studies, inconsistencies in the data, differential loss to follow-up, confounding, and other potential sources of bias.”<sup>16</sup> She also stated that the limitations of MD Anderson’s study “highlight the need for better post-market evidence generation, including active surveillance capabilities,”<sup>17</sup> and that, toward that end, FDA is engaged in efforts to develop breast implant registries and to establish, in partnership with others, the National Evaluation System for health Technology (NEST).<sup>18</sup>

Given the deficiencies in the MD Anderson study, Dr. Ashar clarified in the FDA press release that “the agency continues to believe that the weight of the currently available scientific evidence does not conclusively demonstrate an association between breast implants and connective tissue diseases.”<sup>19</sup> This conclusion is consistent with FDA’s prior analysis of those studies, which the agency communicated in a 2011 Safety Update.<sup>20</sup> In that update, based upon review of the



LPAS studies, FDA stated that “[t]here is no apparent association between silicone gel-filled breast implants and connective tissue disease, breast cancer or reproductive problems.”<sup>21</sup>

Nonetheless, Dr. Ashar stated, in her editorial accompanying the press release, that patients who are considering breast implants should be aware that:

- “Breast implants are not lifetime devices and the longer a patient has the implants, the more likely they are to experience local complications and adverse outcomes requiring breast implant removal.
- Local complications and adverse outcomes include capsular contracture, reoperation, removal, and implant rupture. Many patients also experience breast pain, wrinkling, asymmetry, scarring, and infection.
- Breast implants are associated with BIA-ALCL, a cancer of the immune system. While most patients with BIA-ALCL may be treated only with breast implant removal, some patients have required radiation therapy, chemotherapy or both, and some patients have even died from BIA-ALCL.
- At the present time, there is not sufficient evidence to show an association between breast implants and rheumatologic or connective tissue diseases.”<sup>22</sup>

Dr. Ashar went on to state that FDA “remains committed to [a] thoughtful, scientific, transparent, public dialogue concerning breast implant safety and effectiveness,” and that the agency would hold an advisory committee meeting in 2019 to ensure that patients and health care professionals have “accurate, scientific information about breast implant safety and effectiveness.”<sup>23</sup>

## II. KEY TAKEAWAYS

With FDA’s November 2018 announcement of its new objective— to be the first among regulatory agencies worldwide to identify and act upon safety signals associated with medical devices— we are witnessing a clear pendulum swing. Indeed, in 2012, the Device Center announced a decidedly different goal— to ensure that devices were “first in the world” to market in the U.S.<sup>24</sup>— and that goal was repeated frequently, and as recently as January 2018, in the Device Center’s 2018-2020 Strategic Priorities.<sup>25</sup> This recent shift is clearly due to mounting pressure from media reports, like the *Implant Files*, as well as a recent AP report stating that during Dr. Jeffrey Shuren’s tenure as the Center Director (since January 2010), device “approvals” have tripled while “warning letters to device manufacturers about product safety and quality issues have fallen roughly 80 percent.”<sup>26</sup>

This type of media scrutiny, regardless of whether it is warranted, often leads to high level finger-pointing, and it is clear that the Device Center is working hard to provide itself with cover. Indeed, the tone of Dr. Ashar’s September 2018 press release was notably defensive. The vast majority of the release was dedicated to enumerating FDA’s past efforts to monitor the safety and effectiveness of breast implants.

As FDA endeavors to show its rigor regarding device safety, the agency is likely to demand more data from device sponsors in both the pre-market and post-market space. Indeed, in the pre-market space, FDA has already telegraphed that it is exploring the legality of sunseting the use of certain devices as predicates, to drive more devices from the 510(k) process to the *de novo* process; and in the post-market space, stakeholders are likely to see more demands for Section 522 post-market surveillance studies and more sophisticated uses of data analytics. Industry stakeholders also should expect more advisory committee meetings regarding the safety of devices that have been scrutinized by the media and clear calls by FDA for additional warnings. Although FDA’s actions in this space will likely affect a wide array of devices, FDA itself has stated that it is focusing on women’s health. Accordingly, we expect that the agency’s activities in this space will disproportionately affect devices that impact women.



Longer term, manufacturers of medical devices (and pharmaceuticals), as well as healthcare professionals, can expect an explosion of gender-specific research and results. More information will flow, not only from the Agency’s focus on women’s health, but also from a greater societal awareness of long-standing deficits in women’s health and healthcare. The “me too” movement, while not a health movement *per se*, is giving strength to voices advocating for women’s health and human rights. While it is tempting to assume that heightened agency scrutiny will expose manufacturers to more product liability risk, a broader focus on women’s health might just enhance the safety profile of many drugs and devices and decrease litigation risk.

This potential for decreased litigation risk stems from the fact that many of the most common health issues faced disproportionately by women (e.g., chronic pain, autoimmune diseases, and migraines) are poorly understood compared to health issues that are more common in men. New research and data may help illuminate the true causes of symptoms that have been blamed by default on medical devices. For example, fibromyalgia has long been alleged to be linked to breast implants, but connective tissue diseases such as fibromyalgia have been understudied, and many clinicians are ill-prepared to address them. In the absence of good science to explain a patient’s symptoms, it is often easier to blame the device. Hopefully, increased study of women’s health will help illuminate the true underlying cause for many of the most noxious health problems women confront.

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<sup>1</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>2</sup> See *id.*

<sup>3</sup> U.S. Food & Drug Admin., Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, Notice of Meeting; 83 FED. REG. 63516, 63516 (Dec. 10, 2018), <https://www.federalregister.gov/documents/2018/12/10/2018-26626/obstetrics-and-gynecology-devices-panel-of-the-medical-devices-advisory-committee-notice-of-meeting>.

<sup>4</sup> U.S. Food & Drug Admin., 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 U.S. FOOD & DRUG ADMIN, BREAST IMPLANTS, <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/breastimplants/default.htm> (last visited Feb. 8, 2018).

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- <sup>5</sup> Sasha Chavkin, *Breast Implant Injuries Kept Hidden as New Health Threats Surface*, ICIJ—THE IMPLANT FILES (Nov. 26, 2018), <https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/>.
- <sup>6</sup> See Munira Z. Gunja *et al.*, *What is the Status of Women's Health and Health Care in the U.S. Compared to Ten Other Countries?*, THE COMMONWEALTH FUND (Dec. 19, 2018), <https://www.commonwealthfund.org/publications/issue-briefs/2018/dec/womens-health-us-compared-ten-other-countries>.
- <sup>7</sup> Scott Gottlieb, Tweet Announcing March 25 -26 Meeting on Benefit-Risk Profile of Breast Implants (Jan. 28, 2019), <https://twitter.com/SGottliebFDA/status/1089971948396969984> (last visited Feb. 8, 2019).
- <sup>8</sup> Breast Implant Advisory Committee Meeting Notice, at 4476.
- <sup>9</sup> See U.S. FOOD & DRUG ADMIN., STATEMENT FROM BINITA ASHAR, M.D., OF FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH ON AGENCY'S COMMITMENT TO STUDYING BREAST IMPLANT SAFETY ("September 2018 Statement") (Sept. 14, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620589.htm>.
- <sup>10</sup> See Christopher J. Coroneos, M.D. *et al.*, *U.S. FDA Breast Implant Postapproval Studies: Long term Outcomes in 99,993 Patients*, 269 ANNALS OF SURGERY 30, 30 (official publication, Jan. 2019).
- <sup>11</sup> See *id.* at 32-34.
- <sup>12</sup> *Id.* at 30.
- <sup>13</sup> *Id.*
- <sup>14</sup> See Stuart Bondurant, *et al.*, *Institute of Medicine (US) Committee on the Safety of Silicone Breast Implants*, Nat'l Academy Press (1999), executive summary.
- <sup>15</sup> See September 2018 Statement.
- <sup>16</sup> Binita S. Ashar, *Assessing the Risks of Breast Implants and FDA's Vision for the National Breast Implant Registry* ("Ashar Editorial"), 269 ANNALS OF SURGERY 37, 37 (official publication, Jan. 2019).
- <sup>17</sup> *Id.*
- <sup>18</sup> *Id.*
- <sup>19</sup> See September 2018 Statement.
- <sup>20</sup> See U.S. Food & Drug Admin., *FDA Update on the Safety of Silicone Gel-Filled Implants*, at 7, 20-21 (June 2011), <https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260090.pdf>.
- <sup>21</sup> *Id.*
- <sup>22</sup> Ashar Editorial.
- <sup>23</sup> *Id.*
- <sup>24</sup> U.S. Food & Drug Admin., *CDRH's 2018-2020 Strategic Priorities: Achieving Our Vision of Timely Patient Access to High-Quality, Safe and Effective Medical Devices*, Jan. 2018, at 3 (citing the 2012 Vision Statement), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM592693.pdf>
- <sup>25</sup> *Id.* See also U.S. Food & Drug Admin., *2013 Strategic Priorities, FDA Center for Devices and Radiological Health*, at 4, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm>
- <sup>26</sup> Matthew Perrone, *At FDA, a New Goal, Then a Push for Speedy Device Reviews*, AP NEWS (Nov. 27, 2018), <https://www.apnews.com/9f8ea03a4d324d1ba5585680d280804b>