FDA Issues Safety Alert for Cancers in Scar Tissue Around Breast Implants

Squamous cell carcinoma and lymphomas have been reported in the scar tissue of breast implants, but the FDA believes the risk is rare.

September 14, 2022 By Food and Drug Administration (FDA)

On September 8, the U.S. Food and Drug Administration issued a safety communication informing patients and providers about reports of squamous cell carcinoma (SCC) and various lymphomas located in the capsule or scar tissue around breast implants. After an initial extensive review, we currently believe that the risk of SCC and other lymphomas occurring in the tissue around breast implants is rare. However, in this case, and when safety risks with medical devices are identified, we wanted to provide clear and understandable information to the public as quickly as possible.

In some reported cases, patients were diagnosed years after having breast implants and presented with findings such as swelling, pain, lumps or skin changes. These emerging reports of lymphoma in scar tissue are different from Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), which the FDA began communicating about as a potential risk more than a decade ago.

The FDA's work in the area of patient-centered risk communication for these devices has accelerated in recent years, including convening stakeholders to share perspectives that have informed the FDA's regulatory oversight and implementation of new requirements for manufacturers. We continue to engage top cancer experts and are consulting with our Oncology Center of Excellence to ensure a coordinated approach informed by leaders in the field. Additionally, the agency continues to closely monitor various data sources, such as the scientific literature, adverse event reports submitted to the agency and is soliciting information from manufacturers regarding any reports they may have regarding SCC and other lymphomas related to the tissue around an implant.

We know that breast implants are not lifetime devices, and that the longer a patient has breast implants, the more likely they will need to be removed or replaced. We also understand that information regarding breast implant risks can be overwhelming for a patient. For this reason, we encourage review of our website with attention to patient labeling, which has easy to understand information in the patient brochure.

Right now, we do not have enough information to say whether breast implants cause these

cancers or if some implants pose higher risk than others. For this reason, instances of SCC, lymphoma and any cancer located in the scar tissue around breast implants should be reported to the FDA. Our collective understanding has advanced significantly because of the efforts to study, communicate and act when needed. As the agency moves further into adopting modernized approaches to our regulatory responsibilities to promote faster science-based decision-making, accurate data is crucial.

If a patient with breast implants is experiencing a problem, or there is a case of SCC, lymphoma or any other cancer of the breast implant capsule identified, the FDA strongly encourages reporting this through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Reporting strengthens our ability to work with manufacturers and others to improve safety.

Today's safety communication underscores our commitment to sharing the information that we regularly gather and analyze so that patients may fully consider and thoughtfully discuss implant risks with their doctors. We will continue to collaborate with other regulatory authorities, clinical and scientific experts, breast implant registries and patients as a part of our commitment to educate and enhance evidence generation on these potential new risks.

Looking ahead, the FDA will soon complete a thorough literature review and continue our partnership with the American Society of Plastic Surgeons as we work to identify ways to collect more detailed information regarding patient cases where cancer in the breast implant capsule has been reported. As we learn more about these cases, we hope to better understand the patient risk and communicate findings to the public.

The safety signal issued today is an emerging issue that will require steadfast, ongoing evaluation and communication with patients, healthcare providers and manufacturers. We remain committed to informing the public of important and emerging medical device safety risks and appropriately take action on behalf of patients and public health.

This announcement was originally published September 8, 2022, by the Food and Drug Administration (FDA). For a related post, see "FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants."

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