Breast Implant Manufacturers Get Labeling Guidance

New final guidance from the FDA is meant to ensure that patients have accurate, timely information on the risks and benefits associated with breast implants.

Stemming from discussions with its General and Plastic Surgery Devices Advisory Panel in 2019, the FDA has recommended that manufacturers’ labeling include a prominent boxed warning and a standardized patient decision checklist that covers contraindications, surgical risks, the risk of developing breast implant–associated anaplastic large cell lymphoma (BIA-ALCL), and related information.

Manufacturers also should include rupture screening recommendations for patients with silicone gel–filled breast implants, an easy-to-find description of materials in the implant shell and filling, and a patient device card that facilitates finding device information in an emergency. The FDA also updated its guidance for manufacturers to submit premarket approval applications.

In recent years, the FDA has received new information about BIA-ALCL, a type of non-Hodgkin lymphoma, and breast implant illness (BII), a set of symptoms attributed to implants that can include fatigue, brain fog, muscle or joint pain, and rash.

The agency reported 733 reports of BIA-ALCL as of January 5, 2020. It said the risk of developing BIA-ALCL is low, but the diagnosis is serious and can be fatal, especially if not diagnosed early or treated promptly. Reports of symptoms consistent with BII have increased—the FDA received 2497 from November 2018 to October 2019 compared with 1080 between January 2008 and October 2018. The FDA said growing awareness is a likely explanation.

FDA Commissioner Stephen Hahn, MD, said in a statement that the new arrangement will help both countries create a modern regulatory framework for food safety. The FDA said the agencies have already worked together on preventing Salmonella in papaya and Cyclospora in other produce, conducting whole-genome sequencing of foodborne pathogens, and encouraging new training opportunities for industry.

According to the FDA, about one-third of all food and 60% of produce imported into the US come from Mexico.

The partnership aligns with the FDA’s New Era of Smarter Food Safety Blueprint, released in July, which outlines strategies for the next decade, including implementing tracing technology to rapidly identify sources of contamination, using analytic tools to determine how food becomes contaminated, and fostering a culture of food safety at farms and retail establishments.

Earlier this year the Centers for Disease Control and Prevention (CDC) reported a lack of progress in reducing foodborne illness. The study noted that in 2019, foodborne infections from Campylobacter, Cyclospora, Shiga toxin–producing Escherichia coli, Vibrio, and Yersinia increased compared with those reported from 2016 through 2018. However, Listeria, Salmonella, and Shigella infections remained unchanged from the 3 prior years.

In all, the Foodborne Diseases Active Surveillance Network identified 25 866 infections, 6164 hospitalizations, and 122 deaths from foodborne pathogens in 2019, according to the CDC report.

Warning Concerns Respirator Decontamination System

The FDA has warned the Battelle Memorial Institute, a research and development company in Columbus, Ohio, that its adverse event reporting process for an N95 respirator decontamination system is deficient.

The company was given 15 working days to notify the agency of steps it will take to correct the problems.

In June, Battelle’s Critical Care Decontamination System received an Emergency Use Authorization (EUA) that enabled health care personnel to decontaminate and reuse their N95 respirators, which have been in short supply during the coronavirus disease 2019 pandemic. The respirators are designed to form a seal around the nose and mouth, protecting wearers from airborne particles and liquid.

FDA officials said in a statement that they became aware of possible deficiencies in the company’s adverse event reporting process, and in August they asked for information about those procedures. The agency also provided examples of relevant reportable events such as allergic reactions or evidence that decontaminated masks don’t function properly.

However, the FDA determined that Battelle didn’t comply with the EUA’s regulatory requirements. Inadequate reporting compromises the FDA’s ability to detect and address safety and performance problems, Binita Ashar, MD, director of the FDA’s Office of Surgical and Infection Control Devices, said in the statement.

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Note: Source references are available through embedded hyperlinks in the article text online.