FDA wants stronger warning on breast implants about risks

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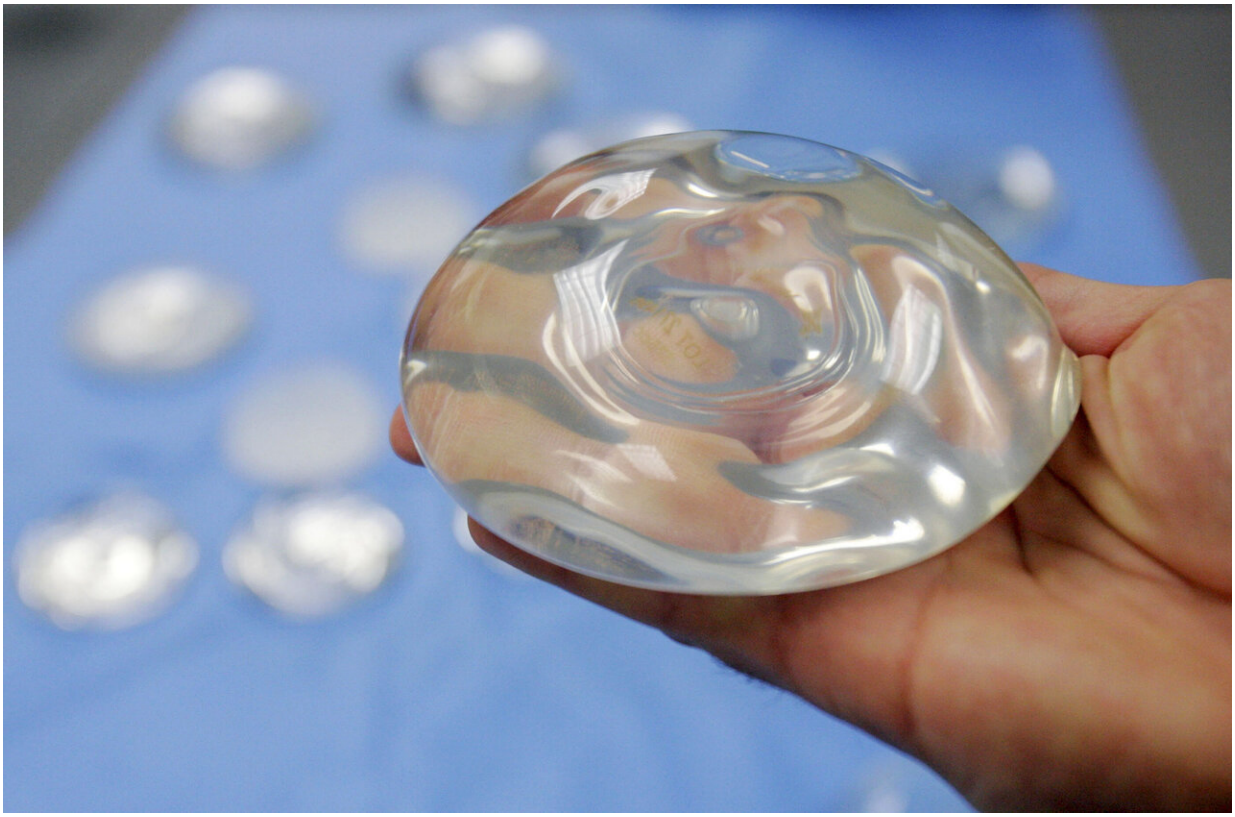

This Dec. 11, 2006 file photo shows a silicone gel breast implant in Irving, Texas. On Wednesday, Oct. 23, 2019, the U.S. Food and Drug Administration said that breast implant manufacturers should add a boxed warning—the most serious type—to information used to market and prepare patients for implants. (AP Photo/Donna McWilliam, File)

U.S. health officials want women getting breast implants to receive stronger warnings and more details about the possible risks and complications.

The Food and Drug Administration said Wednesday that manufacturers should add a warning highlighted by a box—the most serious type—to the information given to women considering implants.

The agency is also recommending patients complete a checklist to make sure they understand all the possible side effects of the implants, such as scarring, pain, rupture and even a rare form of cancer.

"We have heard from many women that they are not fully informed of the risks when considering breast implants," the agency said in a statement detailing the recommendations.

The agency also wants companies to explain that breast implants often require repeat surgeries and they should not be considered lifelong devices. About 1 in 5 women who get implants for cosmetic reasons need to have them removed within 8 to 10 years, according to the FDA.

The agency will take public comment on the proposed guidelines before adopting them.

The new proposal is the FDA's latest attempt to manage safety issues with the devices primarily used for breast augmentation, the most frequently performed cosmetic surgical procedure in the U.S. Roughly 400,000 women get implants each year; 100,000 after cancer surgery.

In recent years, the FDA and regulators elsewhere have grappled with a link between a rare cancer and a type of textured implant. In July, the FDA called on manufacturer Allergan to pull its Biocell implant after it was tied to heightened risk of a form of lymphoma. The company issued

a worldwide recall for the implants, which had already been restricted or removed from numerous countries.

In a separate issue, the FDA has received thousands of reports from women who blame their implants for a host of health problems including rheumatoid arthritis, chronic fatigue and muscle pain.

Earlier this year, the FDA held a meeting at which dozens of women urged the agency to place new warnings and restrictions on implants.

The FDA has stood by its longstanding position that the implants are essentially safe so long as women understand they can have complications. But following the meeting, the agency said women should get more explicit, understandable information about implant risks.

The devices have a silicone outer shell and are filled with either saline or silicone.