

## FDA takes new look at breast implant safety

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(HealthDay)—Questions about breast implant safety are getting new attention from the U.S. Food and Drug Administration as thousands of women say their implants cause debilitating joint pain and fatigue.



The claims have long been dismissed by doctors and implant makers, and most consumers believed concerns about breast implant safety had been resolved about a decade ago, *The New York Times* reported.

On Tuesday, the FDA warned two breast implant makers that they had failed to conduct adequate long-term studies of their implants' effects on women's health. Those studies were a condition of approval, and the implants could be taken off the market if the companies do not fulfill that requirement, the FDA said. On Friday, the agency issued a statement acknowledging that breast implants and other implantable devices may contain materials that affect people's health, including "inflammatory reactions and tissue changes causing pain and other symptoms that may interfere with their quality of life," the *Times* reported.

The FDA said it plans to collect more information "to further our understanding of medical device materials and improve the safety of devices for patients." One of the materials being looked at is silicone. Next week, the FDA has scheduled a two-day meeting about <a href="mailto:breast">breast</a> implants and will hear from researchers, patient advocacy groups, and manufacturers, the *Times* reported.

**More information:** <u>The New York Times Article</u>

**More Information** 

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