Breast implant injuries hidden as patients' questions mount

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Jamee Cook poses for a photo at Rayburn House Office Building after meeting with congressional leaders on Capitol Hill, Thursday, Sept. 6, 2018, in Washington. Cook had breast implants that ruptured and which she believes caused her medical problems. She now is lobbying the FDA and congressional leaders to do a better job of tracking and regulating medical devices. (AP Photo/Jose Luis Magana)

To all the world, it looked like breast implants were safe. From 2008 to

2015, the U.S. Food and Drug Administration publicly reported 200 or so complaints annually—a tiny fraction of the hundreds of thousands of implant surgeries performed each year.

Then last fall, something strange happened: Thousands of problems with breast implants flooded the FDA's system. More than 4,000 injury reports filed in the last half of 2017. Another 8,000 in the first six months of 2018.

Suddenly, women like Jamee Cook had evidence suggesting their suffering might be linked to their breast implants. An emergency room paramedic, Cook had quit her job because of a vague but persistent array of health problems that stretched over a decade, including exhaustion, migraines, trouble focusing and an autoimmune disorder diagnosis.

Why had it taken so long for complaints like hers to see the light of day?

Makers of breast implants were required to track patients and their health. But for more than a decade, manufacturers with high numbers of recurring problems—in the case of implants, ruptures that required surgery to remove—were allowed to report issues in bulk, with one report standing in for thousands of individual cases and no way for the public to discern the true volume of incidents.

That agreement stood even as the FDA began closely monitoring a rare type of cancer and acknowledged in 2011 that it might be linked to breast implants.

"It looked like these devices had become safer, but they hadn't," Cook told The Associated Press. "The data was hidden. It's a deceptive practice."

Once Cook's textured saline implants were removed, she said the

majority of her symptoms disappeared. Her experiences prompted her to become a patient safety advocate, lobbying lawmakers and organizing groups of women online who have concerns about breast implants.

Public health advocates who've watched the debate over breast implant safety rage for nearly three decades say summary reporting is yet another way that information about the devices has been elusive for patients.

"They were told those devices were safe—the FDA would go back and say 'We only have this many reports,'" said Madris Tomes, a former FDA staffer who founded a company to analyze medical device reports. "But data was coming in another way that wasn't public. It leaves the patients demoralized—they don't understand how many other people are suffering."

The data came to light after the FDA instructed manufacturers in mid-2017 to go back and file individual reports in each case of patient injury, in response to a lawyer's discovery that reports from his clients weren't represented in the agency's data. Patient advocates took up the issue, complaining about a lack of transparency and voicing concerns about a host of autoimmune problems they believed stemmed from their implants.

But even as the FDA was dealing with the problems of how breast implant manufacturers had used summary reporting, the agency was moving to expand device makers' flexibility in how they report problems, saying it was trying to reduce the industry's paperwork requirements.

This August, the agency began allowing roughly 90 percent of all medical devices—including all breast implants and more than 160 types of other high-risk implanted devices like artificial hips and replacement heart valves—to report malfunctions in a quarterly tally, instead of

individually. They will not be able to report cases involving deaths or injuries that way, however.

The FDA rejected claims that expanding summary reporting could harm public health by making problems with devices less transparent, saying the plan "will also yield benefits . such as helping FDA process malfunction reports more efficiently and helping both FDA and the public more readily identify malfunction trends."

FDA officials also said that the agency has closely monitored the breast implant industry in the past decade and issued updates about potential risks.

Two of the largest breast implant manufacturers, Mentor and Allergan, said they stood behind the safety of their products, citing years of studies that have led to inconclusive evidence that autoimmune problems are linked to breast implants.

"Our medical devices undergo extensive laboratory testing before they are submitted to government health experts for a science-based review," Mentor spokeswoman Mindy Tinsley said. "Many of our devices undergo careful reviews by not just one, but multiple regulatory bodies around the world."

Still, it can be hard for breast implant patients and advocates to track problems that do arise.

Insurance claims make no mention of the specific device or model implanted in a patient, and patients' electronic health records aren't required to record that either. In addition, products sold overseas can be renamed or carry a different model number, making international recalls or tracking across borders nearly impossible.

Meanwhile, the FDA's main database on medical device problems, which requires manufacturers to report patient deaths and serious injuries to the government within 30 days, relies on hand-typed entries from a variety of people—from patients to device manufacturers—to help track troubled products. That can lead to underreporting, along with missing and flawed data.

Tomes said accurate, complete and publicly accessible data is crucial to identifying problems quickly and making sure devices are safe. The FDA numbers, she said, offer the lowest possible count of reports about problems with breast implants.

"You can assume that the numbers are probably much, much higher," she said.

A Duke University report funded by the FDA in 2016 found that even though the agency collected data on device malfunctions for more than two decades, "reliably and efficiently tracking the medical device safety and effectiveness outcomes of most interest to patients remains a generally unfulfilled promise" that "significantly affects the public health."

Insurers, auto buyers and regulators all use a car's VIN number to track a vehicle's history, down to the line it was manufactured on at a specific factory, and the FDA's own pharmaceutical drug oversight works similarly. But medical devices didn't have a similar unique identifier until 2015, and many of the least-risky devices won't put an ID into use until 2020. On top of that, experts say it could be years before their use is required in patient records, on insurance claims and in the FDA's own data.

What are the most common makes and models of breast implants reported as having caused injury? The FDA's answer is still quite often

"Unknown."

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The FDA requires manufacturers and medical facilities to file a report when any kind of medical device causes serious injury, death or malfunctions.

The resulting database—called MAUDE, for Manufacturer and User Facility Device Experience—is available online to the public, so consumers can search for a device type, manufacturer, the details of an incident and the date on which it occurred. That is, if the forms are filled out properly.

But categories often are left blank, with no indication of the model or who submitted the report. And device names and manufacturers also are often misspelled, making it nearly impossible for users to find all the reports of problems with a specific device or company. For example, the data contains roughly 2,000 variations of the name Medtronic plc, one of the world's largest medical device manufacturers.

Overall, the MAUDE data contains reports of more than 1.7 million injuries and nearly 83,000 deaths over the past 10 years for all types of medical devices, according to an analysis of FDA data by the International Consortium of Investigative Journalists, which collaborated with the AP on a global investigation of medical device safety.

But in looking at problems with the MAUDE data, the investigation found an additional 2,100 cases in the past five years where people died but their deaths were misclassified as "malfunctions" or "injuries." Of those, 220 deaths could be directly linked to medical device failure; the other reports did not include enough information to determine conclusively if the device played a role.

Beyond the misclassified data, FDA inspections at 17 hospitals in 2015 and 2016 found that only a fraction of "adverse events" were even being reported anyway. The review —which included major facilities in Los Angeles, New York, Boston and Chicago—found more than half failed to report deaths of patients with medical devices, as required by the agency's rules. Jeffrey Shuren, the head of the FDA's device division, said at the time that underreporting problems from hospitals was widespread. The agency enhanced compliance training for hospital employees nationwide as a result.

Part of the problem, advocates say, is that the FDA's guidelines for reporting problem devices is vague—the agency states that reports are required from manufacturers within 30 days of an event when evidence "reasonably suggests" that a device was involved, allowing companies to make their own judgments.

S. Lori Brown, now a retired FDA senior researcher, used MAUDE for years in her studies of breast implants, ruptures and possible links to rare forms of cancer and a host of autoimmune disorders.

"It's a difficult database to use, because there's no good way to confirm what's reported, and there's no denominator—you don't know how many people have received breast implants," Brown said. "The MAUDE database was just not very helpful in finding out how frequently things happened or how severe the impact was."

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Where it was helpful, she said, was in gathering patient stories and seeing general trends. In the 1990s, even as manufacturers claimed breast implants were durable enough to be run over by a car without breaking, MAUDE showed silicone implants leaking gel into thousands of women's bodies.

"As a signal, it was a burning bush, for sure," Brown said. "Because there were so many reports of ruptured implants from every manufacturer."

After the FDA removed silicone breast implants from the market in 1992, the public attention around ruptures and leaks resulted in a huge spike in the number reports about problems. During the 1990s, silicone implants represented the third-highest number of adverse events reports in MAUDE. At the time, the data show patients also complained about other symptoms, with hundreds of reports about chronic fatigue, headaches, autoimmune problems and fibromyalgia.

In 2006, silicone implants returned to the market, under the requirement that companies track patients for at least a decade. Although more than half the women dropped out of the studies within the first two years, researchers at the University of Texas MD Anderson Cancer Center in Houston released a study this September using the data the companies did collect and found that certain rare health problems—including immune system and connective tissue disorders—might be more common with silicone gel implants. The FDA, which mandated the original data collection, later criticized the study, citing "inconsistencies in the data."

Last year, the FDA did confirm a link between breast implants, particularly textured saline or silicone models, and anaplastic large cell lymphoma—a rare cancer documented in only a few hundred cases.

On its website, the FDA also noted more common problems with implants, such as ruptures, which can send silicone gel throughout the body. And the agency warned that implants "are not lifetime devices," but will likely need to be removed or replaced at some point.

The return of silicone implants, which advocates say feel more natural, has fueled a surge in surgeries. The American Society of Plastic Surgeons reported 400,000 procedures took place in 2017, up nearly 40 percent since 2000.

More than three-quarters of the implant surgeries were for cosmetic, not reconstructive, reasons. And there were about 20 percent fewer removals compared to 2000, the data show.

The increase in implants worries Diana Zuckerman, a medical researcher who was a congressional staffer during the earliest contentious House hearings on breast implant safety. She said poorly performed studies, research funded directly by manufacturers and the lack of data have left most women in the dark about the risks involved.

"Somehow, it's the most studied device and we have almost no useful information about it," said Zuckerman, the president of the National Center for Health Research, a nonprofit think tank that performs its own research, assesses the quality of others' research and works with patients.

Zuckerman's center reviewed more than 20 studies it says has been used by the industry to claim there is no evidence breast implants cause connective tissue problems and other long-term illnesses. She said almost all the studies were too small to detect rare diseases and conditions, only one required that participants have a medical exam and most didn't focus on patients who had implants long enough for problems to develop.

In September, Cook and 19 other breast implant patients-turned-health-advocates visited Washington to lobby the FDA for more stringent regulation, testing and reporting on breast implants. Among their requests—that all types of textured implants, which are more closely associated with lymphoma, be banned from the market, and that manufacturers be required to disclose the chemicals in silicone implants' shell and gel filling, which the makers claim is a trade secret.

The FDA has scheduled an advisory committee hearing for early 2019 on breast implant safety to address some of the U.S. group's concerns and determine whether additional actions are needed to protect public

health. The agency did not rule out the possibility of including a "black box warning," the notification it puts on its most dangerous devices to draw attention to serious risks.

However, the FDA said in a statement: "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."

Cook, who leads several breast implant groups on Facebook from her home near Dallas, said she chose to get her implants, but did so with almost no information on the potential dangers.

"If you had sat down with me and said 'this is the list of chemicals you're about to put in your body and you could get lymphoma,' no way in hell I would have done it," she said.

Her implants, a textured saline model made by Poly Implant Prothese of France, were used in the U.S. for four years before the FDA implemented more stringent standards for breast implant approval in 2000. Under the new rules, the FDA denied the company's application to sell implants in the U.S. after officials toured the company's French plant and cited 11 major deficiencies in quality control and manufacturing practices.

Poly Implant went bankrupt in 2010 after doctors in France noted abnormally high rupture rates of the implants, which were found to be filled with industrial-grade gel. The company's president was found guilty of aggravated fraud, and French authorities advised tens of thousands of women to get their implants removed as a precautionary measure.

Cook, 41, said she and others who already had the saline implants never

were warned of the FDA's actions.

"I'm not going to sit back and be embarrassed about my decision when I can try to change the way that the future is going to occur for women younger than me," she said. "We need to make sure we're giving that patient the most safe device we possibly can. And above that, we need to make sure she understands what the risks are before she makes that choice."

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The FDA may now require an identifying number on medical devices, but Zuckerman and other advocates note one big issue with the code associated with breast implants: The number is not actually stamped on the implant itself, but on the packaging.

"For the most part, these devices don't cause immediate problems—they cause problems later," Zuckerman said. "What good does it do to have these numbers if they're not in your medical records and they aren't on the implant itself?"

The unique device identifier, or UDI, is intended to help standardize device names and manufacturer information and make it easier to track devices to help in recall efforts and analyses of problems.

But that doesn't work if the codes aren't in the FDA's own database. Tomes, whose company Device Events analyzes MAUDE data, said UDIs are still rarely included in adverse event reports and, even when they are, often are removed from the public data so they can't be used to identify specific devices.

"The whole point of having a UDI is so that hospitals and providers and insurance companies and anyone else would be able to say 'I'm seeing a

pattern, it's all this serial number,'" Tomes said. "But it's redacted."

Similarly, Tomes and others say the FDA's expansion of summary reporting and its use of device registries—databases funded and maintained by outside organizations to track a singular specific device—may ultimately make less data available to consumers.

This fall, the agency announced a breast implant registry run through the Plastic Surgery Foundation that will collect patient and device data—including UDI numbers for breast implants—and allow surgeons to track patients' medical history, complications and follow-up surgeries.

The participation of plastic surgeons in the registry is voluntary, and patients also can opt out. Doctors and researchers will have access to the collected data, but the public will not.

As the FDA weighed its expansion of the summary reporting program earlier this year, Cook and a dozen other patients with medical device problems, along with the patient-advocacy group Public Citizen, urged the agency to rethink its plan.

But the FDA sided with manufacturers and industry organizations, which had asked for easier reporting requirements for malfunctions, freeing them in some cases from filing tens of thousands of individual reports a year. Under the new rules now in place, roughly 90 percent of devices can report malfunctions quarterly.

"Thousands on thousands of consumers are harmed every single year by medical devices and we are discussing making it easier to hide the information that we need to make an informed decision," Cook wrote in her dissent to the plan.

"While the goal is not to 'hide' the data," she wrote, "in essence that is

what is happening."