FDA to end program that hid millions of reports on faulty medical devices

May 6 2019, by Christina Jewett

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The Food and Drug Administration announced it is shutting down its controversial "alternative summary reporting" program and ending its decades-long practice of allowing medical device makers to conceal

millions of reports of harm and malfunctions from the general public.

The agency said it will open past records to the public within weeks.

A Kaiser Health News investigation in March revealed that the obscure program was vast, collecting 1.1 million reports since 2016. The program, which began about 20 years ago, was so little-known that forensic medical device experts and even a recent FDA commissioner were unaware of its existence.

Former FDA official Dr. S. Lori Brown said ending the program now is a "victory for patients and consumers."

"The No. 1 job of the FDA—it shouldn't be 'buyer beware' - is to have the information available to people so they can have information about the devices they are going to put in their body," Brown said.

FDA principal deputy commissioner Dr. Amy Abernethy and its device center director, Dr. Jeff Shuren, announced the decision to terminate the program in a statement on increasing transparency about the safety of breast implants.

The agency has for years allowed makers of breast implants to report hundreds of thousands of injuries and malfunctions out of the public eye, federal records show.

"We believe these steps for more transparent medical device reports will contribute to greater public awareness of breast implant adverse events," Abernethy and Shuren said in a statement on Thursday. "This is part of a larger effort to end the alternative summary reporting program for all medical devices."

FDA spokeswoman Angela Stark said the agency will also end

"alternative summary reporting" exemptions still in place for makers of implantable cardiac defibrillators, pacemakers and tooth implants. The FDA has said the program was originally designed to allow for more efficient internal review of well-known risks.

The agency said it began winding down the program in mid-2017, revoking many reporting exemptions, including those for saline breast implants and for balloon pumps used inside patients' blood vessels.

At that point, the agency required device makers with ongoing exemptions to file quarterly reports in its public device-harm database known as MAUDE, short for the Manufacturer and User Facility Device Experience.

Still, FDA data provided to KHN shows that during the first nine months of 2018 the FDA continued to accept more than 190,000 injury reports and 45,000 malfunction reports under the hidden "alternative summary reporting" program.

Ronni Solomon, vice president and chief policy officer of the ECRI Institute, which studies device safety, said the staff uses the FDA's open data on a daily basis to look for signals that might show heightened risks with a particular device.

"We think it's really vital for the sake of transparency, for the sake of policy, for sake of science," she said. "We're really glad to see this, the sooner the better."

The agency said its forthcoming data release will be for the alternative summary reports filed before mid-2017. The FDA for years reached agreements with makers of about 100 devices, allowing them to cease public reports of certain types of problems. The agency previously said the agreements and resulting records were available only by filing a

Freedom of Information Act request, a process that can take months or even years.

Going forward, device makers will be required to file individual reports describing each case of patient harm related to a medical device.

The FDA has not said it will stop allowing device makers to file other types of device-harm exemption reports that are withheld from the public, such as when there is mass litigation over a device or when a company is submitting reports from an independent device-tracking registry. Nor has a plan been announced to open those records, which contain reports of harm related to pelvic mesh and surgical robots and reports of deaths related to several cardiac devices.

The FDA had granted Covidien, now a division of Medtronic, a long-standing "alternative summary reporting" exemption for its surgical staplers, a device used to cut tissues and vessels and quickly seal them during a variety of surgeries.

In 2016, when just 84 reports of stapler-related harm were disclosed in the FDA's MAUDE database, almost 10,000 more malfunction reports were sent directly to the FDA's in-house database, the agency acknowledged.

The device has been subject to numerous lawsuits over patient deaths and grave harm.

Doris Levering alleged in court that a stapler malfunction during liver surgery caused profuse bleeding that left her husband, Mark, 62, with serious brain damage and unable to walk. She applauded the agency's decision to open the database. "It's just wonderful to know that this information is going to be out in the open and not covered up," she said. "Now doctors who need to find the information will be able to find it."

The surgeon, hospital and device maker have all denied wrongdoing in an ongoing legal case.

The FDA has announced a May 30 advisory board meeting to review the agency's oversight of surgical staplers.

The FDA will leave in place a newer summary-reporting program that allows makers of more than 5,500 types of devices to send the agency spreadsheets logging device malfunctions. Unlike the "alternative summary reporting" program, device makers will not be allowed to report serious injuries using that approach.

Over the years, the FDA has had an uneven record of disclosing its "exemption" reports to advisers who review the safety of individual devices.

In February, FDA officials presented an advisory panel on gynecological devices with data showing 476 adverse events in 2017 related to a certain type of pelvic mesh. That panel was not briefed on nearly 12,000 reports filed by eight mesh makers in 2017, under a special exemption for lawsuit-related reports, according to an agency spokeswoman and a review of public records.

FDA spokeswoman Deborah Kotz said in an email that those "litigation" summary reports did not contain enough detail for the FDA to determine whether they shed any light on the safety question at hand.

The FDA ultimately took decisive action, though, ordering makers of the type of mesh under review to stop marketing those products, which were used to support sagging pelvic organs.

In late March, after KHN's investigation landed, the FDA convened another panel to review breast implant-related injuries and a rare form

of lymphoma. For that meeting, the agency did provide a full tally of previously unreported injury and malfunction reports related to breast implants.

As of Thursday, though, the agency said it would leave the textured breast implants linked to a rare lymphoma on the market.

Matt Baretich, a Denver-area biomedical engineer who advises health systems on device safety, is eager to examine the hidden reports as they're released by the FDA.

"I'm really interested to see what information has been hidden so I can go back," Baretich said. "I may have been looking for that information and not found anything and thought there was not a problem."