Five things found in the FDA's hidden device database

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After two decades of keeping the public in the dark about millions of medical device malfunctions and injuries, the Food and Drug Administration has published the once hidden database online, revealing 5.7 million incidents publicly for the first time.

The newfound transparency follows a Kaiser Health News investigation that revealed device manufacturers, for the past two decades, had been sending reports of injuries or malfunctions to the little-known database, bypassing the public FDA database that's pored over by doctors, researchers and patients. Millions of reports, related to everything from breast implants to surgical staplers, were sent to the agency as "alternative summary" reports instead.

Here's what we found in those newly public reports:

1. Blood glucose meters for patients with diabetes had more unique incidents than any other device in the database, logging 2.4 million reports over the past 20 years.

Almost all the products were made by LifeScan, which had been a Johnson & Johnson company until it was sold to a private equity firm in 2018. Common problems included displaying incorrect messages, losing power or being damaged before customers started using them, according to the database.

"When you're trying to manage a chronic disease, and especially if your

numbers are dangerously high, that's life-threatening," said Linda Radach, who chairs the medical device committee for the Patient Safety Action Network.

LifeScan did not return requests for comment.

The FDA said the number of glucose meter problems in the alternative summary reporting database shouldn't be a surprise.

"Approximately 10% of the U.S. population has diabetes and most rely on these devices several times a day," said FDA spokesman Michael Felberbaum. The agency also sees a "high volume" of adverse events for glucose meters in its longtime public database, called MAUDE, he said.

He reiterated that the alternative summary reporting program was intended for "well-understood" adverse events "so that we could focus more resources on identifying and taking action on new safety signals and less understood risks."

2. There were 2.1 million reports for bad dental implants. And 114,200 were reported last year.

This kind of implant goes into the bone to support an artificial tooth or implant. Many of the reports were for problems with connections between the device and the bone.

"A lot of people have gone out and gotten these and probably don't know about these risks," said Madris Tomes, a former FDA manager who now runs a website to make the notoriously clunky MAUDE easier to work with.

Dental implants were among the last device types to lose permission to report harm via alternative summary reports instead of the public

database. Although the device harm data doesn't include what happened to patients, Tomes said that if a dental implant has to be removed, it often can't be replaced because the underlying bone is so damaged.

Felberbaum said that the high number of reports for dental implants is expected because these are commonly used devices, and that more companies have brought new products to market in the past two decades.

3. There were 176 deaths reported through the alternative summary reporting system.

Alternative summary reports are not supposed to include deaths, except for cardiac arrest potentially caused by certain kinds of heart valves that were implanted at least five years beforehand. Those accounted for two-thirds of the deaths in the hidden database, KHN found.

The most recent death was reported last fall by Medtronic, and it was for a MiniMed Paradigm insulin pump that was hard to program or calibrate. Deaths reported to the once-hidden database also included fatalities associated with two different kinds of pacemakers, a breast implant, an intra-aortic balloon pump and a ventilator.

When asked why these were there, the FDA said its "standard practice" was to reach out to the manufacturer for more information when it detected an "ineligible event" in the alternative summary reports. Sometimes, a death was reported in error. Sometimes, the FDA required the manufacturer to report an incident to the public database as well.

KHN found that of the 59 ineligible deaths, only eight appeared to be revised in updated alternative summary reports.

"In some cases, the FDA revoked ASR exemptions following continued reporting of ineligible events in ASRs," said Felberbaum, adding that

ineligible deaths represented "0.001% of all reports received through the ASR program."

When asked whether the FDA had contacted the company about the 2018 insulin pump death, Medtronic was unavailable for comment.

"One has to wonder what other information wasn't made public if something that clear-cut (the instruction not to include deaths in the ASR) was included and hidden from the public," said Diana Zuckerman, president of the nonprofit National Center for Health Research. "Did FDA notice?"

4. Surgical stapler-related malfunctions accounted for more than 66,000 previously hidden incidents since 2001.

The KHN investigation spotlighted problems with staplers, which tend to be used in minimally invasive surgery to cut and seal tissue and vessels quickly. Although the FDA received only 84 reports for stapler-related harm in the public database, it acknowledged earlier this year that it had received nearly 10,000 reports through alternative summary reporting.

The most common problems were staplers that failed to fire or fired malformed staples. Nearly 4,700 stapler problems were reported through the hidden database in 2017 alone. If a stapler fails to seal tissue properly during surgery, it can lead to serious bleeding or infection.

An FDA advisory panel in May recommended the agency switch staplers to a higher-risk classification with more safety requirements.

5. Breast implant injuries and malfunctions accounted for nearly half a million unique reports over two decades, including implants that leaked, deflated or migrated.

More than 6,600 incidents have been reported in 2019 by three companies: Allergan, Mentor and Sientra. The most common problem was rupture.

Tomes was especially concerned about cancer attributed to breast implants, which was the subject of an ICIJ investigation last fall. But without publicly available data tracking patient problems, which exists in adverse events data for drugs but not devices, it's impossible to say.

"How is the public supposed to make sense of this if they've redacted patient safety codes?" she asked.

Plus: Thousands of medical device types are still eligible for reporting outside the FDA's public database.

There are still ways that device makers can avoid submitting individual injuries and malfunctions to the MAUDE database.

To replace the ASR program, the FDA has launched the Voluntary Summary Reporting Program. More than 5,600 device types—or 87% of them—are eligible for summary reporting of device malfunctions, according to FDA records.

Patient advocates say they fear that these will be just as difficult to tally and track as ASRs. For example, a summary report for 156 injuries would appear to be a single MAUDE report with a note that it represents 156 injuries, not one.

"Why would you end one (hidden data program) just to start another?" Radach asked.

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METHODOLOGY

To avoid double-counting adverse events, KHN counted each event identified with a unique report ID only once, unless otherwise noted.

Although this isn't the norm, some companies appear to have recycled report IDs, using them for more than one event. As a result, our counts may be underestimated.