MEDTECH INSIGHT
CITELINE COMMERCIAL

21 Jun 2019 | **News**

FDA Ends Summary Reporting Program, Releases 20 Years Of Adverse Events, Vows To Make MAUDE 'User-Friendly'

by Shawn M. Schmitt

The US FDA today formally shuttered its Alternative Summary Reporting (ASR) Program and released to the public millions of adverse event reports received by the agency between 1999 and 2019. The FDA also wants to make its Manufacturer and User Device Experience (MAUDE) database – where all adverse events are stored – easier to use.

The US Food and Drug Administration officially shuttered its Alternative Summary Reporting (ASR) Program today and released to the public millions of adverse event reports received by the agency between 1999 and 2019.

The move comes more than a month after the FDA announced it would end its problematic program, which caused reports of medical device failures to be hidden from the public. (Also see "*FDA Quietly Sunsetting Summary Reporting Program For Adverse Events, Readies Public Release Of Millions Of Pre-2017 Summarized MDR Reports*" - Medtech Insight, 16 May, 2019.)

The ASR Program allowed device-makers to submit abbreviated reports in a summarized, line-item format. It was established in 1997 in an effort by the agency to review adverse events more efficiently for well-established risks.

The FDA allowed 108 companies to take part in the program since its inception, but that number dwindled over the past two years as the agency wound down the program. As of this month, ASR exemptions were in place for only three product types.

"To formally end the program, we've issued revocation letters to the remaining 13 manufacturers with ASR exemptions, which covered … dental implants, implantable cardiac defibrillators and

pacemaker electrodes," Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, wrote in a 21 June *statement*.

"Since 2017 we have taken steps to gradually sunset the ASR Program and to streamline Medical Device Reporting as we implemented the Voluntary Malfunction Summary Reporting Program," he added.

Launched in August 2018, the *VMSR Program* addresses goals outlined in a 2016 MDUFA IV commitment letter that directed the FDA to allow manufacturers of a majority of devices to report adverse events quarterly in a summarized, line-item fashion. (Also see "*Makers Of An Array Of Devices Can Now Report Malfunctions In Summaries To FDA. Did Your Product Make The Cut?*" - Medtech Insight, 17 Aug, 2018.)

> *"Our goal is to make MDR data more usable and easier to find." – Jeff Shuren*

Meanwhile, *the agency released today summarized MDRs sent to the firm over the past 20 years* – a data dump of millions of adverse events, according to a *Medtech Insight count*.

In his statement, Shuren also vowed to make the agency's Manufacturer and User Device Experience (*MAUDE*) database – where all MDRs are stored – easier to use.

The FDA "intends to make MAUDE more user-friendly in the next few years as part of a broader effort to modernize the medical device program's information technology systems," Shuren wrote. "Our goal is to make MDR data more usable and easier to find, furthering our efforts to increase transparency in Medical Device Reporting."

The ASR Program was the center of controversy in early March after an *investigative report* was published by Kaiser Health News spotlighting safety issues with surgical staplers, which the report says were shielded from public view because of the program. (Also see "*FDA Eyes Upclassification, Labeling Guidance To Address Stapler Risks*" - Medtech Insight, 8 Mar, 2019.)