



FDA Shuts Down Program that Allowed Medical Device Makers to Hide Reports of Malfunctions

The United States Food and Drug Administration (FDA) recently announced that it is ending a decades-long program that allowed medical device manufacturers to conceal from the public millions of reports of malfunctions and harm linked to their products.

The “alternative summary reporting” program, started nearly two decades ago, is reported to have collected more than 1.1 million reports since 2016. The FDA said that it will begin to release records collected by the program in the coming weeks.

The program was originally developed, the FDA reported, as a way to allow device manufacturers to more efficiently run internal reviews of well-known risks with their products.

The FDA allowed developers of breast implants to use the program to file reports of hundreds of thousands of malfunctions and injuries while still keeping them hidden from the public. Many records were only available through Freedom of Information Act requests, which can take months or, in some cases, years, to process.

The FDA began discontinuing the program in 2017 by doing away with many reporting exceptions, includ-

ing reports about saline breast implants and for balloon pumps used to open clogged blood vessels.

Even so, data has shown that in the first nine months of 2018, the FDA still accepted more than 190,000 injury reports and 45,000 malfunction reports in the “alternative summary reporting” program that excluded them from public access.

In addition to these products, FDA Spokesperson Angela Stark said the agency will also end exemptions still in place for manufacturers of pacemakers, implantable cardiac defibrillators and tooth implants.

Former FDA official Dr. S. Lori Brown lauded the discontinuation of the program as 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.

Once the program ends, device manufacturers will be required to submit individual reports detailing each episode of harm related to specific medical devices.

Source: PBS.org

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