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NEWS

THE IMPLANT FILES

FDA recommends "modernizing" review of devices in wake of global investigation

Jeanne Lenzer *associate editor*

The BMJ

The US Food and Drug Administration is making changes to how medical devices are cleared for sale after a scathing investigation into the industry.

The global investigation into the medical device industry by journalists from 36 countries, including *The BMJ*, BBC *Panorama*, and the *Guardian* and led by the International Consortium of Investigative Journalists, unearthed thousands of documents to reveal rising numbers of malfunctions and injuries.[1]

Scott Gottlieb, FDA commissioner, and Jeff Shuren, director of the Center of Devices and Radiological Health, said in a statement that there would be changes to the 510(k) pathway that is used to clear four in every five devices for sale.[2] The pathway approves devices not on the basis of testing in humans but on how similar devices are to previous devices, called "predicates," some of which were approved decades ago.[3]

Gottlieb and Shuren said that about a fifth of devices were cleared on the basis of predicates that were more than 10 years old. They said they were "encouraging" manufacturers to "use more modern predicates," adding that the use of older predicates didn't mean a device was unsafe. This change, they said, was the "most impactful" change they could make to "modernize" 510(k).

However, the reform didn't go far enough, said Diana Zuckerman, epidemiologist and president of the National Center for Health Research in Washington, DC. She told *The BMJ* that using more "modern" predicates says nothing about safety or effectiveness. She said that "newer doesn't mean better" and that "since less than 5% of 510(k) devices undergo any type of clinical trials, there's no assurance that any devices cleared through that pathway are safe or effective."

In 1996 the US Supreme Court concluded that "since the 510(k) process is focused on equivalence, not safety . . . if the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective."[4]

A recent study found that 16% of mesh clearances were based on recalled devices.[5] When the FDA was asked why it cleared mesh implants on the basis of predicate devices that had been withdrawn because of safety concerns, the agency said that it didn't evaluate the performance of predicate devices when clearing devices for sale.

A study of high risk implanted cardiac devices found that only 5% underwent clinical testing that even partly approximated the testing required for drug approvals.[6]

Nor is safety surveillance reliable. A Government Accountability Office analysis found that 99% of device related "adverse events" were never reported to the FDA and that the "more serious the event, the less likely it was to be reported."[7]

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For more on the worldwide Implant Files investigation go to https://www.icij.org/investigations/implant-files.

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jlenzer@bmj.com