

Insight on the Issues

IMPLANTABLE DEVICES: REGULATORY FRAMEWORK AND REFORM OPTIONS

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Implantable devices, like cardiac pacemakers and artificial hip replacements, offer substantial benefits but can also pose serious risks. Against this backdrop of potential risk—and, in some cases, inadequate regulation—this *Insight on the Issues* focuses on the Food and Drug Administration’s oversight of implantable devices and suggests reform options to help improve the existing regulatory framework. A second *Insight on the Issues* deals with the lack of price transparency and the need for greater competition in the marketplace for implantable devices.

INTRODUCTION

Millions of Americans have had some type of medical device implanted in them with the expectation that it will remain in the body and function properly for many years. Americans receive about 370,000 cardiac pacemakers and about 1 million total hip and knee replacements per year.¹ Experts estimate that 7.2 million Americans are living with joint implants.²

In the United States, medical device expenditures amounted to over \$170 billion and accounted for about 6 percent of total national health expenditures of \$2.9 trillion in 2013.³ Industry reports suggest that implantable device sales accounted for about \$43 billion in 2011 and are expected to grow to \$74 billion by 2018.⁴

Implantable devices often provide substantial benefits. Cardiac pacemakers save lives and artificial hips help people recover function and relieve pain. On the other hand, the widespread use of implantable devices has raised a number of concerns. For example, many implantable devices have not been tested for safety or effectiveness, as discussed below. Existing systems are limited for monitoring the safety of implantable devices, and when problems

arise, they are sometimes ineffective for detecting defects. Systems for notifying patients of problems are slow and inefficient.

Despite oversight by the Food and Drug Administration (FDA), implantable devices continue to be associated with patient injuries and deaths. For example, FDA recalled certain all-metal hip implants in 2010 because friction between the metal cup and metal ball resulted in toxic metallic debris.⁵ As a result, many people needed to have their hip implants removed and replaced in sometimes risky surgery.

Another example involves widely used heart defibrillators designed to correct potentially fatal irregular heart rhythms. The defibrillators developed cracked insulation on high-voltage electrical wires after they were implanted, causing severe shocks and deaths.⁶ Patients who had the defective implants had to decide whether to undergo dangerous surgery to replace the device or simply monitor it. Until the defective device is replaced, patients run the risk that it will deliver an unnecessary high-voltage jolt of electricity—described as feeling similar to being hit across the chest with a baseball bat—or simply fail, which could lead to cardiac arrest and death.



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Against this backdrop of potential risk, and in some cases inadequate regulation, this report focuses on FDA's oversight of implantable devices. It provides a rundown of the current policy and market environment, various stakeholder concerns, and, without endorsing or ranking them, a number of policy options that could both strengthen and streamline FDA's oversight while speeding patient access to the devices.

The policy landscape is complex, with dozens of regulations affecting the current environment. Therefore, the paper splits the landscape into two categories: premarket and postmarket oversight. For policy areas that appear throughout the paper, "Context," "Issues," and "Options" are highlighted. (A brief and simplified summary of policy options also appears in the conclusion.) Nothing in this paper is intended to imply that any particular device is ineffective or unsafe.

PREMARKET REVIEW OF IMPLANTABLE DEVICES

With the passage of the Medical Device Amendments of 1976,⁷ Congress gave FDA comprehensive jurisdiction over all "devices intended for human use." Under the law and subsequent court rulings, FDA's oversight of the medical device industry includes two sometimes competing goals. It is charged with (1) "protecting the public from unnecessary illness or injury by subjecting medical devices to a regulatory scheme designed to ensure that the devices are safe and effective," while, at the same time, (2) "encouraging the development and marketing of medical devices by crafting a nationally uniform regulatory scheme that prevents overregulation and thus ensures that development can be economically feasible."^{8,9,10}

An implantable device must receive FDA approval or clearance to be sold in the United States. FDA categorizes medical devices into three classes according to complexity and degree of risk to patients. Low-risk (Class I) devices (e.g., tongue depressors, non-powered wheelchairs, crutches, and bandages) must be registered with FDA but are not required to undergo premarket review. Moderate-risk (Class II) devices, like powered wheelchairs and many implantable devices, are cleared for market if companies assure FDA that they are similar to other devices already on the market. High-risk (Class III)

devices, including some implantable devices such as pacemakers and artificial heart valves, could pose serious risk to patients and thus require extensive testing, as described below. About one-third of medical devices require FDA premarket review because they pose more than low risk to patients.

Riskiest Devices: Premarket Approval Required

Context

Class III devices that FDA determines pose significant risk to patients must undergo scrutiny through the premarket approval (PMA) process.^{11,12} This process requires the manufacturer to receive FDA's approval for an Investigational Device Exemption (IDE) before the device can be used on patients.¹³ FDA typically requires that these "high-risk" devices demonstrate safety and effectiveness through a clinical trial,¹⁴ which can be expensive and take years to complete. In addition, FDA charges manufacturers a user fee to review a premarket approval application. These user fees are based on a sliding scale depending on the size of the applicant. In fiscal year 2017, large device companies are required to pay \$234,495 for a PMA application. User fees are waived for the first PMA application of small device companies, while they must pay \$58,624 for subsequent applications.¹⁵ The user fees allow FDA to hire additional staff, which helps speed its review of these applications.

While it is possible to complete the premarket approval process without a face-to-face meeting, FDA encourages applicants to meet directly with FDA staff to plan and review study protocols and results.¹⁶ During preapproval meetings, FDA often makes recommendations to improve the quality of proposed clinical research and strengthen the reliability of study results. If, as a result of these meetings, FDA endorses a company's proposed clinical trial protocol, the company receives protection from objections. FDA may later raise concerns regarding study design, clinical outcomes, and analytic issues, provided the company conducts the trial as planned. However, manufacturers are not required to meet with FDA or follow FDA's recommendations regarding proposed trial protocols.

Issues

Although clinical trials represent the most rigorous approach to premarket approval, they are often not of sufficient size to find rare complications or detect

long-term problems that may arise with an implantable device. In addition, device studies often lack a control group, which makes it difficult to determine whether the device has caused an adverse event. In some cases, studies have found that trials are prone to bias that can produce artificially favorable results, such as in the case of some cardiovascular devices.¹⁷

Some patient advocates and researchers have criticized FDA as being too quick to approve devices and not tough enough on industry.¹⁸ Researchers studying FDA recalls have also suggested that by accelerating the review process, FDA may put speed before safety by approving inadequately tested devices that pose serious risks to patients.¹⁹

Option: Require FDA approval of clinical trial protocols.

The premarket approval process could be strengthened by authorizing FDA to require a face-to-face meeting with an applicant to discuss and clarify proposed study protocols for testing devices and giving FDA the option of issuing recommendations for improving study protocols.

Accelerating the Premarket Approval Process

Context

Currently, FDA can expedite the premarket approval process for certain innovative devices by designating them for “Priority Review.” Upon a manufacturer’s request, FDA has discretion to apply the Priority Review criteria to devices that are subject to the premarket approval process or the 510(k) clearance process described below. Eligible devices must be intended to diagnose or treat a life-threatening or irreversible debilitating disease or condition and meet certain other criteria.²⁰ FDA charges manufacturers a fee to cover the added cost of the Priority Review process.

FDA also has authority to grant an exemption from the premarket approval process for humanitarian reasons to encourage the development and use of medical devices (1) that are intended to diagnose or treat rare diseases that afflict fewer than 8,000 patients per year, (2) for which no other comparable device is available to meet the specific clinical need, and (3) which could not otherwise be brought to market.²¹ About 50 products have been granted a humanitarian device exemption since 1997.

Issues

Some have criticized FDA for both over-regulation and under-regulation of implantable devices. The device industry has argued that the premarket approval process is too expensive and takes too long, which could delay access to devices that save and improve patient lives. Companies and investors also have complained that “regulatory uncertainty” regarding if and when FDA will approve a device discourages investment in innovative medical devices.²² In some cases, critics point to devices that European and other foreign markets have approved for use long before FDA takes action.

Other experts have cautioned that FDA should not place too much emphasis on innovation. In 2015, then FDA Commissioner Margaret Hamburg said, “Just because something is new doesn’t mean that its better ... doesn’t mean that it will make a meaningful enduring difference in the lives of individuals.”²³

Critics have complained that the humanitarian device exemption has created a loophole through which ineffective devices can remain on the market. Devices that receive the humanitarian device exemption are not required to collect postmarket surveillance data. Since there is no requirement that these devices demonstrate effectiveness, many of them remain on the market for long periods of time.

Option: Broaden Priority Review pathway.

In an effort to balance its competing missions of promoting patient safety as well as innovation,²⁴ policy makers could consider broadening the range of Class III implantable devices that could be eligible for Priority Review by relaxing the requirement that eligible devices be intended only for life-threatening or irreversible conditions. The availability of such an expedited process might encourage manufacturers to submit more implantable devices for approval through this less-time-consuming pathway while still protecting patient safety. The cost of expanding the Priority Review process could be covered by an additional fee paid by the manufacturer.

Option: Target incentives for innovation.

To encourage innovative research in designated areas that could spur the development of innovative implantable devices, policy makers could also consider other incentives, such as expanding the number of exemptions for humanitarian

use devices. However, devices that receive a humanitarian use exemption should be subject to collection of postmarket surveillance data to allow FDA to quickly identify safety concerns, and the exemption should be time limited to encourage the manufacturer to complete the premarket approval process by demonstrating that the device is effective.

The Premarket Clearance (510(k)) Process

Context

FDA allows many implantable devices that it deems low to moderate risk to be sold without requiring clinical data. Over 95 percent of implantable devices that require FDA review are intermediate risk and subject to premarket “clearance” through the 510(k) process, a designation that refers to the relevant section of FDA regulations.²⁵ Under this process, new implantable devices that FDA deems “substantially equivalent” to a previously marketed device, referred to as a “predicate” device, can receive clearance for marketing.²⁶ Substantial equivalence means that many new implantable devices reach the market by piggybacking on one or more legally marketed predicate devices.

In December 2016, Congress enacted legislation that will accelerate the approval process for new medical devices.²⁷ However, this legislation did not substantially alter the 510(k) process.

According to an expert panel convened by the Institute of Medicine (IOM), the 510(k) process is fundamentally flawed.²⁸ Until Congress takes further action to reform the 510(k) process, a variety of incremental approaches could be considered to strengthen the premarket process for some implantable devices while improving their safety and effectiveness. For example, IOM acknowledged that FDA is authorized to use an alternative to the 510(k) process to streamline review of devices for which no clear predicate device exists. This *de novo* process can include special controls that allow FDA to require manufacturers to submit clinical data and conduct postmarket studies as a condition for clearance.^{29,30} This clearance process can provide evidence of safety and effectiveness, which, in many cases, the 510(k) process does not, without the higher cost and time required under the full premarket approval process.

Issues

While patients might expect that most, if not all, implantable devices would require clinical testing, the 510(k) process does not require a device to demonstrate safety or effectiveness. The dearth of clinical trial data for these implantable devices raises obvious patient safety concerns. Estimates of the frequency of serious injuries and deaths associated with implantable devices vary. While adverse event reports are relatively rare,³¹ the seriousness of complications and the potential to avoid more injuries through appropriate safety measures suggest that further steps may be both necessary and appropriate to ensure the safety and effectiveness of implantable devices.

Option: Replace the 510(k) process with the *de novo* process.

To ensure adequate oversight, wider use of the *de novo* approach could be used in conjunction with FDA’s other oversight tools, such as working with companies to ensure proper testing during the premarket review process and clearance with special controls, such as performance standards, labeling requirements, patient registries, and postmarket surveillance, as discussed below.³²

The 510(k) Process and “Grandfathered” Devices

Context

Devices that were marketed prior to 1976 were “grandfathered” under that year’s landmark Medical Device Amendments legislation.³³ Eventually, FDA is required to review the status of riskier grandfathered devices, but this process has been slow. For instance, only in 2011 did FDA start to review the status of a device used for electroconvulsive therapy, or “electroshock,” that has been in use since the 1940s. Some grandfathered devices that FDA has deemed too dangerous for approval have been taken off the market. For instance, oral glass thermometers were banned because they contained poisonous elemental mercury in a thin glass tube that could easily break when held in the mouth or dropped.

Some potentially high-risk devices continue to serve as predicate devices in the 510(k) process because they were being sold prior to 1976 and FDA has not reclassified them. FDA is in the process

of reclassifying the last of these grandfathered devices and expects to complete the process soon.³⁴ In the meantime, manufacturers continue to cite these grandfathered devices as predicates for newer devices that can then go through the less-stringent 510(k) process.

Issues

Implantable devices that were previously cleared for market based on these outdated predicate devices will remain on the market unless FDA reclassifies them. In a 2013 report, the US Department of Health and Human Services' Office of the Inspector General cited concerns about the use of grandfathered high-risk devices as predicates.³⁵

Option: Require testing of devices based on grandfathered devices.

FDA could review the status of implantable devices that have been cleared for market based on grandfathered Class III predicate devices.

Predicate Devices with No Time Limits

Context

Under the 510(k) process, FDA does not impose any limitation on the age of devices that may serve as predicate devices. As a result, FDA often clears new devices for marketing based on much older devices. Some predicate devices were on the market prior to 1976 and thus may have been developed and marketed without testing over four decades ago.

Issues

Due to evolution of technology, these older predicate devices may be outmoded or discontinued, or may not reflect current standards of care.³⁶ Thus, the same could apply to any newer versions of these predicate devices.

Option: Impose time limits on the age of predicate devices.

Congress could direct FDA to establish criteria, such as a time limit or other metric, for how long a device could serve as a predicate. (FDA could make exceptions if reevaluation reveals a device can appropriately be considered a predicate for newer devices.)

Recalled Devices Serve as Predicate Devices

Context

Any device that has been recalled and removed from the market by FDA or found by a court to have been adulterated or misbranded is not supposed to be used as a predicate for a new device.³⁷ However, a device's status as a valid predicate is nullified only if the recall is mandatory, which occurs in rare instances where the manufacturer fails to voluntarily withdraw a product that poses a health risk. The vast majority of recalls are carried out voluntarily by companies. A report by the Government Accountability Office found that from 2005 to 2009, firms voluntarily recalled an average of just over 700 medical devices per year.³⁸ FDA did not initiate any mandatory recalls during this time.

Issues

The use of voluntary recalls has created a loophole in the 510(k) clearance process.³⁹ Devices that were withdrawn from the market because of safety issues are allowed to continue serving as predicate devices for clearance of subsequent implantable devices. In fact, the Congressional Research Service has determined that FDA lacks the authority to deny clearance for a subsequent device that is substantially equivalent to an unsafe predicate device.⁴⁰ As a result, some new implantable devices have been cleared for market based on predicate devices that have been voluntarily recalled because they were unsafe or defective.^{41,42}

Option: Authorize FDA to nullify the use of recalled devices as predicates.

Congress could authorize FDA to deny market clearance for implantable devices that are substantially equivalent to a recalled predicate device.

Option: Conduct systematic reviews of predicate devices.

As part of strengthening the 510(k) clearance process and protecting patient safety, FDA could conduct a systematic review of the most commonly used predicate devices to ensure that they are consistent with current technology and standards of care.

Important Data Not Publicly Available

Context

By law,⁴³ manufacturers and FDA are required to make publicly available the evidence used to show that a device is substantially equivalent to one or more predicate devices.

Issues

However, this evidence is often not publicly available. A recent study found that much of the scientific evidence of substantial equivalence, safety, or effectiveness was not publicly available for a representative sample of implantable devices cleared from 2008 to 2012.⁴⁴

Option: Enforce public disclosure of evidence.

FDA could more effectively enforce current law requiring public disclosure of evidence serving as the basis for market clearance of 510(k) devices.

POSTMARKET MONITORING OF IMPLANTABLE DEVICES

After an implantable device is approved and sold, FDA is responsible for postmarket surveillance. Current postmarket surveillance methods are a patchwork of voluntary and passive reporting mechanisms. FDA requires manufacturers, importers, and health care providers, such as hospitals and nursing homes, to monitor and report suspected device malfunctions and adverse events such as medical complications, injuries, and deaths associated with the device.^{45,46} This requirement is referred to as Medical Device Reporting of adverse events.⁴⁷ In addition, FDA encourages voluntary reporting of adverse device events by health care professionals, patients, and consumers.⁴⁸

Each year, FDA receives several hundred thousand medical device reports and uses them to monitor device performance, detect potential device-related safety issues, and contribute to benefit–risk assessments of devices that are in use. From 1996 through 2009, the Medical Device Reporting database included over 182,000 reports for about 7,800 devices. Two-thirds of these reports were associated with device malfunction, almost one-third were associated with patient injury, and fewer than 2 percent were associated with patient death.⁴⁹

This passive surveillance system has significant limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, and biased data. FDA cannot determine the frequency of adverse events from this reporting system due to underreporting. The US Government Accountability Office has estimated that less than 1 in 200 actual device failures are reported.⁵⁰ Due to lack of detailed

identification and reporting requirements and incomplete information, FDA has difficulty tracing and notifying patients who have received devices associated with problems, particularly implantable devices.⁵¹ For instance, when silicone breast implants were leaking silicone and causing injury to women who had received them in the early 1990s, FDA and manufacturers had difficulty locating and notifying patients and their doctors because of inadequate identification and tracking information.⁵²

Postmarket Surveillance and Reporting

Context

To monitor the performance of an implantable device, FDA has authority to require the manufacturer to conduct two types of postmarket studies: (1) postapproval studies, ordered at the time of premarket device approval, and (2) postmarket surveillance studies.⁵³ FDA requires postapproval studies to obtain additional information that is not available before a device can be marketed, such as device performance over long-term use. Unlike postapproval studies, FDA may order postmarket surveillance studies at any time after a device goes to market, particularly if safety issues arise. However, these studies may last up to only three years for devices that will be implanted for more than one year and cannot be required as a condition for 510(k) clearance unless the device will be implanted in children.^{54,55}

Issues

Some devices will inevitably fail, although it may happen only rarely, according to experts.⁵⁶ They suggest that such device failures will occur regardless of the approval pathway and despite the best-designed clinical trials and diligent premarket review. Unfortunately, postmarket surveillance studies often do not generate sufficient data to determine whether a device is safe or effective. FDA must rely on manufacturers to pay for and conduct postmarket studies and report on their results. In most cases, manufacturers have performed postmarket surveillance studies with small sample sizes that do not allow researchers or FDA to detect rarely occurring adverse events, compare clinical outcomes for different models of implantable devices, or assess a device's performance in patient subgroups such as the elderly.⁵⁷ Some have suggested that postmarket studies have the potential to improve safety and effectiveness of

high-risk implantable devices without lengthening premarket approval time. This would be possible if manufacturers would initiate studies immediately upon approval and make results publicly available in a timely manner.⁵⁸ However, postmarket studies of the original implant may not provide useful information for patients who are considering revised implants.

Option: Require more postmarket approval studies.

In order to ensure that manufacturers collect postmarket data, FDA could require them to adopt postapproval study protocols before granting premarket approval of implantable devices. This would allow FDA to make greater use of postapproval studies.

Option: Require postmarket surveillance studies as a condition for 510(k) clearance.

Under current law, FDA lacks authority to require postmarket surveillance studies for implantable devices that are cleared for market through the 510(k) process unless the device is intended primarily for children. Congress could authorize FDA to require postmarket surveillance studies as a condition for 510(k) clearance for all implantable devices.

Option: Impose user fees to cover the cost of postmarket surveillance activities.

Currently, manufacturers pay user fees primarily in connection with premarket review processes. Congress could authorize FDA to collect user fees to cover the cost of its postmarket surveillance activities. These fees would allow FDA to enhance and strengthen its postmarket surveillance efforts.

Option: Enforce compliance.

Several tools, such as device tracking and postmarket surveillance studies, are available to FDA to improve postmarket surveillance, but FDA uses these tools only sparingly.⁵⁹ FDA could use its enforcement tools more often to ensure that manufacturers comply with postmarket study requirements. However, substantially increasing the level of FDA enforcement efforts may require additional appropriations.

Implantable Device Registries Rarely Used

Context

In the United States, professional medical societies have established patient data registries for a limited

number of devices. The Center for Medicare & Medicaid Services requires Medicare patients who receive a mechanical heart pump, one of the highest-risk implantable devices available, to participate in a device registry established by the American College of Cardiology. However, patient data registries have not been set up for many implantable devices.

Issues

Experts have criticized FDA for not making better use of patient registries to collect data on implantable devices.⁶⁰ They have suggested that FDA should use this type of data to monitor the postmarket safety of implantable devices. Also, manufacturers could use these data to improve the safety of implantable devices in the premarket development process.

For example, patient registry data from postapproval studies of a new type of implantable heart valve have been used to identify adverse events such as strokes due to clots caused by the artificial valve. A manufacturer has used this patient registry data to develop a “cerebral protector,” an implantable device that protects the brain from stroke-causing blood clots in patients who have received the new heart valve.^{61,62}

However, the data from patient registries are often not available to independent researchers or the public, which hampers broader use and dissemination of findings from registry data. The National Academy of Medicine, formerly known as the Institute of Medicine, has suggested that FDA evaluate regulatory systems in other countries to determine whether it could use components of those systems to improve oversight of implantable devices in the United States.⁶³ In some countries, like Australia, Canada, and some in Europe,⁶⁴ government-run implantable device registries are mandatory.

Option: Make better use of implantable device registries.

Patient data registries could provide FDA with information on the safety, effectiveness, and durability of implantable devices. With congressional authorization, an independent organization under FDA guidance could oversee mandatory registration of implantable devices. Alternatively, FDA could promote the creation of more device registries through an accreditation program that would require registries to meet rigorous standards. However, the device

industry has cautioned against the indiscriminate use of single-purpose device registries, pointing out that registries are expensive and time consuming to maintain and operate.⁶⁵ Thus, funding support for more device registries would be an important enabler.

Option: Improve communication with stakeholders.

Through the use of device registries, FDA could require better postmarket studies of implantable devices and improve its communication with manufacturers, clinicians, and patients about recalled implantable devices and strengthen postmarket oversight.⁶⁶

Other Postmarket Surveillance Approaches

Context

FDA's current postmarket surveillance systems are unable to fully integrate data from various sources, such as premarket studies, postapproval studies, clinical registries, adverse event reports, and published studies.⁶⁷ FDA has acknowledged the shortcomings of current systems and stated that the ability to combine data about device performance and clinical outcome data from diverse sources would enable it to enhance the efficiency of its postmarket surveillance efforts.⁶⁸

FDA is making efforts to upgrade its postmarket surveillance systems. For example, FDA's Sentinel Initiative is a national electronic system for using health insurance claims data to monitor postmarket safety of prescription drugs and vaccines. FDA is moving toward expanding its Sentinel Initiative to include implantable devices, which has the potential to greatly enhance its ability to track and analyze postmarket device data.

FDA has also launched an effort to link and synthesize data from multiple sources, including clinical registries, electronic health records, and health insurance claims. This initiative, designated the National Evaluation System for health Technology (NEST), will allow FDA to collaborate with private-sector partners, such as hospitals and manufacturers, to enhance postmarket surveillance and evaluation of implantable and other medical devices.⁶⁹ However, getting this initiative up and running may take years and cost hundreds of millions of dollars.⁷⁰

In addition, FDA began to require that high-risk devices carry a unique device identifier (UDI) starting in 2014.⁷¹ These identifiers will provide more

detailed information than was previously available and will allow improved identification and tracking of devices to improve safety and facilitate recall of defective implantable devices. However, FDA does not yet have access to systemically collected UDI data. As a result, FDA cannot routinely track implantable devices using these data.⁷² Eventually, FDA hopes to have access to UDI data from one or more sources, such as electronic medical records, health insurance claims, and device registries.

Issues

Experts have complained that FDA does not monitor device safety through continuous surveillance of multiple databases.⁷³ They suggest that FDA should be able to detect safety issues quickly through active and continuous surveillance of device registries. For instance, using automated prospective surveillance could trigger an alert for FDA much as a smoke detector works. FDA has acknowledged that it does not have a postmarket surveillance system that links diverse data systems, which could enable real-time tracking of the risks and benefits of devices, allowing patients, clinicians, and industry to improve device safety and health care decision making.⁷⁴

Option: Expand use of unique device identifiers.

FDA could use UDI data to enhance the effectiveness of implantable device registries by making specific data on devices more complete and accurate.⁷⁵ Health care providers and insurers could make UDI data available through health insurance claims, electronic medical records, and other clinical databases. This would require creating a new optional field on claim forms and electronic medical records in which a bar code scanner could record each device-specific UDI electronically.

Option: Expand postmarket surveillance approaches.

To better assess how implantable devices are actually performing, FDA needs greater access to postmarket data, including timely information about when implantable devices fail and the types of failures. To do this, FDA also needs systems that can better generate high-quality adverse event reports, increase reporting of adverse events, and regularly alert it about problematic devices.⁷⁶

Added Safety Oversight

Context

FDA inspects the facilities of manufacturers that produce FDA-regulated devices to ensure that manufacturers that make implantable devices follow consistent, high-quality standards.⁷⁷ FDA may conduct preapproval inspection of a manufacturer that has submitted an application for approval of a new implantable device.⁷⁸ FDA uses the information to evaluate the pending application and provide further information about the manufacturer's operating procedures. In addition, FDA inspects facilities where manufacturers conduct clinical trials and foreign manufacturing facilities for FDA-regulated devices that are sold in the United States. FDA also inspects imported devices when they reach the US border.

Issues

While FDA does conduct manufacturing inspections, it does not conduct premarket inspections for most implantable devices because it does not have authority to conduct premarket inspections for devices cleared through the 510(k) process.⁷⁹ FDA may conduct "for-cause" inspections to investigate problems and complaints that have come to its attention for implantable devices cleared through either the 510(k) or premarket approval process.⁸⁰ Following an inspection, FDA may issue an inspection report that describes violations and any further action that may be required.

As a result of these limitations, FDA may need to use its recall authority to remove implantable devices from the market for a variety of problems that might have been caught through inspection, such as design defects, poor quality in the manufacturing process, inadequate labeling, defective software, and poor instructions.

Option: Inspect more implantable device manufacturing facilities.

FDA could increase the frequency and intensity of its inspection of manufacturer facilities that produce implantable devices. Such measures would require a change in the law for premarket inspection of devices cleared through the 510(k) process, as well as additional congressional appropriations. Alternatively, Congress could authorize FDA to increase the user fees it charges device

manufacturers. If authorized by Congress, FDA could also redirect fines and penalties it collects to fund enhanced postmarket surveillance efforts.

FDA Has Broad Enforcement Authority

Context

FDA has a broad range of tools available to protect the public from unsafe or defective implantable devices and to sanction manufacturers that violate FDA rules. FDA can take both administrative and judicial actions to protect the public from dangerous and illegal products, to punish individuals and companies that violate the law, and to deter violations.

When FDA identifies a potentially serious safety concern with an implantable device through its postmarket surveillance activities, FDA has the authority to require the manufacturer to remove the device, or "recall" it, from the market. As part of its recall authority, FDA can also require manufacturers to notify device users, and to repair, replace, or refund payment for devices on the market.⁸¹ While a manufacturer or distributor may initiate a device recall, often FDA will recommend a recall to prevent serious injury or gross deception regarding a defective device.⁸² FDA hosts a website database that contains a list of implantable devices recalled since 2002.⁸³

Recalls are not unusual. On average, FDA recalls about 400 to 500 of about 3,000 devices (about 25 percent are implantable) that it clears annually through the 510(k) process.⁸⁴ About one-quarter of devices are recalled more than once.⁸⁵ One study found that, over five years (2005–09), among 113 medical device types (accounting for 112.6 million individual devices) that FDA had recalled for the most serious reasons (e.g., potentially serious health problems or death), 71 percent had been cleared through the 510(k) process.⁸⁶

Issues

Critics have suggested that, despite having broad enforcement authority, FDA has not used it effectively.⁸⁷ For instance, FDA's device reclassification procedures have been cumbersome, slow, and rarely invoked. FDA has used fines and withdrawn market approval only rarely. Based on 223 postmarket studies, FDA has withdrawn only

one device from the market.⁸⁸ FDA's authority to require payment refunds has never been used. At times, FDA has exercised its authority inconsistently. Some have argued that resource limitations are more important than theoretical regulatory authority and that FDA has lacked adequate resources to fully carry out its mission.⁸⁹

Some experts have suggested that FDA may need more explicit authority to conduct adequate postmarket surveillance and oversee safety studies.⁹⁰ Others have argued that FDA has no need for additional regulatory authority, saying it already has sufficient authority to mandate premarket review, postmarket studies, and registries for implantable devices.⁹¹ These experts have asserted that FDA can conduct inspections of manufacturing facilities and get clinical data, even for 510(k) devices, pointing out that FDA currently requires data in about 10 to 12 percent of cases.

Option: Beef up FDA enforcement activities.

FDA could apply its enforcement authority more vigorously and consistently to implantable devices to protect public health and safety.

Option: Improve targeting of recalls.

FDA could better integrate postmarket data collection and surveillance to improve the targeting of implantable device recalls. FDA could use UDI data to enhance postmarket surveillance and better target and accelerate the pace of recalls of implantable devices. UDIs could also help FDA identify exactly which model of an implantable device requires a recall.

Option: Improve communication about recalls.

FDA has emphasized, "The success of FDA's device recall efforts requires prompt notice to patients and health care professionals and efficient recall classification."⁹² FDA could improve its communication with manufacturers, clinicians, and patients about recalled implantable devices. For instance, FDA could establish a system to notify patients directly when their physician is unable to do so for some reason, such as retirement or death.

CONCLUSION: REGULATION THAT STRIKES THE RIGHT BALANCE

A variety of reform options are available to policy makers to strengthen and streamline FDA's

approval process and improve oversight and safety of implantable devices. As previously discussed, without endorsing or ranking them, these options include the following:

- Strengthen the premarket approval process for the riskiest implantable devices.
- Strengthen the market clearance process for devices of moderate risk through increased use of the *de novo* approach.
- Eliminate "grandfathered" market clearance for implantable devices and require testing of devices that were in use prior to 1976.
- Prohibit recalled devices from serving as predicate devices—that is, older devices that have been recalled should not serve as the basis for clearance of newer implantable devices.
- Impose limits on the time that a device can serve as a predicate device.
- Strengthen postmarket oversight and reporting for implantable devices through the use of more postmarket surveillance studies, innovative monitoring techniques, and additional funding for these activities.
- Make better use of implantable device patient registries.
- Expand use of unique device identifiers.
- Improve communication with stakeholders.
- Strengthen quality controls by giving FDA authority to conduct premarket inspection of all facilities that make implantable devices.
- Strengthen FDA enforcement activities through improved targeting of recalls and other actions.

Implantable devices can and do save lives. They improve the quality of life for millions of Americans. Sometimes, they fail. When this happens, people can sustain serious injury or death. Careful regulation and oversight are essential to ensure the safety and effectiveness of these devices both before and after they reach the market. Regulatory oversight needs to safeguard patients while still encouraging innovation that makes implants safer, more effective, and more affordable.

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