



INSTITUTE OF MEDICINE  
OF THE NATIONAL ACADEMIES

Medical Devices and the Public's Health:  
The FDA 510(k) Clearance Process at 35 Years

Written Statement of

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Committee on Health, Education, Labor, and Pensions  
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Mr. Chairman and Members of the Committee, I am David Challoner, vice president of health affairs, emeritus, at the University of Florida. I also served as chair of the Institute of Medicine's Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process. The Institute of Medicine, or IOM, is the health arm of the National Academy of Sciences, an independent, nonprofit organization that provides unbiased and authoritative advice to decision makers and the public.

Thank you for the opportunity to submit testimony for the record based on the IOM's report, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*

### Background

*The Federal Food, Drug, and Cosmetic Act* (FFDCA) requires a “reasonable assurance of safety and effectiveness” before a device can be marketed. The U.S. Food and Drug Administration (FDA) is responsible for enforcing this requirement. Devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the 510(k) process, named for Section 510(k) of the FFDCA.

The 510(k) process has become a major component of medical-device regulation in the United States. Thousands of devices are cleared via the 510(k) process each year—about one-third of devices entering the market. The remaining devices are exempt from any premarket review (67%) or enter the market by the premarket approval (PMA) pathway (1%) or by other means such as the humanitarian-device exemption (1%).

In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the

medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market.

### The Charge to the IOM Committee

The FDA asked the IOM to review the 510(k) process for medical devices and to answer two questions:

1. Does the current 510(k) process optimally protect patients and promote innovation in support of public health?
2. If not, what legislative, regulatory, or administrative changes are recommended to optimally achieve the goals of the 510(k) process?

### The IOM Committee's Conclusion on Safety and Effectiveness

On the basis of its review and evaluation of legislative, regulatory, and administrative components of the 510(k) process and other related components of medical-device regulation, the committee came to the conclusion that the 510(k) process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. Furthermore, the 510(k) process cannot be transformed into a premarket evaluation of safety and effectiveness as long as the standard for clearance is substantial equivalence to any previously cleared device.

## The IOM Committee's Recommendations

The committee believes that the FDA should obtain adequate information to inform the design of a new medical-device regulatory framework for Class II devices so that the current 510(k) process, in which the standard for clearance is substantial equivalence to previously cleared devices, can be replaced with an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle. Once adequate information is available to design an appropriate medical-device regulatory framework, Congress should enact legislation to do so. The committee believes that a move away from the 510(k) process should occur as soon as reasonably possible but recognizes that it will take time to obtain the information needed to design the new framework.

In its report, the committee outlines several actions that the FDA should take in the short term to improve regulatory oversight of medical devices. These actions also will serve to generate the necessary information to inform the design of the new framework for Class II devices.

The committee believes strongly that it is important that regulatory oversight of devices be conducted throughout their lifecycle. Premarket review, including the 510(k) process, and postmarket oversight—from product labeling regulations to the reporting of adverse events associated with use of a device—make up a comprehensive medical device regulatory system. All the components of the system need to be functioning well in order to provide a reasonable assurance of the safety and effectiveness of medical devices.

No premarket regulatory system for medical devices can guarantee that all new medical devices will be completely safe and effective when they reach the market. Robust postmarketing surveillance is essential. The FDA should give priority to postmarketing surveillance as an invaluable investment in short-term and long-term oversight of medical-device safety and assessment of device effectiveness. The committee identified substantial problems in the current postmarketing surveillance of devices, and recommends that the FDA develop and implement a comprehensive strategy to collect, analyze, and act on medical device aftermarket performance information. Congress should support the capacity of the FDA's postmarketing surveillance programs by providing stable and adequate funding.

The appropriate use of postmarket regulatory authorities, such as seizing or banning a device, is an essential component of a successful medical-device regulatory program. The FDA has stated that there are limitations to the use of these authorities but has not identified the limitations. The committee recommends that the agency review its postmarket regulatory authorities to identify these limitations and address them. If it is required, Congress should pass legislation to remove unnecessary barriers to the FDA's use of postmarket regulatory authorities.

It is the committee's assessment that the FDA lacks a continuous quality-assurance process for regulation of medical devices. As a result, the FDA cannot effectively address new issues as they arise. The committee recommends that the FDA develop and implement a program of continuous quality improvement to increase predictability, transparency, and consistency in all regulatory decisions for devices and to address emerging issues that affect decision making.

## Summary

The IOM committee believes that there should be an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of device safety and effectiveness throughout the device lifecycle. In its report, the committee outlines several actions that should be taken by the FDA that will ensure both short-term and long-term benefits. Among the actions recommended by the committee are that the agency strengthen its postmarketing surveillance program for devices, identify limitations in the use of its postmarket regulatory authorities and mitigate them, and develop and implement a program of continuous quality improvement.

Thank you, again. I would be happy to answer any questions the Committee might have.

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