

PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(k) CLEARANCE PROCESS

Balancing Patient Safety and Innovation

Workshop Report

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Committee on the Public Health Effectiveness of the
FDA 510(k) Clearance Process

Board on Population Health and Public Health Practice

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Once a bad decision is set in a 510(k) predicate history, innovation suffers. Additional factors contribute to the substantial-equivalence issue. For example, what are the distinctions between *intended use* and *indications for use*? How do we properly define *technology*? The substantial-equivalence argument rests on parsing such terms. Industry cannot predict how a reviewer will interpret the terms, because they are not consistently defined or applied. That gives rise to poor or delayed decisions of substantial equivalence, which in turn delay innovation. The 510(k) substantial-equivalence process also creates public-confidence issues. The press has wrongly characterized the substantial-equivalence process as a shortcut for industry or an abbreviated review for the agency.

The solution to the 510(k) substantial-equivalence problem, he said, is for FDA to adopt a truly risk-based classification system that is blind to whether a device is innovative or “me-too.” The European and GHTF systems are good examples of well-tested processes for rational risk classification. The IOM committee may need to call for legislation that allows repair of the broken 510(k) risk-classification process. By implementing a modern risk-classification process that has flexibility for continuous improvement, we will increase the agency resources available to review the safety and effectiveness of devices, improve the predictability of the review process, improve public confidence in our work, and begin to restore the environment that fosters innovation for better public health.

Patient-Advocacy Perspectives

The committee heard testimony from representatives of Truth in Medicine Incorporated, a patient-advocacy organization that focuses on educating the public about the potential risks posed by and complications of the implantation of synthetic surgical mesh into the human body. Mesh is used in hernia repair, bladder suspension, and treatment of pelvic-floor disorders. Statements were given by the organization’s president and founder, the executive director, and several individual members, all of whom shared their personal experiences with the device. Those participants attended to represent the thousands of others who have had similar adverse experiences with medical mesh products. The organization noted among its accomplishments its successful urging of FDA to issue a public-health notification warning of the serious risk poses by and complications of the transvaginal placement of synthetic surgical mesh. The warning was issued to health-care practitioners in October 2008.

Participants shared their clinical experiences of chronic pain and discomfort, infection, chronic inflammation, incontinence and urinary retention, disability, multiple surgical attempts to remove mesh and address complications, and other illness, which had brought some of them close

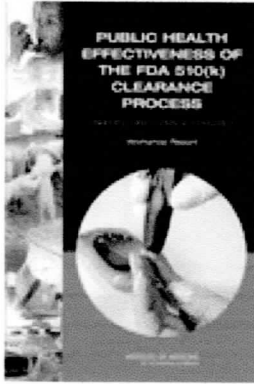
to death. Some described having endured over 20 operations in less than 10 years in attempts to remove mesh that had migrated or eroded. Others described the challenge of finding a doctor willing to perform further complicated and risky operations to continue to remove bits of mesh. They candidly described the toll that those health outcomes had taken on their lives, such as the inability to work, loss of employment or personal business, loss of health-insurance coverage, financial ruin, homelessness, and stress on personal relationships, including effects on intimacy with spouses and partners. It was pointed out that additional people had registered to provide comment at the workshop but were unable to attend because of health issues.

Participants explained how mesh systems were cleared by FDA for marketing through the 510(k) process. They expressed concerns that the 510(k) process allows unproven medical devices onto the market, inasmuch as clearance does not require proof of safety or efficacy of class I or class II devices. As a result, they said, an uninformed, unaware public is endangered daily by unsafe and unproven medical devices.

The organization specifically recommended that the committee consider the following changes in the 510(k) clearance process:

- Educate the American public about the difference between premarket approval and premarket notification.
- Make adverse-event reporting mandatory, with clear consequences for silence by doctors, hospitals, and medical device makers.
- Create a specific guide for FDA and CDRH to make better use of their regulatory authority. The decision-making process for when and how to use FDA's regulatory authority should not be left to the discretion of agency employees.
- Include a mechanism which stops medical device makers from paying doctors to use products off-label to increase the sales of their products.

Participants called for expansion of informed consent, making it mandatory, for example, for a medical implant device package insert to be reviewed by the doctor with the patient 3–7 days before surgery (not on the day of surgery or when the package is opened in the operating room). It was also stressed that stakeholder involvement should be a critical component of the 510(k) process. One suggestion was for FDA to meet regularly with patients who have been adversely affected by the process. Participants also said that the 510(k) process should be more transparent.



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