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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments of the Patient, Consumer, and Public Health Coalition on “Strengthening the Center for Devices and Radiological Health’s 510(k) Review Process”

[Docket No. FDA-2010-N-0054]

The Patient, Consumer, and Public Health Coalition includes nonprofit organizations that represent patients, consumers, scientists, and researchers. We urge the FDA to improve the
standards of the premarket notification process (also know as the 510(k) process) for the review of medical devices. By strengthening the 510(k) clearance process, CDRH will help to ensure that medical devices are both safe and effective.

Many people in the medical device industry claim that stricter standards for clearing or approving medical devices will stifle innovation. Although we appreciate innovation, it should be a means to improving the product by making it safer, more effective, or maintaining safety and effectiveness while making the product more convenient or less expensive. Patients can be harmed if innovation results in products that are less safe and less effective than older products that are already available and often less expensive.

The law states that the standard to clear or approve medical devices is reasonable assurance of safety and effectiveness, which is less stringent than the standard for prescription drugs, which must be proven safe and effective. However, “reasonable assurance” is not met for medical devices when clinical trials are not required for medium and high risk medical devices.

In fiscal year 2006, CDRH received reports of 116,086 device-related injuries and 2,830 device-related deaths, and it received more than 200,000 adverse event reports concerning medical devices. According to a soon-to-be released report by the National Research Center for Women & Families, most Class I recalls were for devices cleared by the 510(k) process instead of the more rigorous PMA process. Class I recalls are FDA’s most serious recalls, defined as “dangerous or defective products that predictably could cause serious health problems or death.”

The 510(k) review process was established in 1976 and has been expanded since then. It was never intended for devices that are life-sustaining of life-saving, because the failure of such devices causes great harm. However, according to a 2009 General Accountability Office (GAO) report, heart valves and other high risk devices are sometimes cleared through the 510(k) process. To address these critical issues, the following areas need FDA’s immediate attention:

**Lack of Scientific Evidence and Data**

Clinical trials are rarely required for the 510(k) process, and usually no clinical data of any kind are provided to show safety or effectiveness. Instead the data provided are biomaterials data or other bench data. According to the GAO, only “10 to 15 percent of premarket notification applications (510(k)s) include clinical data.” Even when clinical data are provided, they are often observational data for very small numbers of patients, rather than clinical trials that provide objective information about safety and effectiveness. In contrast, the FDA requires long-term studies in hundreds or even thousands of patients before it determines that a drug is safe and effective. In addition, FDA needs the authority to require that companies submit requested data. For example, the FDA has stated that the surgical mesh company ReGen “refused to submit all its data [on Menaflex®], arguing that they were not relevant to the 510(k) review standard. Because of limited authority to require the submission of all data about a device in a 510(k), the [FDA] Review Division eventually acquiesced.”

**Post-market Surveillance**
Post-market studies have not been a condition for clearance through the 510(K) process. FDA officials explain that “unlike PMAs, there is no explicit authority for FDA to require a ‘condition of approval’ study for clearance of a 510(k) device” — devices are either cleared or not. The FDA should use the authority it has to require conditions of clearance, even if that authority is not explicit. If that is not possible, then changes in regulations or statutes should be enacted to make that authority explicit. Currently, lack of long term studies and post-market studies on devices put patients at risk because many devices are intended for long-term use, such as heart valves and defibrillators.

**Lack of FDA Authority to Rescind 510(k) Clearance**

The FDA does not have clear authority to rescind clearance once a 510(k) device is cleared. According to FDA’s Director of the Office of Device Evaluation, “it is difficult to fix/modify or remove a cleared 510(k).” Rescission authority is needed since these devices are often cleared with little hard, scientific data.

**Manufacturing Plants Not Inspected**

Although the FDA states that the “majority of recalls are due to manufacturing and design control problems,” the FDA does not inspect the manufacturing plants of 510(k) products prior to clearance, and so the agency misses an opportunity to spot contamination, manufacturing flaws, and changes in device design or materials. In addition, key manufacturing information, such as engineering specifications about the device design and assurances of on-going quality, may not be included in the 510(k) review process. “In contrast, the agency does inspect manufacturing establishments as part of its review of original PMA submission,” according to the GAO.

**Predicate Devices**

The 510(k) process is based on the assumption that a medical device that is “substantially equivalent” to one already on the market does not need clinical trials to determine its safety or efficacy. What does “substantially equivalent” mean? The definition has become very loose, with many devices being cleared through the 510(k) process that are made of different materials or are in other ways substantially different from anything already on the market. The standard is very subjective, causing confusion. For example, the FDA has admitted: “Our review identified multiple sources of disagreement and confusion about 510(k) standards and practices, including the standards in the FDC Act and FDA’s regulations.”

**Third Party Review**

The FDA has publicly expressed concerns about the poor quality of third party review as part of the 510(k) process. For example, they state that “most 3rd-party-eligible devices do not have a device-specific guidance [and] accredited parties do not have access to previous decision/reviews of the device type.” Because 3rd party reviewers lack certain information needed to conduct a thorough review and because of the potential for conflicts of interest (since device companies are likely to hire reviewers who tend to approve their applications), third party review weakens the
already weak safeguards in place for 510(k) review. A review process that depends on the subject of the reviews hiring the reviewers is by definition flawed and subject to unacceptable conflicts of interest.

High Volume of 510(k) Submissions

The 510(k) process is popular among device companies because it is much faster and less expensive than the PMA approval process; the PMA process is more similar to the process required for prescription drugs. FDA’s Center for Devices and Radiologic Health (CDHR) is responsible for monitoring nearly 100,000 medical products. According to the GAO, the FDA’s ability to understand risks “related to the use of medical devices is limited by the fact that the volume of submitted reports exceeded FDA’s ability to consistently enter or review the reports in a routine manner.” In 2008, FDA officials told the GAO that they still cannot review all the reports they receive.

The above problems show fundamental weaknesses in the 510(k) process. It is therefore essential to improve the standards so that medical devices that are life-saving or life-sustaining are never cleared through the 510(k) process. In recent years, for example, heart valves and other cardiac devices have been frequently cleared through the 510(k) process and later recalled after patients died or were seriously harmed. If devices can cause serious harm when they fail—such as implanted devices or diagnostic tools used to diagnose cancer and other life-threatening diseases—then they should not be cleared through the 510(k) process.

At the recent FDA meeting on the 510(k) process, industry representatives urged the FDA to keep the 510(k) process because it encourages innovation. They suggested improving the process by reducing the average review time to 90 days, as it had been previously. Because of other commitments on pressing health policy issues, many public health experts and consumer advocates could not attend the meeting to express their concerns that medical devices must be conclusively proven safe and effective before they can be marketed.

The 510(k) process may be acceptable for low risk medical devices, but not for medium and high risk devices. As a result of the use of the 510(k) process for those higher risk devices, millions of people are relying on medical devices that are not as safe or effective as other available products. This costs patients and the healthcare system billions of dollars each year because hospitals, doctors, and patients buy devices that do not work, or they spend billions attempting to correct health problems that were caused by ineffective or unsafe devices and their iatrogenic effects, including revision surgical procedures, pain, development of medical problems related to the device particulation or inflammatory processes, diminished quality of life, and jobs lost due to medical problems or disability. Allowing this process to remain as it is also seriously weakens the American public’s trust in the scientific integrity of the FDA.

Our recommendations are as follows:

1. The 510(k) process should not be used for implants or potentially life-saving or life-sustaining devices that can harm patients if they are inaccurate or fail, including diagnostic devices;
2. The FDA should require well-designed clinical trials for medical devices when such trials are the most accurate way to determine safety and effectiveness;
3. The FDA should require inspections for device manufacturers aimed at ensuring safety and minimizing risk from contamination or manufacturing defects;
4. The FDA should require longitudinal post-market studies when needed to ensure safety of a 510(k) device;
5. The FDA should adopt clear, fact-based, scientifically defensible standards for determining whether a medical device is eligible for the 510(k) process.
6. For any device that is potentially life-sustaining or life-saving, or where there is concern about patient safety, the FDA should require post-market studies as a condition of PMA approval.
7. Third party review should not be used for medical devices.

Sincerely,

American Medical Women’s Association (AMWA)
Breast Cancer Action
Breast Cancer Fund
Center for Medical Consumers
Community Access National Network (CANN)
Consumer Federation of America
Consumers Union
Government Accountability Project (GAP)
National Consumers League
National Physicians Alliance
National Research Center for Women & Families/Cancer Prevention and Treatment Fund
National Women’s Health Network
Our Bodies Ourselves
Reproductive Health Technologies Project
THE TMJ Association
Truth in Medicine
Union of Concerned Scientists
U.S. Public Interest Research Group (U.S. PIRG)
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References


