FDA should invest in developing a new medical device clearance process

July 29 2011

The U.S. Food and Drug Administration should gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices, says a new report from the Institute of Medicine. The 510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk Class II devices and cannot be transformed into one, concluded the committee that wrote the report.

FDA's finite resources would be better invested in developing a new framework that uses both premarket clearance and improved postmarket surveillance of device performance to provide reasonable assurance of the safety and effectiveness of Class II devices throughout the duration of their use, the committee said. The agency should also ensure that the new process allows devices to reach the market in as rapid and least burdensome a fashion as possible.

As directed by congressional legislation, the 510(k) clearance process provides a more expedient way to evaluate moderate-risk Class II devices than the premarket approval (PMA) that high-risk Class III devices must undergo. Unlike the PMA process, which requires manufacturers to submit results of safety and efficacy tests, the 510(k) clearance generally relies on "substantial equivalence" -- determining if new devices are sufficiently similar to comparable products that have been previously cleared or were on the market prior to 1975 when the 510(k) process was first put in place by legislative action.

However, reliance on substantial equivalence cannot assure that devices reaching the market are safe and effective, the committee concluded. The majority of the devices used as the basis for comparison were never reviewed for safety or effectiveness. This does not mean that they or the devices that followed them are unsafe, and the continual use of many of these products in clinical practice provides a level of confidence in their safety and effectiveness, the committee said. But 510(k) clearance does not determine a device to be safe or effective, the report adds.

"It's not clear that the 510(k) process is serving the needs of either industry or patients, and simply modifying it again will not help," said committee chair David Challoner, emeritus vice president for health affairs, University of Florida, Gainesville. "The 510(k) process cannot achieve its stated goals -- to promote innovation and make safe, effective devices available to patients in a timely manner -- because they are fundamentally at odds with the statutes that govern how FDA must implement the process. While current information is not adequate to immediately start designing a new framework, we believe the agency can get the necessary data and establish a new process within a reasonable time frame."

While the committee was neither charged with nor able to detail what a new framework should entail, the report discusses key attributes of an improved process, including that it be clear, fair, and predictable, and make use of regulatory tools and authority to ensure safety and effectiveness throughout the duration of a product's use. FDA should explore whether a modified version of its de novo process could replace the 510(k) process, the report says. The de novo process reduces the amount of information manufacturers must supply for devices deemed to be of low or moderate risk but that have no predicate devices against which to be compared. Changes would be necessary to fix problems that make the de novo process time-consuming and difficult to navigate before FDA initiates a pilot program.

No premarket regulatory system can guarantee that all medical devices will be completely safe and effective when they reach the market, the committee noted. Because of the differences between devices and drugs, it would be impractical for all devices to undergo the same sort of premarket testing that drugs must go through, and even that more rigorous process cannot ensure that every safety problem is caught. Given that both patients and the industry desire a streamlined process to get new devices to market in a timely fashion, it is essential to have robust postmarket surveillance of these products, the report says.

However, the committee found substantial weaknesses in current postmarket oversight of devices and it heard from FDA that the agency faces limitations on its authority to address problems with products on the market. FDA should analyze what barriers hamper the efficient and effective use of its regulatory tools and identify ways to overcome them, the report says. If necessary, Congress should pass legislation to remove barriers to FDA's use of postmarket regulatory authority. The agency also should develop and implement a comprehensive strategy to collect, analyze, and act on information about devices' performance after clearance.

FDA should promptly complete its task of determining how to handle 26 device types classified as "high risk" that are allowed to reach market through the 510(k) process. FDA can either reclassify these types into a lower risk category if warranted or require them to go through the PMA process. Devices considered substantially equivalent to products in these 26 categories continue to be cleared for the market through the 510(k) process.

Provided by National Academy of Sciences