Bill Introduced to Amend Post-Market Review of Medical Devices

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Three U.S. Senators recently introduced legislation that would alter the U.S. Food and Drug Administration's post-market surveillance of medical devices.

Sens. Chuck Grassley, R-Iowa, Richard Blumenthal, D-Conn., and Herb Kohl, D-Wis. introduced the The Medical Device Patient Safety Act, S. 1995. Currently, the FDA can approve new moderate-risk medical devices through the 510(k) process if the product is found to be as safe and effective as a substantially similar medical device already on the market. Though the agency can request clinical study data on proposed new devices under the 501(k) process, it is still viewed as a fast-track approval process, compared to the premarket approval process for new products in the high-risk device category.

The bill would give the FDA the authority require companies to submit post-market data as a condition for gaining approval for moderate-risk medical devices under the fast-track process. The FDA could also order companies to conduct additional safety studies of devices after they are approved, and could grant conditional approvals pending the result of any ongoing trials. The proposed legislation would also require the FDA to assess recalls to determine whether they were implemented effectively.

The legislation follows concern from a GAO study of the FDA's post-market surveillance of medical devices, and after a controversial Institute of Medicine report last July suggesting the FDA amend its current clearance system for medical devices. FDA had commissioned the IOM to conduct an analysis of the § 510(k) system in 2009. The IOM Committee was composed of twelve members: five doctors, three lawyers, and four academics. Specifically missing were innovators or any product developers familiar with the clearance process, and any representatives of patients or patient advocacy groups that have benefited from the development of medical devices under the current system.

As noted by the Advanced Medical Technology Association, however, expanding the FDA's authority to require post-market studies as a condition of 510(k) clearance is unnecessary given that the agency already has broad authority to require manufacturers to conduct post-market studies for higher-risk devices cleared via 510(k). The bill does not appear to limit when FDA may conditionally clear a device, thus leaving open the possibility that conditions of approval will simply become a regular part of 510(k) clearances.

As to recalls, what may be "effective" for one type of device may not be as effective for another. It is important for the America public to realize that the medical technology industry has a well-documented safety record. Several recent studies have shown that for the vast majority of products cleared by the FDA, less than 0.5 percent are involved in a serious recall, a point GAO has emphasized as well. In addition, nothing in the GAO's recommendations suggested a lack of diligence or inadequacy in medical technology companies' implementation of recalls.