IOM Releases Controversial 510K Device Report

July 29, 2011 by Sean Wajert

Earlier this week, an Institute of Medicine's Committee released its report on the Public Health Effectiveness of the FDA 510(k) Clearance Process. The report offers a variety of recommendations and suggested reforms for FDA's 510(k) premarket notification pathway, describing the device clearance process as badly flawed.

Readers of *MassTortDefense* know how the regulatory clearance process has impacted preemption of state law product liability claims, and the significant medical device litigation we have covered here.

The recommendations will likely spark a heated debate within the larger struggles over the need for future medical device regulations. But even before that step, a variety of observers, including the Washington Legal Foundation, have asserted that the FDA is statutorily barred from adopting any of the report's recommendations. The charge has been made that the Institute of Medicine failed to adequately balance the panel, in violation of §15 of the Federal Advisory Committee Act. Section 15(a) provides that an agency may not use any advice or recommendation developed by the committee unless it has complied with a requirement that the committee membership be "fairly balanced." Using advice from a committee that lacks fair balance would encroach upon the Congressional mandate that each Advisory Committee should be representative of a broad
range of viewpoints.

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.