Lawmakers Concerned About Medical Device Safety

WASHINGTON, D.C. – Representatives Edward J. Markey (D-Mass.), Diana DeGette (D-Colo.), Henry A. Waxman (D-Calif.), Jan Schakowsky (D-Ill.), and Rosa DeLauro (D-Conn.) today sent a letter to the Commissioner of the Food and Drug Administration (FDA) raising concerns about flaws in the agencys 510(k) process for clearing medical devices for the market. Congress is expected to debate the Medical Device User Fee Act, a law that addresses FDAs responsibilities for the approval and clearance of medical devices set to expire in 2012.

Under the 510(k) provision, a manufacturer of a device does not need to provide clinical trial data to FDA, if they can prove that the device is "substantially equivalent" to another device already on the market. However, over the existence of this program, there have been several instances in which a device has been recalled due to serious safety concerns, calling into question all of the devices that were cleared for market based only on being equivalent to the recalled device.

The letter points to the recent example of a surgical mesh implant that Johnson & Johnson had to recall after the material used to make the device caused serious injuries in hundreds of women. FDA had cleared the mesh product because the company had shown that it was similar to a previously approved surgical mesh produced by Boston Scientific Corporation, despite the fact that this original mesh had already been recalled for serious safety concerns more than a decade earlier. "This example is one of several that elucidate a fundamental flaw in the 510(k) device clearance process," the lawmakers write to FDAs Commissioner Margaret Hamburg.

The letter to the FDA can be found HERE [1].

Rep. Markey is Ranking Member of the Natural Resources Committee. Rep. Waxman is Ranking Member of the Energy and Commerce Committee. Rep. DeGette is Ranking Member of the Subcommittee on Oversight and Investigations. Rep. DeLauro is Ranking Member of the Subcommittee on Labor, Health and Human Services, and Education. Rep. Schakowsky is a member of the Energy and Commerce Committee.

Posted by Sean Fenske, Editor-in-Chief, MDT

Links:
[1] http://markey.house.gov/docs/12-16-2011_510k_letter_to_fda.pdf