Markey Calls for Stronger Medical Device Protections in FDA User Fee Act Legislative Package

WASHINGTON, D.C. - Congressman Edward J. Markey (D-Mass.), a senior member of the Energy and Commerce Committee, which has jurisdiction over the Food and Drug Administration (FDA), issued the following statement after the Subcommittee on Health hearing on the discussion draft of the legislative package to update the FDA User Fee Act (UFA). Several provisions from Rep. Markey-authored legislation are included in the current package, including the bipartisan Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) [1]. However, the current discussion draft does not include any provisions to address the faulty FDA approval process that enables defective medical devices to be implanted in patients, causing serious injury and death. In February, Rep. Markey, along with Reps. Henry A. Waxman (D-Calif.), Jan Schakowsky (D-Ill.), and Rosa DeLauro (D-Conn.) introduced H.R. 4156 [2], the Safety Of Untested and New Devices (SOUND Devices) Act to close a major loophole in the device approval process known as the 510(k) by allowing FDA to reject a device if it is based on an earlier product that had to be pulled from the market for causing serious harm to patients.
"While the current version of the discussion draft contains several provisions that I have authored, I am disappointed that it is missing an opportunity to vastly improve the safety of medical devices and protect patients from serious harm. The FDA has made clear that it does not have the legal authority to reject a new medical device outright as long the device proves it is similar to the earlier model, even if the earlier product was recalled for harming patients. I look forward to working with my colleagues to include language in this legislative package to ensure that the FDA has the ability to act on information that a new device could be seriously harmful to patients without having to wait until the device is implanted in patients and people have suffered irreparable harm."

The reauthorization of BPCA and PREA makes significant improvements to the laws to increase the number of studied medications available for children that would help reduce incidences of wrong dosage or age and size-appropriate treatment.

"I am pleased to see that the discussion draft includes much of what was negotiated on a bipartisan basis for the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. I am proud to work with my colleagues Reps. Mike Rogers and Anna Eshoo on these important bills that expand the number of drugs and therapies available for children. Because of these laws, in the past five years alone at least 130 medications have been studied for use in children, providing doctors and patients with vital information about the appropriate use, dosage, and side effects of pediatric drugs."

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Links:
[1] http://markey.house.gov/press-release/markey-eshoo-rogers-introduce-legislation-improve-pediatric-medications
[2] http://markey.house.gov/press-release/markey-waxman-schakowsky-delauro-introduce-legislation-close-loophole-flawed-medical