FOR IMMEDIATE RELEASE
July 29, 2011

CONTACT: Kaelan Richards
(202) 225-3661

DELAURO TO FDA: 510(k) MEDICAL DEVICE APPROVAL PROCESS UNSAFE, MUST BE REFORMED

Washington, DC – Congresswoman Rosa L. DeLauro (CT-3) Ranking Member on the Labor, Health, and Human Services Appropriations Subcommittee, called upon FDA Commissioner Margaret Hamburg to review the Institute of Medicine's findings on the 510(k) medical device approval process and to consider integrating them into the agency's evaluation of the process.

Congresswoman DeLauro states that the findings released today clearly show that the 510(k) process, which grants approval to a range of low, medium, and high risk medical devices is deeply flawed and must be reformed. As the IOM noted, "the 510(k) process generally is not intended to evaluate the safety and effectiveness of medical devices." The Congresswoman also calls for the agency to better ensure a comprehensive review of all medical devices, including both pre-market and post-market surveillance.
The text of the letter is below.

July 29, 2011

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

I write to underscore my continued concern about the Food and Drug Administration's (FDA) medical device approval and post-market surveillance and the agency's response to a new review of that process.

The number of Americans that are affected by the safety and effectiveness of medical devices, specifically those that are life-sustaining or intended to be permanent implants, continues to increase. More than three-quarters of a million Americans have a hip or knee replaced each year. And more than half of the top five elective inpatient procedures reimbursed by Medicare in FY2006 included the insertion or repair of a medical device – a list that included *both* a hip or knee replacement and the repair of a previous hip or knee replacement.

Earlier today, the Institute of Medicine (IOM) released its findings on the 510(k) clearance process. The FDA requested this IOM review in 2009, and yet – on the very day the requested report has been released— FDA officials appear to have already reached a conclusion about the value and implementation of the report and its recommendations.

I am astonished that the agency tasked with protecting the public health may have already determined that the IOM recommendations cannot be implemented. The committee's recommendations warrant meaningful consideration by the agency and advocates for both consumers and industry. They are clearly intended to better protect the public health by ensuring that the medical devices available are safe, effective, and appropriately monitored after approval.

A series of Government Accountability Office (GAO) studies and findings over the years clearly illustrate that the 510(k) process does not optimally protect the public health and needs to be reformed. Just this year, the FDA announced a series of changes and proposed changes to the 510(k) process based on identified shortfalls of the current inadequate process. Yet, as the IOM review clearly reinforces, there are fundamental concerns with the framework of the process that must be addressed if we are to truly protect the public health by ensuring the safety and efficacy of medical devices. A comprehensive review of medical devices, including both pre-market and post-market surveillance, is needed.

The questions and recommendations posed to the agency by the IOM are critical if Congress is to use the opportunity to review the Medical Device User Fee and Modernization Act as an opportunity to make the updates that are desperately needed to ensure the safety and effectiveness of medical devices.

Again, I strongly urge you to consider the IOM findings and recommendations as the agency continues to evaluate the approval and post-market surveillance of medical devices.

Thank you for your attention to this critical public health issue. I look forward to our continued work to protect the health of Americans.

Sincerely,

ROSA L. DeLAURO
Member of Congress

###
DeLauro.House.Gov