The Health Subcommittee of the House Energy and Commerce Committee will meet at 10am this morning to mark-up legislation to reauthorize FDA user fee programs, including the Medical Device User Fee Act (MDUFA). The full Committee will vote on the legislation later this week.

Below is the letter Consumers Union sent to the Subcommittee highlighting our concerns about the bill it has drafted, which fails to address some of the most critical flaws in our current medical device oversight system.

For more information, please contact Michael McCauley at mmccauley@consumer.org or 415-902-9537 (cell) or Lisa McGiffert at lmcgiffert@consumer.org or 512-415-5405 (cell).

May 7, 2012

Dear Chairman Pitts and Ranking Member Pallone:

As you get set to mark-up the Medical Device User Fee Act (MDUFA) reauthorization bill, I urge you to keep consumer safety issues in mind. In the wake of several high profile, device-related public health disasters--such as faulty surgical mesh, metal-on metal hips, and cardiac defibrillators---it is incumbent upon Congress to make some common sense changes to the device regulatory system to ensures the safety of medical devices and protect the public health.

While the Health Subcommittee bill has improved over the previous discussion draft, it fails to address the underlying foundation of the current system for reviewing new medical devices that continues to put patients at risk by allowing too many high-risk devices to be cleared without clinical testing for safety. Further, it fails to create an effective system to monitor devices and notify patients and doctors when there is are safety problems.

Congress is out of step with the public on a number of key issues of medical device safety. A recent national poll by Consumer Reports shows that consumers overwhelmingly support common sense measures that would improve the safety and efficacy of the device regulatory system. Eighty-two percent of the poll respondents believe that preventing safety problems is more important than limiting safety testing in order to prevent delays and encourage innovation. Ninety-one percent believe that each implant should be safety tested before being sold even when similar implants were in use -- 68 percent of them thought they “definitely should” be safety tested.

We offer the following specific comments regarding the current House subcommittee bill:

- The bill continues to allow new devices to be cleared for sale based on their similarity to a predicate that has been recalled for safety reasons and even fails to require manufacturers of new devices to show how they have fixed the flaw present in a predicate device that has been recalled for safety reasons. FDA should have the authority to deny 510(k) clearance when predicates have been recalled for safety reasons or if the safety flaw is not corrected.

- The bill does not streamline the FDA’s ability to upclassify devices, as is done in the Senate bill, in order to require more thorough review of high-risk devices through the premarket approval process.

- While the bill maintains important disclosure requirements for FDA advisory panelists, it removes key protections against conflicted experts such as the directive to the Secretary to try to find non-conflicted experts and removes caps on the number of conflicted experts allowed on panels.

- The bill has been improved to expand the Sentinel program to include medical devices and creates a timeline for the promulgation of a final guidance on the Unique Device Identifier system that was created five years ago. However, Congress should adopt language in the Senate draft, which would create an implementation timeline so UDIs for devices that are implantable, life sustaining or high risk are in place quickly.

Consumers Union, the advocacy arm of Consumer Reports, looks forward to working with you to improve patient safety as the reauthorization process moves forward.

Sincerely,
Lisa McGiffert
Director, Safe Patient Project
Consumers Union