ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

November 15, 2011

Dear Senator,

Consumers Union's Safe Patient Project is writing to urge you to use the opportunity provided by the upcoming reauthorization of the Medical Device User Fee Act (MDUFA) to improve the quality, safety and effectiveness of medical devices. We believe the essential goal of not harming patients can be achieved without harming true innovation.

You have been hearing that the medical device industry faces onerous regulation by FDA. But in many respects, the device industry is far less regulated than the drug industry. For example, the standards for the fuller pre-market approval of devices that require clinical trials are weaker than are used for drug approval. Drugs must show substantial evidence of safety and effectiveness where devices must merely show reasonable assurance of safety and efficacy.

Furthermore, more than 90 percent of devices are cleared through the 510(k) process, a process that does not require clinical trials but merely a showing that the new device is similar to an existing one called a predicate. The predicate device upon which a device is cleared may never have been through a clinical trial. Devices may vary quite considerably from the initial predicate, as each newer model with modifications from the initial predicate can then become the predicate for subsequent models. Once a predicate device has been removed from the market, it is not necessarily removed as a predicate, and subsequent devices approved based on that removed predicate are not automatically reviewed or removed from the market.

Recent high-profile device failures such as those that occurred with metal-on-metal hip implants and surgical mesh-devices that were approved through the 510(k) process (see enclosure) - illustrate that lax approval standards for devices are allowing faulty high risk devices to make it to market, where they have caused considerable harm to patients and cost to the health care system. When an implanted device is recalled or removed from the market, patients cannot simply stop using them. Removal of the device requires surgery, sometimes multiple surgeries, and it may take months or years to repair the damage done by the device. Some patients are permanently disabled or die due to complications from a device.

Below are Consumers Union's recommendations for Congress to improve the safety and effectiveness of devices for consumers:

- Improve the pre-market approval process by:
    - Raising standards of approval for devices from "reasonable assurance" of safety to "substantial evidence" of safety to bring it in line with the standard for drugs.

    - Ensuring that implantable and life-sustaining devices do not go through the 510(k) process - requiring them to go through the full pre-market approval process, which requires clinical trials.
    - Removing recalled devices from the list of predicates upon which other devices may seek to be cleared and requiring that devices approved based on a recalled device be automatically reviewed for safety.
- Improve current Post-Market Surveillance of devices by:
    - Requiring the FDA to implement a national unique identifier system for devices so that patients and health care providers can be contacted when problems with that device are identified. Currently, there is no universal way to find out which devices went into which patients.
    - Ensuring that the FDA has adequate resources to fully implement existing patient protection programs for monitoring and reporting adverse events such as MedWatch, MAUDE and the Sentinel initiative. Used effectively, these programs can help the FDA identify early and ongoing problems with medical devices that are causing harm to patients.
    - Enabling the FDA to use its recall authority more effectively and providing the FDA with authority to call for longer term post market studies and to require device makers to meet their commitments to conduct post market studies.
- Retaining current conflict of interest standards for federal advisory committees. Five years ago, consumer organizations, including Consumers Union, advocated strongly for these standards to ensure the integrity of the advisory committee process. Decisions regarding new drugs and devices must be free from even the perception of bias. We question whether any relaxation of these standards is truly needed.

Finally, in order to ensure the quality and safety of devices, FDA has to be adequately funded from the medical device fees that are the subject of the reauthorization of MDUFA.

We look forward to working with you on ways to improve the medical device user fee program as Congress works through the process of reauthorization.

Sincerely,

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