ConsumersUnion®
POLICY & ACTION FROM CONSUMER REPORTS

June 7, 2012

The Honorable Tom Harkin
Chairman, Committee on Health,
Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Michael Enzi
Ranking Member, Senate Committee on
Health, Education, Labor and Pensions
835 Hart Senate Office Building
Washington, DC 20510

The Honorable Fred Upton,
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Harkin, Ranking Member Enzi, Chairman Upton, and Ranking Member Waxman:

Consumers Union, the advocacy arm of *Consumer Reports*, thanks you for your commitment to ensuring that our national system for approving drugs and devices brings safe products to the market for patient and consumer use. As you move forward in reconciling the differences between the Senate and House versions of the reauthorization of the FDA User Fee Act, please consider our top priorities on medical devices, presented below:

Unique Device Identifier (Senate, Sec. 607) – Support Senate.
We see implementation of this current law as soon as possible as a high priority on medical devices. While it is encouraging that both Senate and House versions address finalizing the UDI rule, we support the Senate version because it sets a deadline for implementing UDIs for high risk, life sustaining and implantable devices. The FDA does not currently have the tools and resources to adequately track and evaluate how patients with implants and other high-risk devices are faring. Effective post-market surveillance is dependent on having UDI in place – that includes effective use of the Sentinel Initiative, device registries, and the ability to more precisely identify problems and inform patients when problems with devices are identified. Five years ago, Congress mandated the creation of UDIs when the last user fee agreement was reauthorized -- setting a timeframe for implementing this system is critical to patient safety in the future.

Reclassification procedures (Senate, Sec. 601) – Support Senate.
The ability to create an expedited process to more appropriately reclassify devices is a tool the FDA needs in this fast-paced market. Our specific interest is in the ability to up-classify devices that have caused serious harm to patients so that similar device applications in the future will require more scrutiny of their safety. This provision does not allow expedited reclassification without cause – it must be based on new information that the agency receives about the particular device. The process outlined in the Senate version strikes the appropriate balance between providing sufficient due process for manufacturers and input from all stakeholders AND protecting patient safety. We remain concerned that this also empowers FDA to down-classify devices more quickly. While the companies will resist down-classification of devices where they

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have invested resources in taking a device through premarket approval, we have seen worrisome examples of down-classification of devices that then go through the De Novo process. We look forward to working with Congress to make sure that this provision works as intended to facilitate moving improperly classified devices to an appropriate classification. The Senate requirement for an annual report will help to monitor the use of this new process.

Investigational device exemption – Oppose House Sec. 701, Support Senate Sec. 606.
Retaining FDA's full range of options in approving IDEs is essential to public health in general as well as the health of the specific patients involved in device clinical trials. The Senate version gives the Secretary authority to put a hold on studies that pose unreasonable risks to their subjects. This allows a time out for re-evaluation and then allows the research sponsors to make adjustments or provide more information to address concerns and resume the study. The House version would tie the hands of the FDA, limiting FDA's ability to reject IDE applications based on the likelihood of approval.

The FDA has a specific responsibility to ensure that the clinical studies done to investigate new devices are worth the risk to the subjects involved and to ensure that the many more people who would be exposed to a device post clearance or approval are not put at risk. If the FDA realizes an investigation will not support approval, patients ought not be exposed unnecessarily to risks associated with the investigation.

Timeline for Post-market surveillance studies (Senate, Sec. 603) – Support Senate.
We strongly support expeditious completion of 522 studies ordered by the Secretary due to concerns about the safety of devices, typically based on reports to the FDA about patient harm. Until these *ordered* studies are completed, doctors continue implanting them in patients and future users of the devices are endangered. It is essential that these studies about the safety of devices be done in a timely manner. The Senate bill requires these studies to begin not later than 15 months after being ordered. Consumers Union specifically advocated for timelines for these studies to be tied to the initial Secretary's order and urges its inclusion in the final bill.

Sentinel (Senate, Sec. 604; House, Sec. 762) – Support Senate.
We strongly support adding medical devices to the Sentinel Initiative and appreciate that both the House and the Senate included devices in this important post-market surveillance tool. The House version is comparable to the Senate except that it strikes a section that requires the Secretary to include reporting data of serious adverse drug experiences and events -- including those submitted by patients, health care providers, and manufacturers – in the post-market risk identification and analysis system. This House language would eliminate critical information from the agency's post-market oversight of drugs (and devices as added in both versions of the bill) and should not be removed from current law.

Condition of Approval Studies (Senate, Sec. 602) – Support Senate.
The Senate bill codifies a current practice that allows the FDA to require approval for high-risk devices to be contingent on completing specified post market studies. This clarifies that the Secretary can impose civil monetary penalties on companies that fail to complete these studies and will level the playing field for companies that do comply with such requirements.

Thank you for your work on this important legislation. If you have any questions about the above recommendations, please don't hesitate to contact us.

Sincerely,

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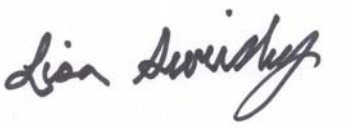

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