Safety Advocates Unveil Device Safety Agenda, Ramp Up Lobbying

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Consumer safety advocates are unveiling a broad medical device reform agenda as they increase lobbying efforts on Capitol Hill, with groups focusing on more rigorous approval for implantable devices, restrictions on using recalled predicates, increased requirements for post-market studies, implementation of the delayed unique identifier system and a national device registry, and greater scrutiny of direct-to-consumer medical device advertising. A safety advocate said there is momentum in the Senate to include some reforms in the user fee act legislation.

Consumers Union's Safe Patient Project this week brought eight patient safety activists from around the country to Washington to meet with lawmakers and press for improvements to the Medical Device User Fee Act. Consumer groups are also meeting with congressional staff as lawmakers work on legislation in this area, according to sources.

The activity comes as FDA and industry work to put the finishing touches on a negotiated agreement on medical device user fees, with a hearing on the issue scheduled for Feb. 15. Consumer advocates said the agreement does not reflect the safety priorities that they had discussed with FDA during the negotiations, such as not allowing companies to use recalled predicates for 510(k) clearance and giving the agency the authority to require post-market studies.

Safety advocates are now turning their attention to Capitol Hill, and banking on news about faulty medical devices to help bolster their cause, although some sources have said medical device safety measures could be a difficult sell as lawmakers increasingly focus on reducing regulation to promote innovation in the medical device sector.

One source said while there is interest in Congress around safety reforms, lawmakers are still working out their plans for moving these ideas forward. Legislation could be introduced as a side-car to the user fee bill, but one source said there have been some bipartisan conversations in the Senate around including some reforms in the user fee act itself.

"They are developing language that will be ready to go one way or another," one safety advocate said.

Reforms aimed at direct-to-consumer advertising for medical devices, like billboards, are gaining traction in Congress, according to one safety advocate, who added that this issue, along with UDI, and predicate reform -- included in a recently introduced House bill -- are getting the most attention on Capitol Hill right now. The source said post-market reforms are more broad at this point.

"While the user fee program is structured in a way that FDA has to be more responsive to industry than to us, Congress is still responsive to their constituents," the safety advocate said.

Consumers Union is pushing a broad medical device safety agenda that includes pre-market and post-market reforms, as well as retaining current conflict-of-interest rules -- an area some in Congress are seeking to loosen although FDA has indicated a legislative fix might not be necessary.

Specifically, the group wants all implantable devices to go through the pre-market approval process, and wants to prohibit use of recalled devices or devices with a warning to be used as predicates in the 510(k) clearance progress. It also proposes to give FDA authority to require post-market studies, including long-term studies to demonstrate longevity of devices, and raise the safety standard for devices in line with prescription drugs by changing the PMA standard from "reasonable assurance" of safety to "substantial evidence" of safety.

The group is also calling on FDA to implement the UDI system, which has been held up at the White House Office of Management and Budget, create a national registry for devices, and ensure the agency has adequate resources for better post-market surveillance programs including MedWatch, MAUDE and Sentinel. In addition, Consumers Union said the current conflict-of-interest standards should be retained, a measure they advocated for five years ago during the last reauthorization of user fees.

Some of these measures have already garnered interest on Capitol Hill, with a group of House Democrats introducing legislation that would prevent recalled devices from being used as predicates. A group of senators also introduced a bill that would require conditional approval for some devices cleared through the 510(k) process, although the legislation has met opposition from industry and some consumer groups, who have said those reforms do not go far enough and could loosen some pre-market requirements. -- *Nanci Bompey* (*nbompey@iwpnews.comThis e-mail address is being protected from spambots. You need JavaScript enabled to view it*)