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Medical Device Industry at a Crossroads: Will Industry Profits Trump Patient Safety?

As Congress Considers Sweeping Changes to the Device Approval Process, Consumer Advocates Call for More Oversight

The medical device industry is reaching a turning point.

The news is full of stories of malfunctioning devices that injure or kill patients and are on the market because of a lax approval process. Reports to the government of device-related injuries and deaths are up dramatically.

This spring, Congress is considering sweeping changes to the way the industry is overseen, as part of a process that occurs every five years to reauthorize user fees that the drug and device makers pay the Food and Drug Administration to review their products for the market. But instead of considering improvements to device safety, more often than not, lawmakers have endorsed industry-backed changes that could lead to more dangerous devices being given to patients, and therefore, more injuries and deaths.

Consumer advocates and patients have pushed back, warning of the unintended consequence of giving the industry virtually free reign. After all, polls show that most Americans want their medical devices to be safe, even if it takes a little longer for them to come to market.

But patients are up against a powerful, well-funded industry that has pulled out the stops to win.

What will the future of the medical device industry hold? That depends on whether Congress puts patient safety over industry profits. On April 25, the Senate Committee on Health, Education, Labor, and Pensions approved a manager's amendment to the user fee legislation companion, formally called the Food and Drug Administration Safety and Innovation Act, which now heads to the Senate floor. A similar measure is to be marked up by the Subcommittee on Health of the House Committee on Energy and Commerce the week of May 7, and soon after by the full Energy and Commerce Committee. The House bill – its contents appearing to be a wish list for device manufacturers – is an affront to the safety of patients. The Senate committee version, while containing incremental safety improvements, also succumbed to industry demands in a variety of ways. No matter what, though, lawmakers have indicated that they are definitely going to pass a version of this "must-pass" legislation.

The current situation: Safety gaps in the government's device review process

If you have or are getting a medical device, you should know that the device's safety and effectiveness are not assured. That's because:

- Your device probably wasn't tested in anyone before it was approved. You are, in effect, a guinea pig for these untested devices;
- If the manufacturer of your device learns that it is faulty, you likely won't know there's a problem until you are injured. That's because the company doesn't know you received it;
- You might be walking around with a device that was cleared for marketing because it was similar to another device on the market – even if that earlier device was later found to have dangerous defects;
- If you have an implanted device, you are more likely to have problems with it. In recent years, recalls for both moderate- and high-risk devices have more than doubled, from 566 in 2007 to 1,201 last year. The Food and Drug Administration (FDA) receives reports of more than 2,000 deaths and more than 200,000 device-related injuries and malfunctions annually.
- If you are injured by a high-risk device that was tested, you probably can't sue the manufacturer. The U.S. Supreme Court in 2008 ruled that manufacturers of most high-risk devices approved by the FDA under the highest level of review, the premarket approval (PMA) process, cannot be held liable for harm.

The device review process is far less rigorous than the approval process for drugs, and it largely is ineffective at keeping dangerous devices off the market. Here's how it works:

There are two general FDA review pathways for devices. The most rigorous, the PMA pathway, is reserved for certain high-risk devices. However, even the standards for FDA approval of a medical device under the PMA process are lower than those for approval of a drug.

With the second pathway, known as the 510(k) process, named after a section of the statute governing medical device regulations, a manufacturer need only demonstrate that the new device is "substantially equivalent" to an already marketed device (referred to as a "predicate device"). This provides little assurance of safety or effectiveness, because most of the existing products were never demonstrated to be safe or effective. The vast majority of devices proceed down the 510(k) route. In fact, this less stringent process is used to clear at least 95 percent of moderate- and high-risk medical devices.

The device approval process is broken – and it shows

Recent news stories have focused on a faulty wire in an implanted cardiac defibrillator made by St. Jude Medical that is prone to breaking through a protective outer coating and causing unintended shocks to patients or other malfunctions. Last month, a

Minneapolis researcher released a study showing that failures in that wire may have killed about 20 people.

But it's not the only device in the news for killing or injuring patients. Also making headlines:

- An implantable pad designed to shield breast tissue from radiation treatment in patients undergoing breast cancer surgery. It sheds small particles of tungsten into the breast, which interfere with subsequent cancer screening tests;
- An infusion pump that shuts down unexpectedly or dispenses an incorrect dose of medicine, leading to potentially fatal under- or overdosing of medication;
- Other faulty cardiac defibrillators that send unintended shocks to patients' hearts;
- A surgical clip designed to clamp off arteries can pop off, causing patients to bleed to death internally; and
- An artificial hip that sheds metal fragments into the bone and surrounding tissue, wearing away tissues and causing extreme pain and limited mobility.

What the $350 billion device industry has pushed for

Amazingly, while more devices than ever are being recalled because they are harming people, the medical device industry is trying to pressure lawmakers to make it even easier for new devices to get onto the market – with *even less* FDA oversight.

Industry lobbyists have used the pending user fee reauthorization as an opening to press Congress to:

- Make "medical innovation" a priority for the FDA, as opposed to patient safety;
- Weaken conflict-of-interest provisions for members of FDA advisory committees charged with deciding whether to recommend a device for approval. Under the proposal, more people with a financial interests in devices under consideration could review the applications;
- Give the FDA a very short window to approve devices;
- Expand the use of private third-party companies to perform regulatory review normally done by FDA staff, which creates an inherent conflict of interest; and
- Prohibit the FDA from disapproving the methods and design used in any type of clinical trial conducted by a medical device company, including clinical trials on humans, which would pose a danger to human subjects.

Why lawmakers are listening to the industry

The medical device industry has engaged in a massive lobbying effort. A recent Public Citizen analysis (available at http://citizen.org/substantially-unsafe-medical-device-report) found that the industry dispatched at least 225 lobbyists, including 107 previously employed by the federal government, to work on medical device regulatory issues in just the third and fourth quarters of 2011. Nearly half of these lobbyists entered the legislative push in the fourth quarter, as Congress prepared to take up the issue. These

lobbyists sponsored at least 40 fundraisers for members of Congress in 2011. The industry spent $33.3 million on lobbying in 2011, bringing its total to $158.7 million since 2007.

Further, the industry has made $19.9 million in campaign contributions to federal candidates since the 2006 election cycle. Members of the key Health Subcommittee of the House Energy and Commerce Committee received double the contributions per election cycle as the average member. Sponsors of 10 House bills seeking to weaken approval standards have received nearly three times as much.

The FDA held a series of meetings with industry and consumer groups on how it should structure its recommendations to Congress for the user fee reauthorization bill. From 2011 through January 2012, industry representatives had 30 meetings with the FDA, while consumer groups had only 12 meetings. Notes summarizing the meetings are a matter of public record. The requests made by industry were largely aimed at speeding up review times for FDA clearance and approval of devices.

What lawmakers should do

In the short term, Congress should fix the significant loophole in the 510(k) process that allows devices to be approved even though they are based on devices that have been recalled. Lawmakers also should make some commonsense fixes. Specifically:

- The FDA should have the authority to reject industry applications for clearance of new devices under the 510(k) process that are based on predicate devices that have been removed from the market because of hazardous safety defects.
- Manufacturers should be required to provide the FDA with information not just about the immediate predicate device on which a 510(k) clearance request is based, but also about the full lineage of predicates leading up to the most recent predicate.
- To facilitate efficient and effective tracking of the status of marketed devices that a manufacturer might use as a predicate for a proposed device, the FDA should be required to maintain an up-to-date and easily searchable database of eligible predicates.
- The FDA should be required to reevaluate the safety and effectiveness of devices that already have been cleared under the 510(k) process whenever a device that served as the predicate for those 510(k) clearances is withdrawn from the market due to safety or effectiveness problems.
- The FDA should be given authority to require postmarketing surveillance studies, including clinical studies, as a condition of clearance of a device under the 510(k) process.

In the longer term, Congress should require that moderate- to high-risk devices – particularly those intended to be life-sustaining, life-supporting or permanently implanted – be subject to the same regulatory scrutiny as drugs.

What lawmakers are doing now

The measure headed to the Senate floor would enhance medical device safety in limited ways. For instance, it would require an FDA advisory panel to review the reclassification of devices and allow the FDA to require postmarket safety studies. However, the measure excludes commonsense proposals to strengthen medical device safety and includes provisions that would weaken device oversight. For a detailed analysis, visit http://www.citizen.org/hrg2023.

The version before the House is substantially worse than the Senate version. In addition to including many of the same provisions that would weaken device oversight, it would fundamentally undermine the FDA's primary mission to protect public health by requiring the agency to promote medical product innovation and the business interests of industry. The House version also excludes most of the provisions from the Senate version that would enhance medical device safety. For a detailed analysis, visit http://www.citizen.org/hrg2019.

The public needs and demands a better process:

Last month, Consumer Reports released a poll showing overwhelming public support for improved safety of medical devices. The bottom line: The public wants to ensure devices are safe, even if it takes a little longer for them to come to market. According to the poll, 82 percent of Americans believe that preventing safety problems is more important that limiting safety testing in the name of innovation. Further, 91 percent said every device should be tested before being sold. The public also overwhelmingly supports a tracking system, so patients can be notified about problems with their devices.

Instead of following the money and hollow arguments from industry, Congress should follow the facts and the calls from the general public for a safer device review process.

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