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Medical Device Loophole Leaves Patients At Risk
Consumers Union Responds to Medical Device Industry on Recalled Predicates
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As Congress reauthorizes the statute governing medical devices this year, it has the opportunity to close a dangerous loophole in the law that puts patients at risk of serious harm. Under current law, the FDA does not have the power to require device makers to prove they've fixed safety flaws when they want to market a new device based on one that has been recalled by manufacturers.

The consequences can be devastating for patients who naturally assume that the FDA has the authority to assure new devices don't repeat design flaws. Consumers Union has joined other consumer and patient safety groups to urge Congress to close this absurd loophole in the law and give the FDA the authority it needs to protect patients.

Incredibly, AdvaMed, the major trade association, which lobbies on behalf of the medical device industry, is opposed to this common sense reform.[1] It insists that the FDA already has the authority to prevent manufacturers from marketing new devices that repeat safety flaws of recalled products. But a review of the law and statements by Dr. Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health,[2] make it clear that they are misleading Congress.

The FDA does not have clear authority to reject the use of a "predicate" device recalled for safety reasons when reviewing a new device under the 510(k) fast track process nor does the agency have the authority to require device makers to prove they have *fixed the flaw* that caused the manufacturer to remove that recalled device from the market. In some cases, devices that go through the 510(k) process don't use predicates that have been recalled, but their predicates may have been cleared based on their similarity to a line of devices that are directly tied to a recalled product. The FDA should have clear authority to require device makers to show how they have *fixed the flaw* of a recalled device in its lineage.

A February 2012 Bloomberg News article on this loophole reported that the FDA's Dr. Shuren agreed that the agency needs more power to prevent device makers from repeating safety design flaws like those that have injured thousands of patients harmed by faulty hip implants and vaginal mesh products. Shuren notes in the article that closing the loophole would be good for both patients and companies because it would prevent safety design flaws from being repeated. Citing FDA records, Shuren said, "The problem now is if there's a problem, it can get replicated…A device is five times as likely to be recalled with a design flaw if it was based on a predicate that was itself pulled for safety problems."[3]

Perhaps the best-known example of this problem involves vaginal mesh implants used to treat urinary incontinence and weak pelvic organs in women. Surgeons implant the mesh in patients to strengthen tissue weakened by childbirth or age and to keep the women's internal organs in place.[4] The FDA first cleared the Boston Scientific ProteGen bladder sling in 1997,[5] and just two years later the company recalled this device after hundreds of women reported serious complications, including debilitating pain and life threatening infections.[6] Despite the recall of this dangerous device, other mesh products were cleared by the FDA based on their substantial equivalence to it.[7]

Not surprisingly, women with these mesh implants have continued to experience problems, with the FDA receiving thousands of complaints. In 2011, the FDA warned doctors and patients that serious injuries associated with these implants are not uncommon: mesh erosion, bleeding, infections, urinary problems, and organ perforation.[8] Many of these injuries require multiple surgeries to repair or attempt to remove the mesh and some patients are permanently disabled.[9]

Neither the Senate nor the House bills address this loophole, which means patients will continue to be at risk. This is especially the case when recalled devices are used to clear new devices that are implantable or otherwise "high risk." These are the kinds of devices -- heart defibrillators and pacemakers, surgical mesh and artificial hips -- that can cause serious harm to people when they fail. While the 510(k) process was intended to be used for low to moderate risk devices, its evolution over three decades has obfuscated this original intent – which is exactly why the Institute of Medicine recommended abolishing it and starting over with a new process.[10] Short of eliminating the 510(k) process, it is imperative to fix it.

Congress must give the FDA the authority to to bar the use of a predicate that has been recalled by its manufacturer for safety problems or a predicate with such a recalled device in its lineage. If the FDA chooses not to take this step, it should have the authority to require manufacturers to prove they have fixed safety flaws when they base new devices on ones that have been recalled. The FDA also needs the authority to refuse to clear a new device if its predicate is in the process of having its clearance rescinded by the agency.

Medical device makers insist this common sense reform isn't necessary,[11] but thousands of women harmed by defective vaginal mesh implants prove otherwise.[12] The following is Consumers Union's response to the misleading arguments AdvaMed has made to stall efforts to close this dangerous loophole:

The medical device lobby says the FDA already has the authority to require device makers to provide whatever evidence is necessary to assure a product's safety and effectiveness

There are numerous restraints on what the FDA can ask when reviewing a 510(k) application.

The FDA has no authority to look at the underlying safety and efficacy of a new device that goes through the 510(k) process. It can only look at whether the device is "substantially equivalent" or as safe and effective as what is already on the market and "does not raise *different* questions of safety and effectiveness than the predicate device." [13] The Institute of Medicine (IOM) explains the history of this provision: "In 1997, Congress restricted the agency further, specifying that the FDA could request information only if it were necessary to make the substantial equivalence determination."[14] This limited authority clearly causes concern when the predicate device has been recalled for safety reasons.

Even if the FDA suspects that a new device may be flawed because its predicate is unsafe, under current law the agency cannot compel the manufacturer to show how it is safer than the dangerous recalled device. The FDA only has the authority to require the company to show if the new device is *as safe* as the recalled one.[15]

Further, in determining substantial equivalence, current law specifically restrains the FDA by requiring the agency to ask for evidence from device makers in the least burdensome way.[16] The IOM found that this provision has limited the FDA's ability to determine if a device is safe or effective.[17] Giving the FDA the power to require device makers to prove they have fixed the safety flaw would provide a targeted way of keeping problematic devices off the market.

Finally, the user fee agreement between FDA and the medical device industry establishes time goals for clearance of devices, which restrains the agency from asking for more information. Failure to meet these goals can be held against the agency as evidence of its inefficiency in approving new devices.[18] The FDA should be allowed to reject a flawed device as a predicate or to require the manufacturer to prove that the new device avoids repeating a safety flaw.

If the medical device industry believes that the FDA already has the authority to prevent companies from repeating flaws, it should have no objection to clarifying the agency's authority.

The medical device lobby says the FDA has many tools it can use to remove dangerous, defective devices from the market and prevent their use as predicates. It argues that a device that has been recalled by the FDA or found to be misbranded or adulterated by a court cannot be used as a predicate device.

But the FDA can only invalidate the use of a device as a predicate if the agency initiated the recall, and the proceedings for a mandatory recall can take years. When a company voluntarily recalls a device, the FDA has no such authority.

Dr Shuren confirmed this fact in the Bloomberg News article, which noted that he said, "By law, the FDA has to OK devices that claim an approved predicate unless the older device has been taken off the market by the agency. Because most companies choose voluntary recalls, the devices can continue to serve as models for future products."[19]

To take a voluntarily recalled product off the predicate list, FDA would have to rely on a court action by seeking a judicial order to find a device adulterated or misbranded.[20] Judicial orders can take years to secure and can be very resource intensive for the FDA. As with all court procedures, this involves filing of formal pleadings, specific timelines set by law or the court, waiting for court scheduling, allowing for responses from all parties, and appeals. In the meantime, the unsafe device could still be used as a predicate and continue to be put into patients' bodies.

The IOM report states, "The FDA is unable to dictate which predicates can be selected for 510(k) decision-making. In some cases, the FDA has published guidance documents advising manufacturers on how to demonstrate the predicate relationship. These guidance documents are nonbinding on the manufacturer or the agency."[21] Thus, the FDA does not have the power to designate a particular predicate, or one with a recalled predicate in its lineage, as faulty or inappropriate for a manufacturer to use in the 510(K) process.

The medical device lobby says voluntary recalls don't prevent the FDA from taking action to make recalls mandatory, which prevents a device from being used as a predicate.

While it is true that the FDA can initiate a mandatory recall, AdvaMed is misleading Congress by implying that this is a simple process for the agency to carry out. Mandatory recalls are time and resource intensive, requiring legal due process steps, during which the dangerous devices can continue to be used and can continue to cause harm. The industry claims that the loophole only affects a small handful of devices,[22] but the time it takes for FDA to recall a single device from the market is enough time to harm many thousands of people.

In reality, voluntary recalls by device makers have become the primary mode of removing dangerous devices from the market. A 2011 GAO report stated, "The most recent comprehensive look at device recalls found that between 2005 and 2009, there were approximately 700 voluntary recalls per year and zero mandatory FDA recalls."[23] If the FDA were to initiate a recall, most device makers would probably voluntarily recall the unsafe device before the years it would take to complete a mandatory recall.

The FDA should not have to issue a mandatory recall on a product that has already been voluntarily recalled in order to keep other similar products off the market in the future. This process suggested by Advamed[24] is redundant, expensive, and slow. A simple common sense policy change that gives the FDA the authority to remove recalled devices from the predicate list would fix the problem. If the FDA chooses not to take this step, it should have the power to require device makers to prove they have fixed the safety flaw when they rely on predicates recalled by their manufacturers.

*For more information about this issue, see **Defective Devices, Destroyed Lives SOUND Act Report**.*

[1] AdvaMed document provided to Consumers Union by Congressional staff.
[2] Nussbaum, Alex, "Medical Device Loophole Needs Closing By Congress, FDA Device Chief Says," Feb 28, 2012 -- http://www.bloomberg.com/news/2012-02-28/fda-device-chief-says-approval-loophole-needs-closing.html
[3] Nussbaum
[4] FDA Safety Communication: Update on Serious Complications Associated With Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse, July 13, 2011
[5] FDA Executive Summary, "Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence," Obstetrics & Gynecology Devices Advisory Committee Meeting, September 8-9, 2011, p 5.
[6] "Defective Devices, Destroyed Lives: Loophole Leaves Patients Unprotected From Flawed Medical Devices," Office of Congressman Edward J. Markey, pp. 8-9.
[7] Markey, p. 9.
[8] "FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence," p 15 -- http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm
[9] FDA website safety alert: "Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication." -- http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm . MeshMedicalDeviceNewsdesk at http://meshmedicaldevicenewsdesk.com/category/patient-profiles/ and stories collected by Safe Patient Project.
[10] Institute of Medicine, "Medical Devices and the Public's Health The FDA 510(k) Clearance Process at 35 Years," prepublication copy, 7-29-11, p 6.
[11] AdvaMed document
[12] FDA Executive Summary, pp. 8&9.

[13] Food Drug and Cosmetic Act, Section 513(i)(1)(A) Substantial Equivalence

For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—(i) has the same technological characteristics as the predicate device, or (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

[14] Institute of Medicine, page 215
[15] FDCMA, 513 (i)(1)(A)
[16] FDCMA, 513 (i)(1)(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.
[17] Institute of Medicine, p. 29
[18] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm292860.htm#date and specifically the user fee agreement document at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf
[19] Nussbaum
[20] FDCMA, Section 513 (i)(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.
[21] Institute of Medicine, p 73.
[22] AdvaMed document
[23] GAO Report, "FDA Should Enhance Its Oversight of Recalls," No. 11-468, June 14, 2011.
[24] AdvaMed document