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Note: The U.S. House Committee on Energy and Commerce's Subcommittee on Health is holding a hearing, titled "Reauthorization of MDUFA: What It Means for Jobs, Innovation and Patients," at 10:15 a.m. today in room 2322 of the Rayburn House Office Building. Public Citizen submitted testimony for the hearing, available at http://www.citizen.org/hrg2000.

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Report: Medical Device Industry Is Waging Massive Lobbying Push for Measures That Would Further Endanger Patients

FDA's Lax Approval Process Should Be Strengthened, Not Weakened; Far Too Many People Are Injured or Killed by Unproven Medical Devices

WASHINGTON, D.C. – The medical device industry is engaging in a massive lobbying effort designed to weaken already lax oversight and speed already quick review of its high-risk products, a new Public Citizen study finds.

The report, "Substantially Unsafe" (available at http://citizen.org/substantially-unsafe-medical-device-report), comes in anticipation of today's hearing in the U.S. House of Representatives over the reauthorization of the Medical Device User Fee Act (MDUFA). As the $350 billion industry pushes for a quicker and easier device review process, Public Citizen instead calls for stronger standards on par with the level expected of newly proposed drugs.

"The industry is campaigning for expanded regulatory loopholes and subpar standards – measures that would put more and more patients at risk for encountering unsafe devices. These demands represent exactly the wrong course of action for Congress," said Negah Mouzoon, researcher with Public Citizen's Congress Watch division and the lead author of the report. "Congress instead should insist that standards be strengthened and that the FDA step up its efforts to remove demonstrably dangerous devices from the market."

The report shows that:

- The device 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 a 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 Food and Drug Administration (FDA) receives reports of more than 200,000 device-related injuries and malfunctions every year, and more than 2,000 deaths. In recent years, recalls for both moderate and high-risk devices have more than doubled.

Recently recalled devices include an implantable pad designed to shield breast tissue from radiation treatment that sheds small particles of tungsten into the breast; an infusion pump that shuts down unexpectedly or dispenses an incorrect dose of medicine; faulty defibrillators that inappropriately deliver severely painful and potentially dangerous electrical jolts to the heart; a surgical clip designed to clamp off arteries that pops 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.

- The FDA process for permitting devices to enter the market is seriously flawed. The process for approving the highest-risk products (called the premarket approval (PMA) process) is much weaker than that used for approving new drugs.

Worse, the process used to clear at least 95 percent of moderate- and high-risk medical devices is shockingly less stringent than that used for the sliver of devices subject to the PMA process. This process, called the 510(k) process after a section of legislation, clears devices based on a mere demonstration that they are "substantially equivalent" to devices already on the market, which provides little assurance of safety or effectiveness, especially because most of the existing products were never demonstrated to be safe or effective. The Institute of Medicine in 2011 recommended that the FDA scrap the 510(k) process because it does not ensure safety or effectiveness.

- Measures to track the performance of devices after they have been cleared for sale are inadequate. For instance, the FDA gives companies too much discretion over whether to report adverse incidents. Further, there is no reliable system for tracking which patients have received faulty devices, so patients may never know that they are harboring products that the FDA views as potentially fatal. Finally, the FDA all too often fails to use its existing authority to order manufacturers to recall harmful devices.

As the FDA worked on its recommendations for MDUFA revision in the fall of 2011, members of Congress – under heavy influence from medical device lobbyists – introduced several bills aimed at greasing the pathway for devices to reach the market.

These bills would further reduce already weak standards for clearing and approving medical devices; shift the emphasis of the FDA's mission from protecting public health to promoting medical innovation; weaken the "conflict of interest" prohibition for serving on the FDA advisory committee that oversees device approvals; expand "third-party" companies that can review a device application to include those with significant financial relationships with the device industry; and more.

‘‘Many patients would be shocked to learn that, unlike prescription and over-the-counter drugs, many moderate- and high-risk devices, including many that are surgically implanted, have either never been tested to ensure that they are safe and effective or have undergone woefully inadequate testing," said Dr. Michael Carome, deputy director of Public Citizen's Health Research Group and co-author of the report. "Congress should reject the medical device industry's lobbying campaign to weaken medical device regulations and instead require a dramatic overhaul of the device approval and clearance processes to improve patient safety."

Public Citizen calls on Congress to replace the medical device clearance and approval processes with a process that requires the same scrutiny as new drugs. In the interim, Congress and the FDA should require additional safeguards for the current 510(k) process, more rigorous clinical trials for PMA applications, stricter reporting of adverse events, the maintenance and analysis of a database of device recalls to ensure that they are implemented effectively, and improved device tracking to patients. In addition, Congress should restore patients' legal rights to sue device manufactures for harm resulting from defective devices. This is needed because a 2008 U.S. Supreme Court ruling said that manufacturers of most PMA-approved devices cannot be held liable for harms.

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