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Consumers Union To Testify For Stronger Medical Device Safety Oversight at House Hearing Today

Congress Shouldn't Sacrifice Patient Safety In The Drive to Speed Up Medical Device Approvals, CU Says

WASHINGTON, D.C. – Lisa Swirsky, senior health policy analyst for Consumers Union, will urge Congress today to strengthen medical device safety oversight in testimony before the House Energy & Commerce Health Subcommittee. The subcommittee will hold a hearing on the reauthorization of the Medical Device User Fee Act beginning at 10:15 AM in Room 2322 of the Rayburn House Office Building.

Recent safety problems with metal hip implants and surgical mesh have underscored how lax federal oversight of medical devices fails to protect patients. Consumers Union has called on Congress to require more rigorous testing before medical implants are allowed on the market and to establish a better system for monitoring devices after approval, including a national system for notifying doctors and patients when safety problems come to light.

‘‘Congress has the opportunity to fix a flawed system that allows too many unsafe medical devices to enter the market," said Lisa Swirsky, senior health policy analyst for Consumers Union, the nonprofit advocacy arm of Consumer Reports. "But so far, the debate in Washington has been all about how to make it easier for industry to rush new devices to the market without addressing the need to protect patients from potential safety hazards. Americans are counting on lawmakers to strengthen the law to ensure timely access to new medical devices without sacrificing patient safety."

In her testimony before the subcommittee, Swirsky notes that the recent user fee agreement negotiated by the U.S. Food and Drug Administration (FDA) and the medical device industry, fails to make *any* patient safety improvements and falls short of providing the resources needed to meet the increasing demands on the agency. The FDA had previously indicated that it needed between $770 million and 1.15 billion to implement the performance goals pushed by industry. Instead, the medical device industry has agreed to $595 million in user fees.

Swirsky's testimony highlights additional concerns about the agreement, including new performance goals for the FDA that may inhibit the agency's ability to get the information it needs to properly evaluate medical device applications. Her testimony also raises concerns about potential conflicts of interests involving industry-funded patient groups that could be involved in evaluating new devices.

In addition, Jim Shull of Browns Mills, New Jersey, will testify at the hearing about his experience as a patient harmed by synthetic mesh used for a hernia operation. Six years after his operation, Shull is living with daily pain from the mesh that has caused severe nerve damage and other debilitating complications.

‘‘The mesh that was put inside of me has caused so much damage that none of the nerves can ever be repaired," said Shull. "Now I face a lifetime of pain and struggle because of it. Surgical mesh and other medical devices should be tested for safety before they are allowed to be implanted into people like myself."

For more details on the reforms Consumers Union is urging Congress to adopt, see the Safe Patient Project's Improve the Safety of Medical Devices fact sheet.

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