

## CONSUMERS UNION NEWS RELEASE

**For Immediate Release:** Monday, February 6, 2012

### Contact:

Michael McCauley, [mmccauley@consumer.org](mailto:mmccauley@consumer.org), 415-902-9537 (cell)  
or David Butler [dbutler@consumer.org](mailto:dbutler@consumer.org)  
or Kara Kelber [kkelber@consumer.org](mailto:kkelber@consumer.org), 202-462-6262

### Consumers Union Steps Up Campaign To Improve Medical Device Safety

#### Consumer Group Teams Up With Patient Safety Activists To Urge Congress to Strengthen Medical Device Oversight

WASHINGTON, D.C. – As the debate in Congress over reauthorizing the statute governing medical devices intensifies, Consumers Union is stepping up its campaign to strengthen the law to better protect patients from potential safety risks. This week, Consumers Union's [Safe Patient Project](http://safepatientproject.org/) (<http://safepatientproject.org/>) is bringing eight patient safety activists from around the country to Washington, D.C. to meet with lawmakers in Congress and press for improvements in the Medical Device User Fee Act (MDUFA).

Consumers Union is urging Congress to require more rigorous testing before all 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. The campaign is up against a powerful lobbying effort by the medical device industry, which is using the MDUFA reauthorization process to try to scale back oversight by the Food and Drug Administration (FDA).

"Most Americans would be surprised to learn of the lax oversight of medical implants," said Lisa McGiffert, director of Consumers Union's Safe Patient Project. "Too many of these devices are allowed on the market without testing to determine whether they are safe and effective. Innovation is important but patient safety should be our first priority. A medical device isn't innovative if it doesn't work and hurts people."

Among those patient safety activists joining Consumers Union this week in Washington is Lana Keeton of Austin, Texas, who has endured ten years of incapacitating pain from the surgical mesh that was implanted during surgery for a prolapsed bladder. Steven Baker of Bloomington, Minnesota, who has suffered from a faulty elbow implant, will be meeting with lawmakers to urge Congress to adopt stricter medical device safety requirements. And Dan Walter, of Deale, Maryland, will share the story of his wife Pam, who nearly died from a defectively designed device used to treat her heart condition.

Unlike prescription drugs, more than 90 percent of medical devices do not require proof that they have been clinically tested and found to be safe and effective prior to being cleared by the FDA for distribution or sale. According to the General Accounting Office, an average of 700 different medical devices are recalled each year. In 2009 alone, the FDA received reports of nearly 5,000 deaths associated with medical devices.

In addition, the system for monitoring and tracking what happens with devices once they are on the market is weak and does not adequately protect people using them. There is currently no national tracking system to identify and inform patients when safety problems emerge.

The FDA has just completed negotiations with the device industry over the shape of MDUFA reauthorization legislation that must be passed later this year. Industry pressure resulted in an agreement that does not include important safety provisions supported by Consumers Union, such as making sure faulty devices aren't used to clear similar implants and giving the FDA the authority to require clinical trials after devices go onto market. Instead, the agreement focuses more on how the FDA can better serve the industry.

"The agreement is disappointing because it fails to include critical safety reforms needed to better protect patients and falls short of the resources the FDA needs to keep up with the volume and complexity of device applications," said Lisa Swirsky, senior policy analyst for Consumers Union. "This year's legislation will govern the safety and quality of medical devices over the next five years. Congress should strengthen the FDA's ability to protect consumers."

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](http://safepatientproject.org/document/improve-the-safety-of-medical-devices-and-save-lives-2) (<http://safepatientproject.org/document/improve-the-safety-of-medical-devices-and-save-lives-2>) fact sheet.

###