



April 2015

YOU SHOULD KNOW

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Dear Jessica,

Too many new medical devices reach the market without extensive testing or review. Read our newsletter this month to learn more about this important issue and ways you can protect yourself and your family from defective medical devices.



Faulty Products Put Patients at Risk

Some Popular Medical Devices Escape FDA Scrutiny

Countless patients around the world depend on advanced medical devices to improve their quality of life. As the \$110 billion medical device industry cranks out thousands of products every year, eye-opening reports continue to surface detailing faulty devices, repeat surgeries and massive recalls. The FDA argues patients need access to life-saving devices



Arthroplasty, the reconstruction or replacement of a joint, as shown here in this hip x-ray, is big business for aging baby boomers.

quickly. However, a speedy approval process means some risky devices are cleared without clinical testing, and once on the market receive limited oversight. *You should know* the risks and realities of medical devices before one is put in your body. [Fatally flawed approvals.](#) >>>

BY THE NUMBERS /

\$133 Billion

The size of the United States medical device market is expected to surpass **\$133 billion** by 2016. At \$110 billion, it is currently the largest medical device market in the world.

71%

A **2011 study** found that 71 percent of Class I medical device recalls (those deemed most likely to cause serious adverse outcomes or death) were cleared

THE DOCKET /

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TOPICS

Failed

through the FDA's 510(k) fast-track approval process.

1,190 Recalls

According to a [recent FDA report](#), recalls of defective medical devices nearly doubled from 2003 through 2012: 1,190 in 2012 compared with 604 in 2003.

BOOKMARK FAVORITES /



Routine Surgical Device May Spread Cancer

Many surgeons use a device called a morcellator as a way to do noninvasive hysterectomy surgery. Amy Reed, a doctor herself, says the morcellator used in her 2013 hysterectomy spread cancer all over her stomach. [View video.](#)



Large Portion of FDA-Approved Devices Lack Safety Evidence

A recent study from the *Wall Street Journal* shows the majority of moderate- to high-risk medical devices approved by the FDA lack scientific evidence to verify safety and effectiveness with patients. [View video.](#)



FDA Knew Device Might Expose Patients to Deadly 'Superbug'

Experts say the FDA has known since at least 2009 that the medical devices involved in a superbug outbreak that infected 179 patients in Los Angeles could transmit lethal infections but did not require more stringent safety standards. [View video.](#)



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SafePatientProject.org

Backed by experts and advocates at *Consumer Reports*, SafePatientProject.org provides a forum for people to speak out about medical harm.

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