MEDICAL DEVICE SAFETY

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MEDICAL DEVICES

- Eye Glasses * Alcohol Swabs * Pulse generators
- Contact Lenses * Surgical Mesh * Cardiovascular Stents
- Breast Implants * Blood Sugar Meters * Hip Replacements
- FDA: "an instrument, apparatus, implement, machine that may be used in diagnoses, cure, treatment or prevention of disease which does not achieve its purpose through chemical action, which would make it a medicine."

Hip Replacement: Terry Sagalow

The Terry Sagalow Story

FDA in charge?

- FDA's safety / surveillance system is inadequate
- 510(k) process - a Class 2 medical device will be approved for marketing if "it is substantially equivalent to a product that is already on the market."
- Even if that pre-existing device has been recalled!

Jaye Nevarez Story

The Jaye Nevarez Story

Specific Failures:MEDTRONIC

- MEDTRONIC - 2010 - 15 deaths related to failure of defibrillator wires - settled suits for $270M - World's Largest maker of heart devices out of Minneapolis. http://www.bloomberg.com/news/2010-10-14/medtronic-to-pay-268-million-settle-suits-over-defibrillator-wire-flaws.html
- Settled when the lower court decision dismissing all claims was being reviewed by higher court.
- $33,000 per person *?* Acknowledged flawed wires

PREEMPTION

- All lawsuits are barred if the medical device can be proven to have passed FDA's "most intensive analysis program."
- Highest deference to FDA since courts are not equipped to determine defects in medical devices

St. JUDE DEFIBRILLATORS

- 15% Failure rate; More than 20 patients killed in March-April 2012 as a result of St. Jude wire not working properly

- 2011 - St. Jude Medical paid doctors as much as $2,000 per patient to convince them to have the company's pacemakers and defibrillators implanted, and the company has agreed to pay $16 million to settle the illegal kickback allegations. http://investors.sjm.com/phoenix.zhtml?c=73836&p=irol-newsArticle&ID=1518402

- May 2012 - St. Jude paid $3.6M to settle allegations that it overcharged patients for devices - Fair Claims Act.
http://www.justice.gov/opa/pr/2012/May/12-civ-694.html

The Big Picture

- FDA: the number of medical device recalls per year increased from 578 in 2005 to 928 in 2010. There were a total of 4,343 medical device recalls during that time

- ExpertRECALL Index: for First Quarter of 2012, the number of actual units recalled this quarter was 82 million, which reflects a 508% increase over the previous quarter, and an 89% increase over the same quarter of last year

- Amazing inventions to save lives - Virtually no testing & Market-Driven incentives - NEED VIGOROUS FDA APPROVAL

Problem

"Fragmented, poorly regulated, market-driven system, with financial incentives to prioritize manufacturers' interests over those of patients, and with no requirement for clinical evaluation of a device's safety or effectiveness." *The Scandal of Medical Device Regulation*, Fiona Goodlee (Oct. 2012)

SOLUTION ? Reporting

MEDSUN: Over 350 hospitals working to improve medical device safety and quality by developing interactive relationship between the MedSun sites and the FDA

- Voluntary Reporting System
- http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork
- They are required to report medical device problems that result in serious illness, injury, or death. MedSun participants are also highly encouraged to voluntarily report problems with devices, such as ‘close-calls,’ potential for harm, and other safety concerns.

MEDSUN

- Voluntary not mandatory reporting system
- Not as wide-spread as it should be.

A small program

information about CBER, visit About CBER.

Contact Information

At this time, we are at our maximum enrollment. However, we are always interested in adding new facilities committed to reporting device safety issues. If you would like to learn more about joining MedSun, please contact us toll free at 1-800-859-9821 or via email at medsun@fda.hhs.gov.

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SOLUTION?

- Informed decision-making
- Talk about it
- Know to ask questions
- Advocacy for legislation to change the approval system of the FDA

Let's Do It, Kentucky!

Kentucky is one of the most aggressive states in the nation for rooting out pharmaceutical fraud! Since 1991, Kentucky has pursued the most claims against pharmaceutical companies and reached more than 30 settlements. http://www.kentucky.com/2012/09/27/2352880/report-kentucky-leads-in-pharmaceutical.html

YOU can make it happen!

> A leader is best when people barely know he exists, when his work is done, his aim fulfilled, they will say: we did it ourselves.
>
> —Lao Tzu