Why give a **Dam** about implants ?

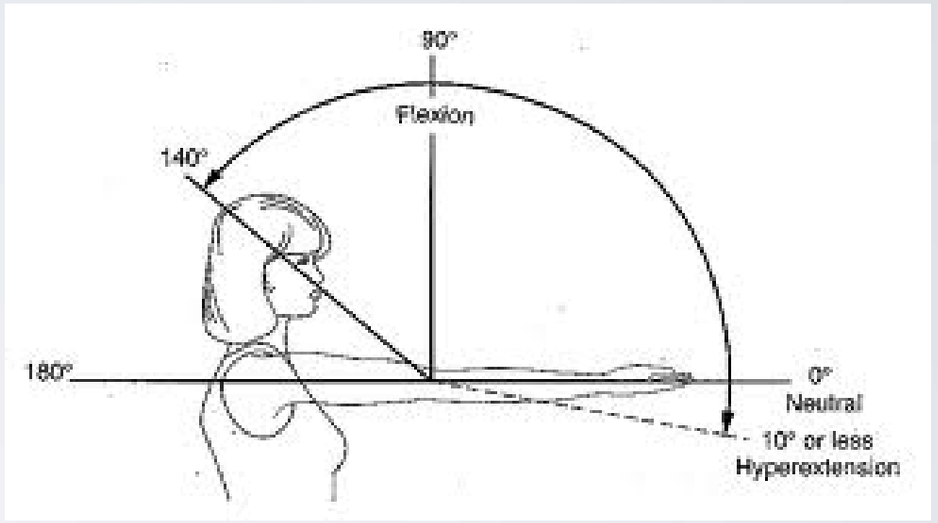
FiDA

FAILED Implant Device Alliance

Joleen Chambers

Patient Advocate

Purpose of implants



PAIN REDUCTION

IMPROVE FUNCTION

- **MEDICAL AND LEGAL PURGATORY**

- **FDA Medwatch #5009052 Adverse Event** (self-reported)

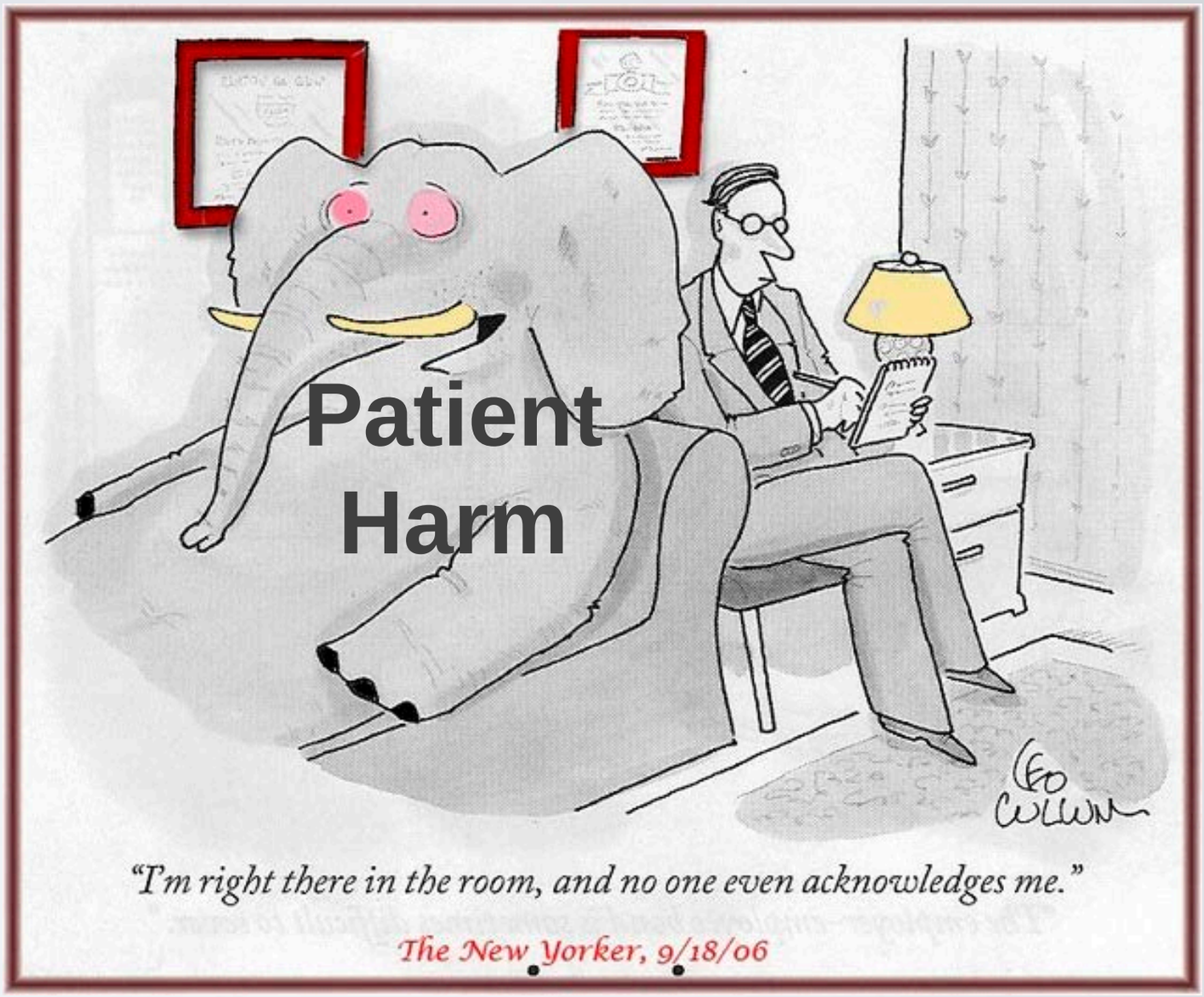
- 2008 Tornier elbow implant (surgeon=designer)MN Mayo Clinic. 4 months later it was <u>un</u>successfully “revised” by removing 2 components

What happens when your implant fails?

- Surgeon
- Patient Affairs
- Hospital Trustees
- State Medical Board
- State Attorney General
- FDA
- Congressional Representatives

PATIENT HARM

- LOSS OF LIFE
- LOSS OF CIVIL RIGHTS
- LOSS OF FUNCTION
- LOSS OF JOB
- LOSS OF FAMILY
- FINANCIAL LOSS
- LOST TRUST

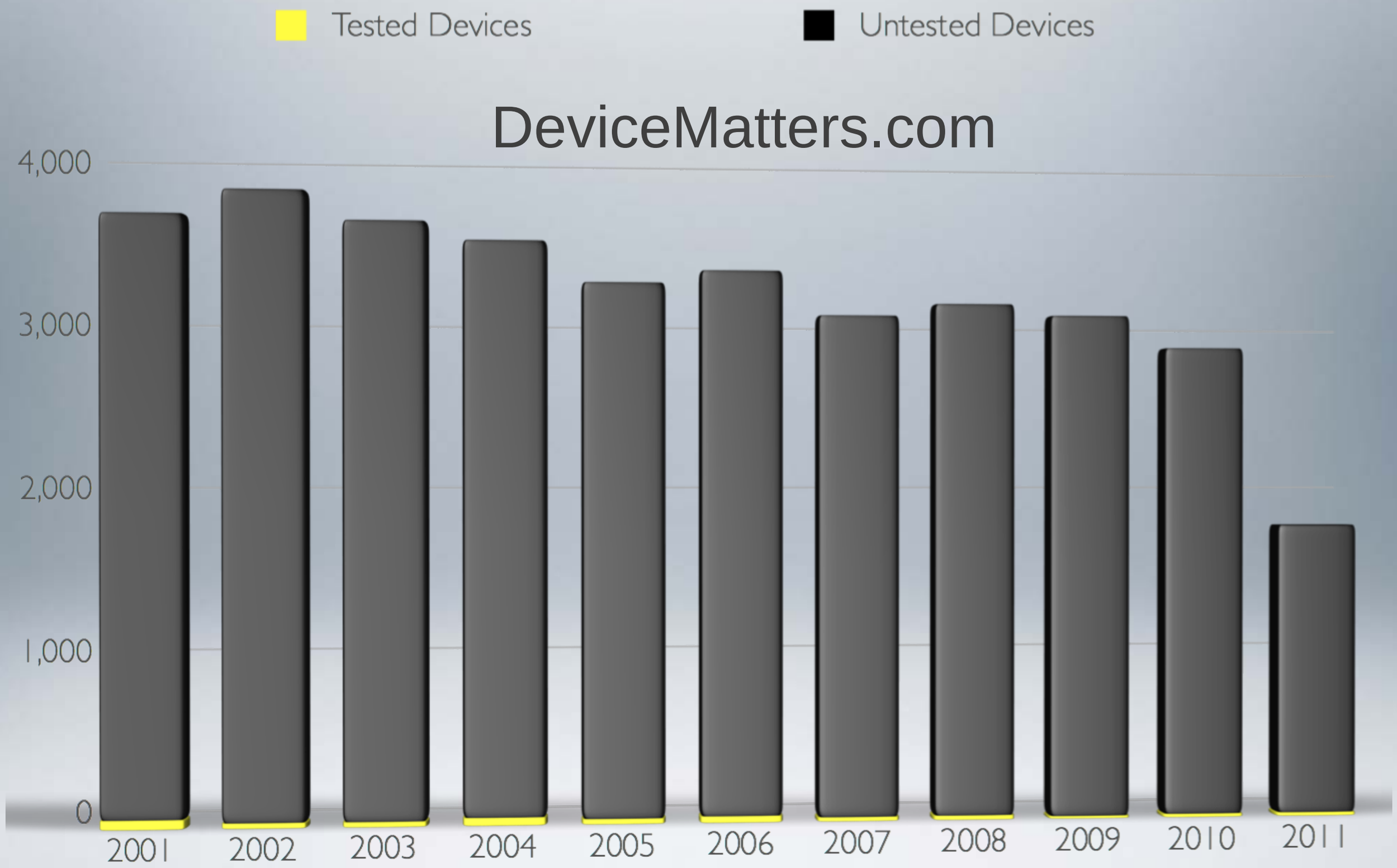


#1 EXPENDITURE OF MEDICARE ?

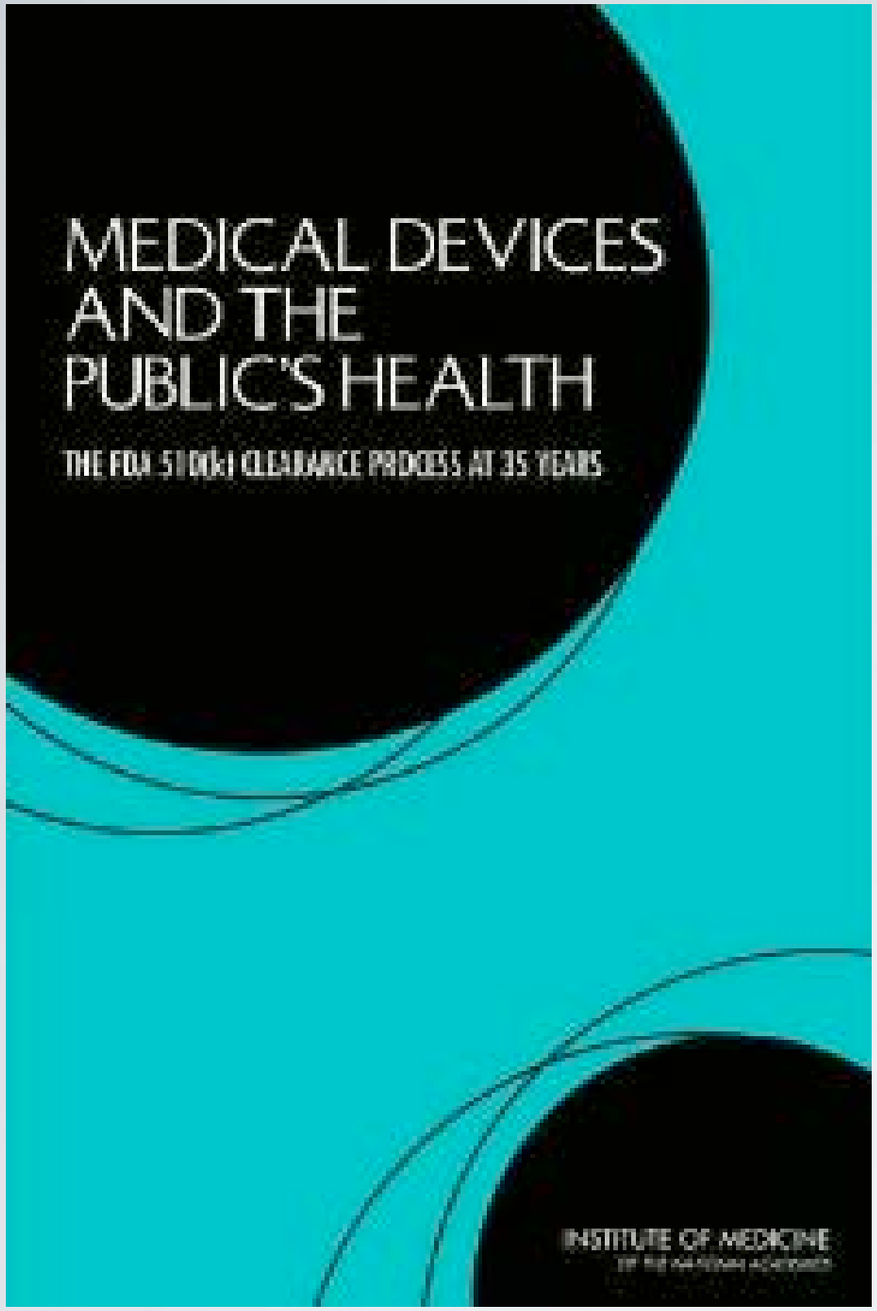
JOINT REPLACEMENTS !

GOVERNMENT SHUTDOWN

PATIENTS: CREDENTIAL AND COST BARRIERS



IMPLANTS: UNTESTED AND UNREGULATED



*Class 3

PMA tested devices that are <u>permanently implanted</u> into a human body or may be necessary to sustain life

*PMA-

clinical testing required pre-market

Class 2

Devices that are cleared using the 510(k) process

510(k)-

must be "substantially equivalent" to a device on the market

The IOM finds that the current 510(k) process is *<u>flawed based on its legislative foundation</u>*. July 29, 2011

PRESS RELEASE
Aug. 21, 2012, 9:43 a.m. EDT

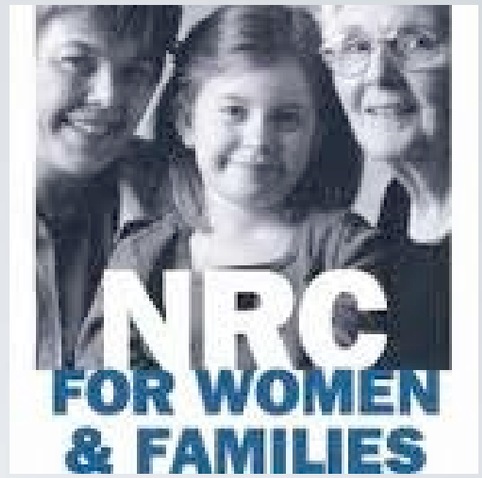
Over 123 Million Medical Device Units Recalled in Second Quarter of 2012, Reaching an Eight-Quarter High, According to the ExpertRECALL Index

Consumer Product Safety Incidents Jump 35 Percent; Slight Uptick in Food Recalls

INDIANAPOLIS, Aug. 21, 2012 /PRNewswire via COMTEX/

Most medical devices recalled in the last five years for “serious health problems or death” had been previously approved by the FDA using the less stringent, and cheaper, 510(k) process.

2011 study published in the **Archives of Internal Medicine**



Cleveland Clinic

Consumer Reports®

"You get a better chance of getting a letter from your car manufacturer if your car is recalled than you do if your hip has been recalled."

Stanford University Chairman of Orthopedic Surgery

JOINT REGISTRY (SILO)

- PROPRIETARY
- NOT ACCESSIBLE TO PATIENT
- OLD TECHNOLOGY
- NOT TRANSPARENT/or INCLUSIVE of all devices
- PATIENT OUTCOME TRACKING LIMITED

metal-on-metal hip

- BMJ/BBC February 2012 report: **global** patient harm
- June 2012 FDA expert panel conclusion: few reasons to use m-o-m implants
- 500,000 m-o-m hips in US

Howard Sadwin

Bayer Essure: birth control implant

Surgical mesh

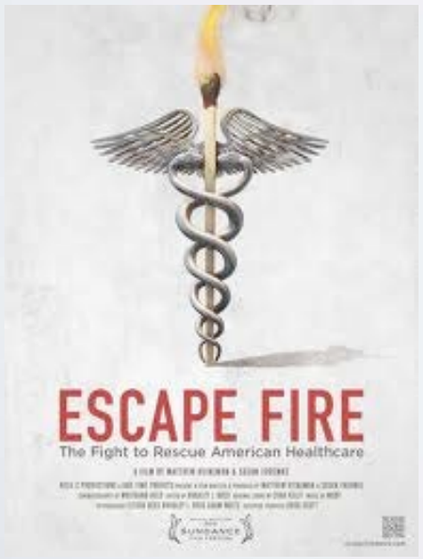
- 2874 adverse events 2008-2010, 7 deaths
- IOM testimony June 2010
- FDA warning of significant harm from transvaginal mesh July 2011
- lawsuits too late

ICD leads - cardiac

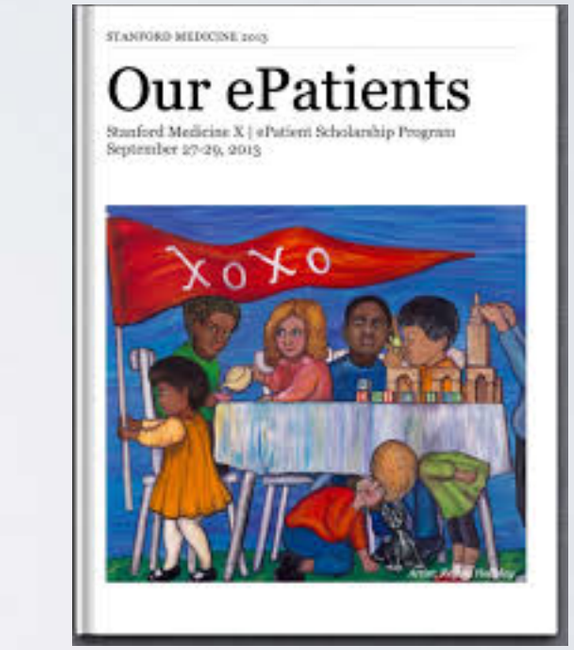
- **Two** failed implants-New York Times September 7, 2012
- No notice from surgeon
- 128,000 St. Jude Riata implanted worldwide
- 20% failure rate

Avery DeGroh

Inspirational !



PROGRESS !


STANFORD MEDICINE 2015
Our ePatients
Stanford Medicine X | ePatient Scholarship Program
September 27-29, 2015
XOXO

goals

UDI - Post-market registry.

Product warranty.

Patient/consumer FDA stakeholder equity.

Rescind industry pre-emptions/entitlements.

FiDA

FAILED Implant Device Alliance

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