

# **Evidence-based Practice And Standards For Medical Devices**

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📷 Jennelle Jeffrey, with son Jose, has decided the defibrillator implant is not worth the risk and has had it removed. Pic: Jamie Hanson

# Medtronic settles suits for \$268M

The cases stem from a 2007 recall of a heart defibrillator wire that shocked some patients.

★ **StarTribune**

By Ji

## Man claims defibrillator fitted in heart is defective

Court has heard doctors believe removing ICD poses greater risk than leaving it there

## FDA says recalled Medtronic guidewires are potentially deadly, deems Class I: Food and Drug recalls

By Brie Zeltner, The Plain Dealer

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on November 18, 2013 at 11:07 AM, updated November 18, 2013 at 3:34 PM

# Jennelle Jernery

David Murray, The Sunday Mail (Qld)

December 3, 2011 6:00am

**The Courier Mail**

# Regulatory Principles

- **Data Transparency and Accessibility**
- **High quality data, according to risk of device**
  - Randomized clinical trial
  - Double-blinded (sham control)
  - Clinically meaningful endpoints
  - Reasonable duration of follow up
- **Safety and effectiveness**
- **Post market data collection – registry, etc.**

- **Systematic review for premarket approval (PMAs) for high-risk cardiovascular devices**
- **Included 123 studies of 78 devices**
- **27% of studies were randomized.**
- **14% were blinded.**
- **Majority of PMAs (65%) were based on a single study.**
- **Populations not representative of actual patients**



# Researchers take on the FDA

JANUARY 7, 2010 BY BRIAN JOHNSON — [LEAVE A COMMENT](#)

It's not often that a few doctors ensconced in the ivy towers of academia can get a lumbering dinosaur like the Food & Drug Administration to turn on a dime, let alone during the week between Christmas and the new year.

But that's exactly what University of California at San Francisco researchers Sanket S. Dhruva, Lisa Bero and Rita Redberg did after the *Journal of the American Medical Assn.* published their paper "[Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices.](#)"



Johnson, B. "Researchers take on the FDA." *Mass Device*. January 7, 2010.

# **FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process**

- **2009 General Accountability Office report**
  - **highest-risk devices are approved, marketed, and used in patients without any clinical trial data**
  - **may increase the risk that unsafe medical devices could remain on the market**

MEDICAL DEVICES: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process. GAO-09-190: Published: Jan 15, 2009.

# Selective reporting in trials of high risk cardiovascular devices: cross sectional comparison between premarket approval summaries and published reports

Lee Chang,<sup>1</sup> Sanket S Dhruva,<sup>2</sup> Janet Chu,<sup>3</sup> Lisa A Bero,<sup>4</sup> Rita F Redberg<sup>5</sup>



- **Review of clinical studies of novel high risk cardiovascular devices receiving PMA**
- **About half (51%) of studies remain unpublished 2+ years after FDA approval**
  - When published, studies sometimes (26 %) differ substantially from FDA summaries
  - Discrepancies in patient population compositions

Chang L, Dhruva SS, Chu J, Bero LA, Redberg RF. Selective reporting in trials of high risk cardiovascular devices: cross sectional comparison between premarket approval summaries and published reports. *BMJ*; 2015; 350:h2613.



# Medical Device Recalls: Get It Right the First Time

## Comment on “Medical Device Recalls and the FDA Approval Process”

Rita F. Redberg, MD, MSc; Sanket S. Dhruva, MD

### ■ High-risk devices are not classified according to their risk for adverse events



- Devices not approved through high risk process subject to high-risk recalls
- Most common category for cardiovascular devices

Redberg RF, Dhruva SS. Medical Device Recalls: Get It Right the First Time. *Arch Intern Med*; 2011; E6-E7.  
Zuckerman DM, Brown P, Nissen SE. Medical Device Recalls and the FDA Approval Process. *Arch Intern Med*; 2011; 171 (11); 1006-1011.

# Postapproval Studies – Small and Slow

- **Postapproval studies (PAS)**
  - **Small sample size**
  - **Mostly prospective cohort studies**
  - **Only 26% completed**
  - **Avg 3 years to complete**

Reynolds IS, Rising JP, Coukell AJ, Paulson KH, Redberg RF. Assessing the Safety and Effectiveness of Devices After US Food and Drug Administration Approval FDA-Mandated Postapproval Studies. *JAMA Intern Med*; 2014; E1-E6.

FDA Ordered Postmarket Studies to Better Understand Safety Issues, and Many Studies Are Ongoing

GAO-15-815; Published: Sep 30, 2015. Publicly Released: Oct 29, 2015.

# WHAT NEEDS TO BE DONE?

# The F.D.A.'s Medical Device Problem

By RITA F. REDBERG and SANKET S. DHURVA JULY 17, 2015

- **Regulatory oversight has not kept pace with increasing complexity of medical device technology**
- **21st Century Cures Act (Dec 2016)**
  - **Allows companies to submit anecdotal instead of scientific evidence**
  - **Shifts burden of evidence to postmarketing**
  - **Subjects millions of Americans to unsafe or untested medical devices**

Redberg RF, Dhruva SS. The F.D.A.'s Medical Device Problem. *New York Times*; July 17, 2015.



# Needed Reforms



- Tainted medical duodenoscopes
- Fixing FDA's postmarketing hampered by lack of government funding
- Medical devices should be monitored similar to prescription drugs:
  - Data-driven approach should be based on insurance claims rather than industry reports
  - Bar codes on devices need to be included on those claims (unique device identifiers)

Terhune C. "Reforming Federal Oversight Of Medical Devices Won't Be Easy." *Kaiser Health News*; February 1, 2016.

# Recommendations

- **FDA approval of high-risk devices should be based on**
  - **high-quality clinical trial data**
  - **effective postmarketing evaluation plan**
- **Quality of studies needs to be improved**
  - **Blinded and randomized controls (shams)**
  - **End points evaluated need to be clinically significant**
  - **Study population needs to represent real patients**

# Recommendations (continued)

- **Postmarket assessment & surveillance**
  - Data should be publicly available
  - Unique device identifier required
  - Registries needed to assess device performance in subgroups
  - Analyze in real time
  - Need longitudinal and long term follow up
- **Balance innovation and safety**
  - Need actual clinical data

**THANK YOU!**

