



Heart Rhythm SocietySM

August 14, 2008

Statement to the FDA Risk Communication Advisory Committee

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No Industry Relationships to Disclose

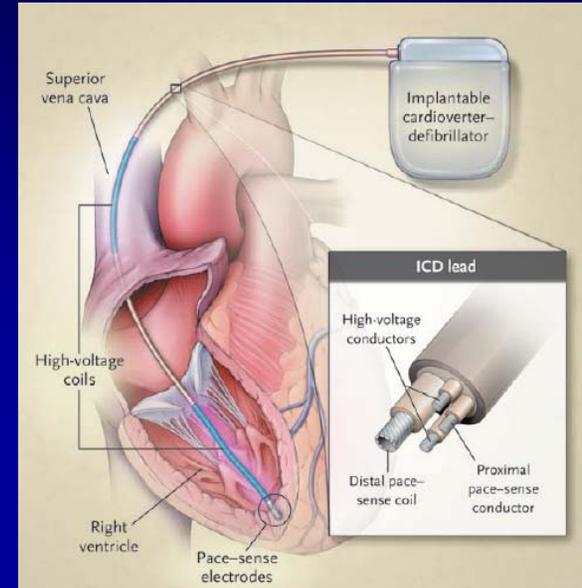
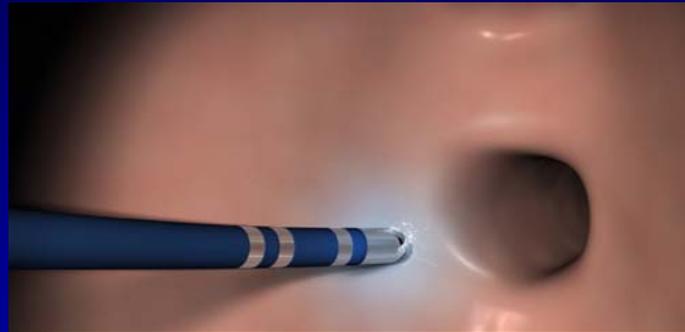
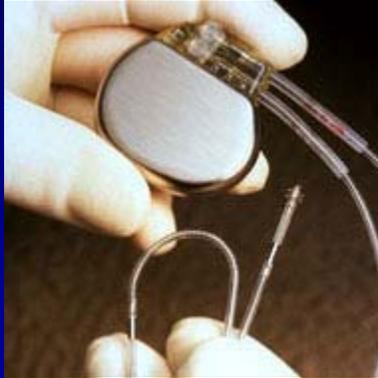
Overview of Comments

- ♥ HRS Background
- ♥ HRS Experience with Product Notifications
- ♥ Why Medical Devices Are Different
- ♥ Terminology For Medical Device Issues
- ♥ Communication
- ♥ Emerging Issues

Heart Rhythm Society

- ♥ International leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders.
- ♥ Represents ~ 5,000 specialists in cardiac pacing and electrophysiology.
- ♥ Arrhythmias are the leading cause of heart disease-related death, with sudden cardiac arrest claiming hundreds of thousands of American lives each year.
- ♥ Millions of additional patients have implanted cardiac rhythm management devices (Pacemakers and Implantable Defibrillators).

Heart Rhythm Society



Tools of Our Trade



William H. Maisel, MD, MPH Images from Google Image Search

Why Devices Are Different

- ♥ May Be Permanent Implant
- ♥ Not Easily Removed
- ♥ Sophisticated Technology
- ♥ Experience “Normal” Wear and Tear

Should Terminology For Medical Devices Be Different?



EXAMPLE:



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Images from Google
Image Search

Communication

Different Meanings for Different Stakeholders

Example: “RECALL”

My device is recalled!



FDA Definition:

A firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers... 21 C.F.R. § 7.1(g).

Communication

Different Meanings for Different Stakeholders

Example: "RECALL"

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FDA Definition:

A firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers... 21 C.F.R. § 7.1(g).

Dictionary.com Definition:

A summons by a manufacturer or other agency for the return of goods or a product already shipped to market or sold to consumers but discovered to be defective, contaminated, unsafe, or the like.

They said I need my device removed!

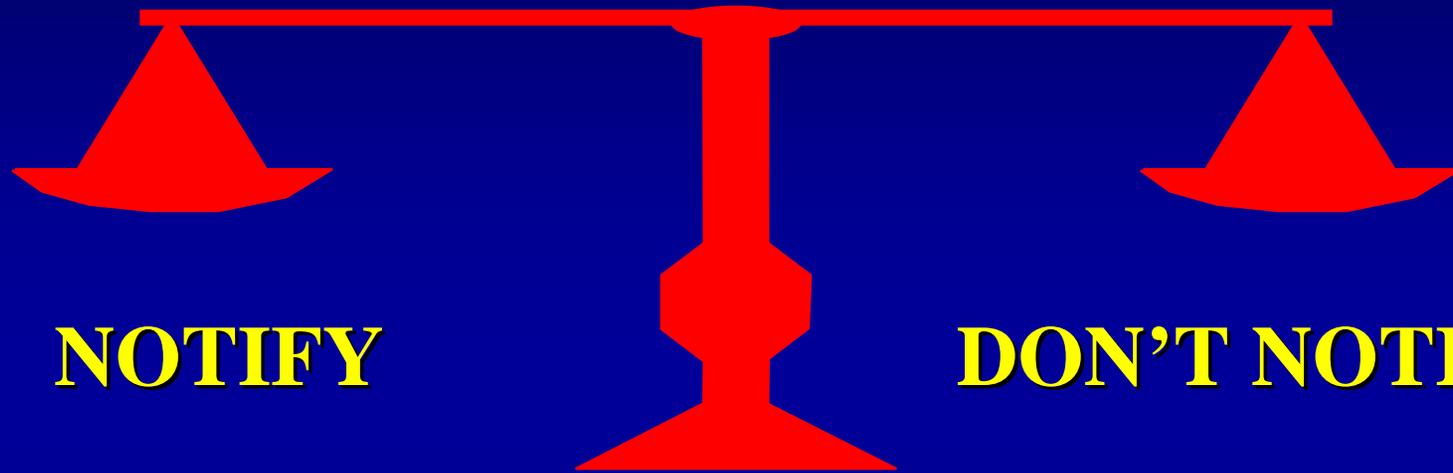


A young child with dark curly hair, wearing a bright yellow t-shirt and a diaper, stands on a sandy beach. The child is holding a long wooden stick vertically, with an orange net attached to the top. The child is standing on a line of sand that has been drawn on the beach. The background is a vast, flat expanse of sand under a clear sky.

**Emerging and
Uncertain Risk**

**Business
as Usual**

Emerging and Uncertain Risk



NOTIFY

DON'T NOTIFY

- ♥ Informed Consent
- ♥ Facilitate Additional Data Collection
- ♥ Accelerate Definitive Answer Regarding Performance Issue
- ♥ May Improve Patient Care

- ♥ Increase Patient Anxiety
- ♥ May Not Turn Out to be True Performance Issue
- ♥ Adverse Impact on Industry
- ♥ May Adversely Affect Patient Care

Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines

October 2006

HeartRhythm

The Official Journal of the Heart Rhythm Society

Recommendations
on Device Performance
page 1250

- ♥ Eliminate the term “recall” in public communications concerning implanted devices
- ♥ Standardized physician and patient communication
- ♥ Direct patient notification after first notifying physicians

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October 2006

HeartRhythm

The Official Journal of the Heart Rhythm Society

Recommendations
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page 1250

Importance of Clinical Recommendations/Perspective

PATIENT MANAGEMENT RECOMMENDATIONS

Verify normal device function (at normal follow-up interval)

Yes

No

Verify normal device function (as soon as possible)

Yes

No

Specific measures to assess:

Programming changes

Required

Recommended

If programming changes are required, specify changes:

Accelerated device follow-up

Yes

No

Timeline - months:

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Emerging and Uncertain Risks

Conclusions

- ♥ Timely, accurate communication is critical.
- ♥ Efforts to standardize and develop terminology by product type (ex: medical devices) to better communicate the intended message should be undertaken.
- ♥ Survey specific audiences (ex: device-dependent patients) to determine which terms best convey the intended message.
- ♥ Professional medical societies can:
 - ♥ Provide clinical perspective
 - ♥ Facilitate delivery of audience-specific messages to educate and inform physicians, patients, and the media



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FDA Risk Communication Advisory Committee

Questions??

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