Medical Device Approval and Product Recalls

Presented by
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Director, Organizational Procurement
Virginia Mason Medical Center
President, WSHMMA
Outline

- Introduction and the Business Environment
- Medical Device Recalls and a Little Bit of History
- More Recent Recall Information
- How Recalls are Discovered at the Facility/Clinic Level
- Recall Management Process
- Questions/Discussion
Where do Recalls Fit in the Triple Aim and CQO?

- Improve the patient experience of care
- Improving the health of populations
- Reducing the per capita cost of healthcare

Cost
CQO
Quality
Outcome
Medical Device Approval and Bringing New Product to Market
From 2001 to 2009 the size of the US medical device industry nearly doubled.

Revenues in the medical device industry grew at a compound annual growth rate of 9%.

Devices in this market have grown increasingly complex and sophisticated.

Reference: Food and Drug Administration Medical Device Recall Report
**FDA Regulatory Approvals**

<table>
<thead>
<tr>
<th>Pre-Market Notification (510K)</th>
<th>Pre-Market Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>“the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA)”</td>
<td>“PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Humanitarian Device Exemption</th>
<th>De novo Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year</td>
<td>option provides an alternate method to classify novel devices of low-moderate risk. Devices classified through the de novo process may be marketed and used as predicates for future 510(k) approvals.</td>
</tr>
</tbody>
</table>
The “Simple” Process

**The path to patients**

Most medical devices are cleared for public use by the U.S. Food and Drug Administration not according to how safe they are but whether they are "substantially equivalent" to devices already on the market.

1. **New device is compared to marketed device**
   - Does the new device have the same indication statement? **NO**
   - Does the new device have the same intended use and may be "substantially equivalent"? **YES**
   - Does the new device have the same technological characteristics (design, materials, etc.)? **NO**
   - Are the descriptive characteristics precise enough to ensure equivalence? **NO**
   - Are performance data available to assess equivalence? **YES**
   - Does the performance data demonstrate equivalence? **NO**
   - The device is not substantially equivalent.

2. **New device has new intended use**
   - Could the new characteristics affect safety or effectiveness? **NO**
   - Do the differences alter the intended therapeutic/diagnostic effect? **YES**
   - The device is not substantially equivalent.

3. **The device is not substantially equivalent.**

4. **The device IS substantially equivalent.**

Source: Food & Drug Administration
The FDA’s standard review speed has improved, especially for devices

The FDA Approval Timeline from 2008-2011

*Estimate as cohort is still open for review
**Drugs includes applications for new drugs and biologics
†Premarket Notification (also known as 510(k) clearance), initiates FDA review to determine if a new device is substantially equivalent to a device already approved. In contrast, Premarket Approval (PMA) is a stricter form of review intended for more complex devices or for devices with no existing equivalent.

Note: Figures represent median review times in months
Source: FY13 FDA PDUFA Performance Report and FY12 FDA MDUFA Performance Report
Concerns with the 510K Approval Process

Promotes development of higher cost items with only small tech improvements

“Substantially equivalent” products released without clinical trials

many devices cleared for use in patients had no clinical data accessible in the literature to support their use

Reference: Food and Drug Administration Medical Device Recall Report
FDA Regulatory Approvals Trends

### 510K Approvals

<table>
<thead>
<tr>
<th>Year</th>
<th>Approvals</th>
</tr>
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<tbody>
<tr>
<td>2001</td>
<td>3,496</td>
</tr>
<tr>
<td>2002</td>
<td>3,689</td>
</tr>
<tr>
<td>2003</td>
<td>3,515</td>
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<tr>
<td>2004</td>
<td>3,372</td>
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<td>2005</td>
<td>3,159</td>
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<td>2006</td>
<td>3,221</td>
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<td>2007</td>
<td>2,962</td>
</tr>
<tr>
<td>2008</td>
<td>3,054</td>
</tr>
<tr>
<td>2009</td>
<td>3,007</td>
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-2% p.a.

### PMA Approvals

<table>
<thead>
<tr>
<th>Year</th>
<th>Approvals</th>
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<tbody>
<tr>
<td>2001</td>
<td>656</td>
</tr>
<tr>
<td>2002</td>
<td>663</td>
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<td>2003</td>
<td>660</td>
</tr>
<tr>
<td>2004</td>
<td>619</td>
</tr>
<tr>
<td>2005</td>
<td>743</td>
</tr>
<tr>
<td>2006</td>
<td>1,079</td>
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<tr>
<td>2007</td>
<td>1,120</td>
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<tr>
<td>2008</td>
<td>1,505</td>
</tr>
<tr>
<td>2009</td>
<td>1,489</td>
</tr>
</tbody>
</table>

+11% p.a.

Reference: Food and Drug Administration Medical Device Recall Report
Medical Device Recalls and a Little Bit of History
Why do Medical Device Recalls Matter

Patients injured in serious adverse events
Number of patients injured

 Patients injured per $billion in medical device spend

Reference: Food and Drug Administration Medical Device Recall Report
Classes of Medical Device Recalls

- **Class I recall**: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

- **Class II recall**: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- **Class III recall**: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
The FDA Recall Process

- The annual average time from firm awareness to recall posting during this time period ranged from 233.7 days to 256.6 days

Reference: Food and Drug Administration Medical Device Recall Report
Medical Device Recalls
FDA Study 2003-2012

Class 1 Recalls:
- 1% of total recalls in 2003
- 5% of total recalls in 2012

Class 2 Recalls:
- More than doubled between 2003 and 2012

Class 3 Recalls:
- Declined by 35% from 2003 to 2012

Reference: Food and Drug Administration Medical Device Recall Report
The most frequent device procodes for Class I recalls were:
1. Pump, Infusion
2. Automated External Defibrillators
3. Ventilator, Continuous
4. System, Test, Blood Glucose
5. Introducer, Catheter
Categorized Recalls

AN- Anesthesiology
CH- Chemistry
CV- Cardiovascular
DE- Dental
EN- Ear, Nose and Throat
GU- Gastro and Urology
HE- Hematology
HO- General Hospital
IM- Immunology
MI- Microbiology
NE- Neurology
OB- OB and Gynecology
OP- Ophthalmic
OR- Orthopedics
PA- Pathology
PM- Physical Medicine
RA- Radiology
SU- General Surgery
TX- Toxicology

Reference: Food and Drug Administration Medical Device Recall Report
Capital market penalties for medical device recalls are not severe and that market reaction to recall announcements is varied in heterogeneous firms

Reference: Food and Drug Administration Medical Device Recall Report
## Root Cause Behind Recalls

Model recalls (case numbers), 2003-2009, N=4,391

<table>
<thead>
<tr>
<th></th>
<th>Design</th>
<th>Suppliers</th>
<th>Manufacturing</th>
<th>Postproduction &amp; change ctrl</th>
<th>Other</th>
<th>Unknown</th>
<th>Total by product attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hardware</strong></td>
<td>15%</td>
<td>12%</td>
<td>2%</td>
<td></td>
<td></td>
<td></td>
<td>29%</td>
</tr>
<tr>
<td><strong>Software</strong></td>
<td>8%</td>
<td></td>
<td>7%</td>
<td></td>
<td></td>
<td></td>
<td>15%</td>
</tr>
<tr>
<td><strong>Labeling</strong></td>
<td>4%</td>
<td></td>
<td>3%</td>
<td>1%</td>
<td></td>
<td></td>
<td>8%</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>1%</td>
<td></td>
<td>3%</td>
<td></td>
<td></td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td>3%</td>
<td>2%</td>
<td>18%</td>
<td>1%</td>
<td></td>
<td></td>
<td>24%</td>
</tr>
<tr>
<td><strong>Regulation</strong></td>
<td></td>
<td></td>
<td></td>
<td>1%</td>
<td></td>
<td></td>
<td>1%</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9%</td>
<td></td>
<td>9%</td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Total by value stream</strong></td>
<td>31%</td>
<td>14%</td>
<td>24%</td>
<td>12%</td>
<td>10%</td>
<td>9%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Reference: Food and Drug Administration Medical Device Recall Report
Manufacturing Causes Related to Medical Device Recalls

- **Design**: 36%
- **Change Control**: 13%
- **Process Control**: 17%
- **Materiel/Component**: 28%
- **Packaging/Labeling**: 6%
More Recent Recall Information
A Breakdown of 2015 Recall Alerts

2015 Total Alerts

- Pharmaceutical Products, 30%
- OR Products, 20%
- Medical Supplies, 11%
- Laboratory Products, 10%
- Food, 4%
- Information Systems, <1%
- Engineering - Facilities, 3%
- Children’s Consumable, <1%
- Blood Products, <1%
- Biomedical Devices, 9%
- Other Supplies, <1%
- Biologics, <1%
- Tissue, <1%
- Radiology Products, 8%
Resources: OpenFDA

Reference: Food and Drug Administration Medical Device Recall Report
How Recalls are Discovered at the Facility/Clinic Level
## Medical Device Recalls

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Recall Class</th>
<th>Recall Date</th>
<th>Recalling Firm</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBS Insight Version V 3.0.1 Product Usage: TBS Insight Is A Medical Device Software That Is Inst...</td>
<td>2</td>
<td>Nov-05-2016</td>
<td>Medimaps Group</td>
</tr>
<tr>
<td>Zimmer® Air Dermatome II Handpiece Loaner, Item Number 01-8851-001-00, Device Is Packaged Inside Of ...</td>
<td>2</td>
<td>Nov-05-2016</td>
<td>Zimmer Surgical Inc</td>
</tr>
<tr>
<td>X-Force Nephrostomy Balloon Dilation Catheter Kit With Inflation Device, PTFE Sheath, 9Mm X 15Cm, ...</td>
<td>2</td>
<td>Nov-04-2016</td>
<td>C.R. Bard, Inc.</td>
</tr>
<tr>
<td>Symbiq One Channel Infuser: An Rx Medical Device Infusion Pump Used To Administer I.V. Fluids, List...</td>
<td>2</td>
<td>Nov-04-2016</td>
<td>Hospira Inc.</td>
</tr>
<tr>
<td>Symbiq Two Channel Infuser: An Rx Medical Device Infusion Pump Used To Administer I.V. Fluids, List...</td>
<td>2</td>
<td>Nov-04-2016</td>
<td>Hospira Inc.</td>
</tr>
<tr>
<td>TANDEM (TM) COCR SHELL UHMWPE LINER BIPOLAR, REF NUMBERS: 71322040, 71322041, 71322042, 7132204...</td>
<td>2</td>
<td>Nov-03-2016</td>
<td>Smith &amp; Nephew, Inc.</td>
</tr>
<tr>
<td>TANDEM (TM) INTL COCR SHELL UHMWPE LINER BIPOLAR, REF NUMBERS: 71324038, 71324039, 71324040, 71...</td>
<td>2</td>
<td>Nov-03-2016</td>
<td>Smith &amp; Nephew, Inc.</td>
</tr>
<tr>
<td>Heater Cooler Unit Usage: The Heater-Cooler Unit (HCU 30) Supplies Temperature-Controlled Water ...</td>
<td>2</td>
<td>Nov-03-2016</td>
<td>Maquet Cardiovascular US Sales, Llc</td>
</tr>
<tr>
<td>Infusion Set: Comfort, 23&quot; Hosp 10, Comfort 13mm, 23&quot;, STD 5/5; Comfort 13mm, 23&quot; Hosp 10; Infusion ...</td>
<td>2</td>
<td>Nov-03-2016</td>
<td>Unomedical As</td>
</tr>
<tr>
<td>Silhouette Paradigm 13mm, 18&quot;; Silhouette 43&quot;; Silhouette 23&quot;; Silhouette Paradigm 43&quot;; Silhouette P...</td>
<td>2</td>
<td>Nov-03-2016</td>
<td>Unomedical As</td>
</tr>
</tbody>
</table>

Reference: Food and Drug Administration Medical Device Recall Report
Company Websites

Cook Medical issues global voluntary recall of catheters with Beacon Tip technology

Cook Medical has initiated a global, voluntary recall of all catheters with Beacon® Tip technology. This recall includes all lots of catheters with the Beacon Tip technology. The catheters were recalled on April 15, 2016 due to complaints of tip splitting and/or fracture. The U.S. Food and Drug Administration (FDA) has not yet classified the recall. A complete list of products affected by this recall can be found below.

Catheters with Beacon Tip technology have been found to exhibit polymer degradation of the catheter tip, resulting in tip fracture and/or separation. Most of the fractures and/or separations were discovered prior to patient contact. The FDA and other regulatory agencies around the world have been notified of this action.

In 2015, Cook recalled specific lot numbers of Beacon Tip catheters and then expanded that recall to all 4 French lots. Due to an increase in complaints about tip splitting and/or fracture, in April 2016 Cook has now recalled all lots and sizes to assure patient safety around the world.

“We’ve been investigating a variety of factors including environmental influences and it’s been difficult for us to reproduce the exact failures that our customers have experienced,” said Pete Yonkman, president of Cook Medical and Cook Group. “If we cannot tell our customers how to keep our products safe, then we aren’t comfortable leaving them on the market. It’s a risk we’re not willing to take. Patient safety comes first – period.”

Reference: Cook Medical Website
Recall Letters (Email or Snail Mail)

April 15, 2016

URGENT: MEDICAL DEVICE RECALL

ATTENTION:
Risk Management / Recall Administration

Our records indicate that you may have received some of the affected products listed below.

Details on affected devices:

<table>
<thead>
<tr>
<th>Product Brand Name</th>
<th>Catalog Identifier*</th>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beacon® Tip Torcon NB® Advantage Catheter</td>
<td>HNBR5.0</td>
<td>All lots</td>
</tr>
<tr>
<td></td>
<td>HNBR6.0</td>
<td></td>
</tr>
<tr>
<td>Beacon® Tip Royal Flush® Plus High-Flow Catheter</td>
<td>HNR5.0</td>
<td>All lots</td>
</tr>
<tr>
<td>Beacon® Tip Centimeter Sizing Catheter,</td>
<td>NR5.0</td>
<td>All lots</td>
</tr>
<tr>
<td>Beacon® Tip White Vessel Sizing Catheter,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference: Cook Medical Website
Recall Management Process
Managing Product Recalls

“The burden of proof that all reasonable efforts have been made to remove the product rest on the recalling firm”
Managing Product Recalls: Policy

Supply Chain
Patient Safety
Clinical Teams
Contracting

Policy
Facility
People
Materiel
Leadership
Process
Training

Standard Work
Communication Plan
Managing Product Recalls: Process

- Receive Notification
- Process Notification
- Identify Recalled Product
- Identify Impacted Patient Populations
- Patient Notification Processes
- Research Alternative Products
- Sequester Product
- Coordinate Return Goods
- Notify Supplier
- Close the Recall Action
Managing Product Recalls: Leadership

Executive Oversight

Committee Responsibility

Policy

Facility

Process

People

Training

Materiel

Leadership

Subject Matter Experts

Patient Safety

Supplier Rep

Clinical Leader

Suppliers

Patient Advocate
Managing Product Recalls: Materiel
Market Solutions: Third Party

### Coordinator General Search Results Detail

<table>
<thead>
<tr>
<th>Accession Number</th>
<th>Priority</th>
<th>Publication Date</th>
<th>Headline/Source/Title</th>
<th>Action Taken</th>
<th>Action Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>A25251</td>
<td>High</td>
<td>10/22/2015</td>
<td>CareFusion—SmartSite Extension Sets May Disconnect and Leak</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

**User Name**: [OR/Surgery] Kristina Cybularz

<table>
<thead>
<tr>
<th>Date</th>
<th>Status</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/23/2015</td>
<td>Viewed</td>
<td></td>
</tr>
<tr>
<td>10/23/2015</td>
<td>Applicable - Closed</td>
<td>Isolated Affected Product</td>
</tr>
</tbody>
</table>

**Action Note**: affected quant:2 lot#1234

**User Name**: [Materials Management] Irina Tracker

<table>
<thead>
<tr>
<th>Date</th>
<th>Status</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/23/2015</td>
<td>Applicable - Closed</td>
<td>Isolated Affected Product</td>
</tr>
</tbody>
</table>

**Action Note**: [Proxy entry recorded by Kristina Cybularz]

**User Name**: [OR/Surgery] Kay Kiss

<table>
<thead>
<tr>
<th>Date</th>
<th>Status</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/23/2015</td>
<td>Applicable - Closed</td>
<td>Isolated Affected Product</td>
</tr>
</tbody>
</table>

**Action Note**: [Proxy entry recorded by Kristina Cybularz]

**User Name**: [Materials Management] Steven Rohs

<table>
<thead>
<tr>
<th>Date</th>
<th>Status</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/23/2015</td>
<td>Applicable - Closed</td>
<td>Isolated Affected Product</td>
</tr>
</tbody>
</table>

**Action Note**: [Proxy entry recorded by Kristina Cybularz]

### Alert Current Status Details

**Status**: Applicable - Open
**Action Taken**: Called Supplier
**Action Notes**: Called supplier at 800-123-4567...

### Alert Tracking

**Status**: Applicable - Closed
**Action Taken**: Isolated Affected Product
**Action Notes**: Isolated 7 boxes of affected tubing from cath lab and returned to mfr. using RA#12345-6-789
Managing Product Recalls: People

- Quality Assurance
- Supplier Quality Engineer
- Customer Relations Manager
- 100’s of other options
Managing Product Recalls: Facility

Recalled product must have a segregated location, that restricts the ability to put product back into the supply flow.
Where Should We Go Now

• Customers pay for expedited shipments, special handling, and similar circumstances... why shouldn’t expenses associated with recalls be passed on to suppliers?

• Clinical decision authorities need to provide a change dynamic that makes repeated recall situations punitive

• Contracts should be drafted that place recalls as a failure to comply and not an exempted occurrence
References


• Cook Medical. 2016. Cook Medical Beacon Tip Catheter Recall. Cook Medical Website. [https://www.cookmedical.com/](https://www.cookmedical.com/)

• ECRI Alerts Tracker 2016. Emergency Care Research Institute Alerts Tracker Presentation


Questions/Discussion