Orthopedic Recalls: the FDA Perspective

Matthew Krueger, M.S.
Chief
Orthopedic and Physical Medicine Devices Branch
Division of Enforcement B
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Presentation Overview

• Regulatory Background on Recalls
• Orthopedic Recall Analysis
• Case for Quality
• Questions
Regulatory Background on Recalls

• Regulations on Device Recalls
  – 21 CFR 806: Reports of Corrections and Removals
    • Requirements for firms conducting a Correction or Removal (a Recall)
  – 21 CFR 7: Enforcement Policy
    • Subpart C: Recalls – Guidance on Policy, Procedures, and Industry Responsibilities
    • Parts 7.40 through Part 7.59
What is a Recall?

• A recall is an action taken by a firm to:
  – Reduce a risk to health posed by the device 
or
  – Remedy a violation of the act caused by the 
device
(21 CFR 7.40)
How Recalls areHandled

- Almost all recalls are initiated by a firm voluntarily
- Firms determine a correction or removal is needed
- Firms notify consignees and the FDA District Office
  - Each district has a Recall Coordinator
- District Recall Coordinator gathers information and sends to CDRH
- CDRH Office of Compliance reviews and classifies the recall
- District works with firm to ensure the recall is completed
The Districts and the Center

• District’s Role
  – Know and interact closely with the firm’s in their district
  – Ensure compliance and serve as a “local” resource

• Center’s Role
  – Serve as the device experts
    • Know the technical and clinical specifics of the devices
    • Know the device specific regulations

• Two tiered approach offers local contacts as well as technical expertise
Center Activities in Reviewing Recalls

• Review the Recall Strategy
  – Firm’s plan for recovering violative product
  – Firm’s plan for communicating with consignees to ensure the risks are communicated and mitigated
    • May include letters to distributors, doctors, patients, and press releases
  – Firm’s plan for addressing the issues resulting in the recall

• Assign a Classification based on Risk
  – Class I (highest), Class II, or Class III (lowest)
Perspective on Orthopedic Recalls

• A review of orthopedic recalls for the time period of Calendar years 2007 to 2011
• Focus on 4 common types of recalls
  – Mislabeled Devices/Instruments
  – Fracturing
  – Sterilization
  – Out of Specification
Why Focus on 4 Specific Types?

• Represent a significant number of the recalls conducted
• The device problems causing the recalls are similar
• We believe that reducing the number of recalls for these problems is an achievable goal
Orthopedic Five Year Recall Data: 2007-2011
578 Total Recalls

- Other Recalls: 237 (41%)
- Mislabeled: 137 (24%)
- Specification: 110 (19%)
- Sterilization: 51 (9%)
- Fracture: 43 (7%)
Results

• Percentage for each Recall Issue
  – Mislabeled 24%
  – Specification 19%
  – Sterilization 7%
  – Fracture 9%
Results: Mislabeled Devices

<table>
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<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
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<td>Mislabeled Percents</td>
<td>22</td>
<td>31</td>
<td>26</td>
<td>19</td>
<td>20</td>
</tr>
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Results: Firm Example

Firm's Five Year Recall Data: 2007-2011
75 Total Recalls

- **19** (26%) Mislabeled
- **18** (24%) Specification
- **18** (24%) Sterilization
- **13** (17%) Fracture
- **7** (9%) Other Recalls

Total Recalls: 75

Data: 2007-2011
Common Themes

• Over 50% of all Orthopedic Recalls in the years 2007-2011 were due to manufacturing errors.
• These numbers are not being driven by “smaller” or “less experienced” firms.
• Individual firms are seeing much of the same distribution of types of recalls within their own companies, whether large or small.
Limitations

• Somewhat subjective data analysis
  – Recalls that cross multiple fields i.e. Mislabeled Sterilization
  – Recalls hard to specifically categorize

• High level analysis
  – What can we take away from this type of recall analysis?
Recurring Recall Causes

• Recurring patterns:
  – Within firms
    • Same or similar product requiring multiple recalls
  – Between firms
    • Patterns across manufacturers
Working Towards a Common Goal

- Reducing the number of errors requiring recalls benefits everyone!
  - Manufacturers
    - Less time and money spent mitigating defective product
    - Better Reputation for a Reliable and Quality Products
  - Patients
    - Less concern about getting a device and its longevity
  - Doctors
    - Fewer complications intra-operatively and post-operatively
  - FDA
    - Public gets quality devices
    - Fewer recalls to review and classify
Identifying the Cause of Recalls

• Working with Manufacturers to help identify the Underlying Recall Cause (a.k.a. Root Cause)
  – Asking manufacturers to provide information on their determination of the fundamental cause of the defect.
    • Allows us to understand where problems arise
    • Allows us to understand why similar issues continue to recur
    • Do firms really address the fundamental cause?
      – Example: Do these recalls result from human errors or a failure of the process to ensure product is not defective by catching defects before product is distributed?
Identifying the Cause of Recalls
(Continued - 2)

• Firms should be asking:
  – What is the defect?
  – What is the primary cause?
  – Is this the most fundamental cause possible and if not what allowed this primary cause to occur?
• Example: Operator error may have resulted in defective product, but what happened that resulted in the operator making that error and why didn’t quality checks catch the defective product?
Identifying the Cause of Recalls
(Continued - 3)

• OPMD Branch is gathering data on the underlying recall cause
  – To help both FDA and industry understand where the problems occur
  – To ensure the real cause is being identified and addressed
  – To develop ways to catch and address these defects before they result in defective product that must be recalled
The Case for Quality

- Support and ownership of quality go beyond quality/compliance units

- A culture of quality yields benefits:
  - Enhanced process stability
  - Cross-functional skills and collaboration
  - Reduced compliance risks and costs
  - Fewer complaints and investigations

- Recent trends highlight the importance of quality:
  - Rapid growth of the U.S. device industry
  - Adverse event reports outpace market growth
  - Risks are unevenly distributed across product types
  - Design failures consistently account for about ½ of all recalls
Case for Quality: GOALS

- **Focus on quality**
  - Enhance focus on quality while maintaining compliance

- **Enhanced transparency**
  - Data transparency:
    - Drive quality by *improving ease of access to information*
    - Provide *one integrated data source* that affords maximum flexibility
  - Improved analyses:
    - *Leverage wealth of Agency data* to refine FDA’s initiatives
    - Provide *consistent and regular publically available analyses* that will guide compliance and quality discussion

- **Stakeholder engagement**
  - Forums to explore with stakeholders issues that will arise during our transition to a more quality-focused approach
  - Collaboration beyond these forums
Imports of devices have risen dramatically

Import lines per center

- Foods
- Devices and electronic products
- Drugs
- Veterinary medicine
- Biologics

Imports have increased by +365%.
The number of inspections with OAI outcomes has remained high, with frequent recurrences

We are consistently seeing a high volume of the same issues.

Are we using the right methods to improve device quality?
# Initial Activities

## Subprojects

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<th>Subprojects</th>
<th>Description</th>
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| **Focus on Quality**         | • Engaged internal/external stakeholders in 2012 to assess perceived quality/compliance gap  
• including forums and interviews  
• Identification of methods that can be utilized by both FDA and industry to promote a focus on quality, not merely compliance |
| **Data Transparency**        | • Developed concepts that identify and share maximum amount of data and work products for public to conduct effective analyses of medical device availability, quality and safety.  
• Obtaining feedback on concepts at forums |
| **Stakeholder Engagement**   | • Convened multiple local and national forums in 2012 - more scheduled for 2013                                                             |
Questions?

Matthew.Krueger@fda.hhs.gov
Phone: 301.796.5585