Using Recall Data to Assess the 510(k) Process

Ralph F. Hall
Distinguished Professor and Practitioner
University of Minnesota Law School
July 28, 2010
Acknowledgments

Kauffman Foundation
- Grant support
- Academic independence

University of Minnesota Law School
- Additional support and encouragement

Research Assistants
- Mark Jones
- Amanda Maccoux
- Ron Song
- Chris Walker
## Disclosures

| University of Minnesota Law School | • Distinguished Professor and Practitioner  
|                                 | • Supported in part by NSF and NIH Grants |
| 510(k) research supported by Kauffman Foundation | • Complete academic freedom |
| Part time Counsel – Baker & Daniels | • Advise clients on FDA regulatory matters including 510(k) submissions and reform, PMA issues and regulatory policy issues |
| CEO – MR3 Medical LLC | • Start up medical device company  
|                                 | • Probably PMA pathway if product successful |
Agenda

I. Research questions

II. Research Methodology
   A. Why examine recalls
      1) Issues with other data sources
   B. Description of Research
   C. Strengths and limitations

III. Data results
   A. 510(k) and PMA products
   B. Analysis of sub populations

IV. Conclusions and open questions
510(k) Research Challenge
Avoiding “Ready, Fire, Aim”

- 510(k) system subject to substantial criticism
- However, no systemic data exists assessing whether the system is working
  - Many anecdotes exist on all sides
- Changes should address real issues, not opinions
- Research needed to assess FDA’s performance in clearing 510(k) devices
- Is FDA clearing unsafe products?
Specific Research Questions

Does the 510(k) review system permit products onto the market without a “reasonable assurance of safety and effectiveness”?

- Key question
- Does FDA make the “right” safety decision in product clearances?

Are there areas or concentrations of issues?

Do specific parts of the 510(k) process lead to greater or lesser risk?
Unaddressed Research Issues

Impact of 510(k) system on innovation
- Development of new ideas
- Ability to fund new ideas
- Testing and review challenges
- Review issues

Administrative and process issues
- Timeliness
- Review processes
- Certainty and transparency

Impact of slow or uncertain reviews on patients
Methodology
Methodology

Review all Class I recalls for 5 year period

- Calendar years 2005-2009
- Class I recalls represent highest safety risk
- FDA, not industry, determines classification
- Substantial data available

Recalls identify new issues or problems

- All devices have risks that should be balanced with product benefit at approval/clearance
- Using recalls eliminates known and accepted risks from the assessment
Key Methodology Observations

- While not perfect, Class I recalls provide best safety related performance measure of the 510(k) system
  - Mandatory reporting
  - FDA oversight
  - Permits one to separate review issues from non-review issues

- MDR data not a good tool
  - Reports include known risks
  - Highly variable reporting rates
  - Inaccurate and unconnected events reported
  - No quality control or confirmation
  - MDRs are anecdotal reports

- Number of products involved in recall not useful
  - No denominator
  - Can’t separate single and multiple use products
  - Can’t determine actual failure rate or rate of actual harm
  - Includes non-defective products
Why Use Class I Recalls?

- Class I recalls represent FDA’s view of serious safety issues
  - “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.”
  - Includes risks of death
  - Includes issues with less than 1% risk of failure

- Class II represents temporary or reversible medical issues or remote risks

- Class III – no safety issues

- FDA assigns recall class
Methodology

Key Data Sources

FDA data bases
- Recall database
- 510(k) and PMA databases
- Product classification
- New TPLC database

2009 GAO Report and related materials

Ancillary internet searches

Several calls to companies and FDA
Methodology and Data

474 total recalls identified
- Used date listed on FDA recall

Multiple records for one event
- Different sizes, model numbers or trade names

Consolidated multiple records into one

118 unique Class I recalls

Coded all recalls
- Data tied to FDA records
- Data audited and confirmed
Methodology and Data

Data collection system established

- Coding forms and instructions
- RA training
- “Beta” coding test
- PI oversight and review of coding decisions
- PI decision on reason for recall

Data entered and checked
Methodology

Data coded included:

- Product name
- Recall date
- Approval/clearance pathway
  - PMA
    - Type of sPMA
    - 510(k)
      - Traditional
      - Abbreviated
      - Special
- Implantable
- Reason for recall
- Product class (I, II or III)
- CFR section and subsection
- Third party review
- 3 letter product code
- Medical specialty
- Dates
- Reported deaths

Reported deaths: 15
Methodology

Recalls are caused by one of three broad root causes

- Premarket issues
- Post-market issues
- Miscellaneous actions often by unrelated third parties
  - Counterfeit products
  - "Quack devices"

Robustness of FDA review process relates only to the first set of issues

Need to determine root cause as initial analysis step
Methodology

13 categories for reason for recall

- Premarket issues
  - Design issues
  - Clinical data gaps

- Post-market issues
  - Manufacturing issues
  - Labeling mistakes
  - Sterilization issues

- Miscellaneous
  - Counterfeits and quacks

PI reviewed and assigned all reasons for recalls

Blind review of 10% of recalls
Challenges to Methodology

- Data from FDA data bases used – assumed accuracy of FDA data
  - Sampling supported FDA data
- There may be “missing” recalls
  - Violation of law
  - Probably aren’t major events
- Emphasis on Class I recalls
- Use of FDA’s recall classification as the risk assessment
  - Consistency of FDA determinations
Data Overview

118 unique Class I recalls

- 6 counterfeit/quack recalls

112 core recalls

- Most recalls were initiated in the 2005-2009 period
- 4 were initiated earlier but not entered by FDA until 2005-09
- Average of 22.4 Class I recalls per year
  - 50,000+ listed devices (2009 GAO Report)
  - 0.2% recall rate over 5 years

Adequate data available on vast majority of all recalls

Data from FDA databases used – assumed accuracy of FDA data

- Sampling supported FDA data
### Date Recall Conducted

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>1</td>
</tr>
<tr>
<td>2003</td>
<td>1</td>
</tr>
<tr>
<td>2004</td>
<td>2</td>
</tr>
<tr>
<td>2005</td>
<td>27</td>
</tr>
<tr>
<td>2006</td>
<td>16</td>
</tr>
<tr>
<td>2007</td>
<td>23</td>
</tr>
<tr>
<td>2008</td>
<td>13</td>
</tr>
<tr>
<td>2009</td>
<td>35</td>
</tr>
</tbody>
</table>

Occasional delays in posting recall

Vast majority of recalls (96.6%) occurred within 5 year data period

A few 2008 or 2009 recalls may not have been posted

Any such timing differences should be irrelevant to analysis
Causes of Recall Critical

510(k) system can only be expected to prevent “premarket” issues

Post-market issues such as manufacturing errors are a separate issue

Any assessment of the correctness of 510(k) clearance decisions or robustness of 510(k) system should look at premarket issues only
## Primary Reason for Recall

(N = 118)

<table>
<thead>
<tr>
<th>Primary Reason for Recall</th>
<th>PMA</th>
<th>510K</th>
<th>Class 1</th>
<th>Other or Unknown</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing</td>
<td>6</td>
<td>31</td>
<td>2</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>Labeling Error</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Design Issue</td>
<td>6</td>
<td>25</td>
<td>1</td>
<td>0</td>
<td>32</td>
</tr>
<tr>
<td>Software Design</td>
<td>1</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Software Manuf. Failure</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Supplier Issue</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Failure to Identify Clinical Risk</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Failure to Warn/Inadequate Instructions</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Missing Parts</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sterilization</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Regulatory Violation</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Packaging/Handling</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other (Counterfeit, Sham)</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
</tbody>
</table>
# Recalls by Approval Pathway and Recall Reason (n=118)

<table>
<thead>
<tr>
<th>Approval Pathway</th>
<th>Total Recalls</th>
<th>Recalls for Pre-Market Issues</th>
<th>Recalled for Post-Market Issues</th>
<th>Recalled for Other Issues</th>
<th>Percent of Recalls to Total Recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I or u/k</td>
<td>7</td>
<td>1 (14.2%)</td>
<td>6 (85.7%)</td>
<td>0 (0%)</td>
<td>5.9%</td>
</tr>
<tr>
<td>510(k)</td>
<td>95</td>
<td>43 (45.3%)</td>
<td>46 (48.4%)</td>
<td>6 (6.3%)</td>
<td>80.5%</td>
</tr>
<tr>
<td>PMA</td>
<td>16</td>
<td>7 (43.8%)</td>
<td>9 (56.3%)</td>
<td>0 (0%)</td>
<td>13.56%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>118</td>
<td>51</td>
<td>61</td>
<td>6</td>
<td>118</td>
</tr>
</tbody>
</table>
Essentially 45% of Recalls Relate to Premarket Issues

Percentage of Recalls Relating to "Pre-Market" Issues
(Excludes Counterfeit & 'Sham' Products n=112)
Key Observations

- 55% of recalls relate to post market issues
  - Premarket review systems irrelevant to these issues
- Design issues (including software design) are the major cause of premarket issues
  - ~75-80% of 510(k) premarket recalls are design issues
- Role of QSR (design controls, etc.) is critical
- Role of bench testing and design controls to identify design issues without endangering patients is important
  - Let’s avoid human experimentation whenever possible
- Improving QSR related design control and validation could have a substantial positive effect
Observations

- No recalls identified relating to newly discovered clinical risks
  - Inadequate labeling may be a surrogate description of newly discovered risks but also includes human factor issues
    - Note no PMA labeling recalls identified
  - Approximately 7% of recalls for any such reason

- Major difference compared to pharmaceutical recalls
- Human clinical trials often used to identify clinical risks

- Would additional human clinical studies have a significant impact on Class I safety recalls?
  - This data indicates very little impact
Observations

- Supplier issues appear to be a smaller issue than I would have guessed
  - Are supplier issues “buried” in manufacturing issues?
  - Software issues are real but concentrated in a smaller subset of products
- No Class I recalls for handling, packaging, content issues
- Relatively few label mix-up issues rise to Class I significance
- Should human clinical trials be the preferred system for identifying design issues?
  - Bench testing and design controls seem better approach
Recall Rates

The absolute number of recalls is just one measure of how effective FDA is in its premarket assessments.

To broadly assess the robustness of FDA’s review, one must look at the rate of recalls compared to submissions.

Submissions, not approvals/clearances, is the best measure of the robustness of FDA’s processes as it includes situations in which the product was not cleared for market – thus eliminating any safety risk.
Caveats

- Finding an exact denominator is impossible as there is no precise time relationship between submission, clearance and initiation of a recall.
- These calculations use average submission rates – they are close but not exact.
  - Looked at data over 10 years, created a one year average and multiplied by 5.
- Submission data is the best comparator.
- Using related data approaches (5 year average, 2005-2009 actual, etc.) yields similar results.
Total 510(k) Approvals in 10 years: 39,747
Average Submissions in 5 year time period: 19,873
Total 510(k) Recalls for 2005-2009: 89
Total 510(k) Recalls for Pre-Market Issues for 2005-2009: 43

Very Few 510(k) Clearances Have Been Subject to a Class I Recall

Total 510(k) Recalls for the Last 5 Years (2005-2009)

- 0.45% (89/19,873) Recalled
- 99.55% (19,784/19,873) Not Recalled
- 0.22% (43/19,873) Recalled for Pre-Market Issues
- 99.78% (19,830/19,873) Not Recalled

(Chart showing percentage and counts of recalls and non-recalls over the 5-year period.)
Observations

99.78% of 510(k) submissions do not result in a Class I (safety) recall due to premarket issues.

- Majority of 510(k) Class I recalls are due to postmarket issues:
  - 55% overall
  - Role of QSR important

Design issues are the predominate reason for premarket recalls.

Given the need to balance safety and access and the inability to be all knowing, can one expect more?
Some Interesting Comparisons

2.3% of Medicare hospitalizations result in a patient safety event

- Approximately 99,000 deaths per year

2-4% risk of hospital acquired infection

- [http://www.ahrq.gov/qual/nhdr09/Chap2c.htm#safety](http://www.ahrq.gov/qual/nhdr09/Chap2c.htm#safety)
- [http://www.cdc.gov/mmwr/preview/mmwrhtml/00001772.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00001772.htm)

15+% of patients over 65 receive a potentially unsafe prescription

- [http://www.ahrq.gov/qual/nhdr09/Chap2c.htm#safety](http://www.ahrq.gov/qual/nhdr09/Chap2c.htm#safety)

0.22%/0.45% recall rate for 510(k) clearances (many of which do not negatively affect a patient)
Approximate Submission Percentages

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional</td>
<td>77%</td>
</tr>
<tr>
<td>Abbreviated</td>
<td>4%</td>
</tr>
<tr>
<td>Special</td>
<td>18%</td>
</tr>
</tbody>
</table>

Note 4% abbreviated submissions but 5.7% of recalls. Not statistical but interesting.
PMA/sPMA Approvals have a Similar Pattern

Pre-Market Recalls 0.12% 7
Other Recalls 0.16% 9
Not Recalled 99.71% 5,594
TOTAL 5,610

PMA/SPMA Recalls for 5 Year Period
2005-2009

Recalled for Pre-Market Issues
Recalled for Other Issues

Recalled for Pre-Market Issues 43.75% (7/16)
Recalled for Other Issues 56.25% (9/16)

University of Minnesota Law School
Observations

- PMA data very similar to 510(k) data
- Larger relative denominator as more changes subject to sPMA filing than 510(k) filing
  - “Could effect” vs. “could substantially effect” standard
- Does additional review under the PMA system provide same level of protection for these higher risk products?
- Do all parts of the PMA submission add to safety assessment?
Logically, PMA products account for a disproportionate number of Class I recalls. Similarly, exempt products are rarely the subject of recalls.
## Subtypes of sPMAs

<table>
<thead>
<tr>
<th>PMA Recalls for Changes Being Effected (CBE)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recalled for Pre-Market Issues</td>
<td>3</td>
</tr>
<tr>
<td>Recalled for Post-Market Issues</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PMA Recalls for Manufacturing Changes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recalled for Pre-Market Issues</td>
<td>2</td>
</tr>
<tr>
<td>Recalled for Post-Market Issues</td>
<td>0</td>
</tr>
</tbody>
</table>
## Do Particular Device Types Pose Greater Risk?

<table>
<thead>
<tr>
<th>CFR Section</th>
<th>Total</th>
<th>Recalled for Pre-Market Issues</th>
<th>Recalled for Post-Market Issues</th>
<th>% of Pre-Market Recall Issues to Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>862</td>
<td>8</td>
<td>2</td>
<td>6</td>
<td>25.00%</td>
</tr>
<tr>
<td>864</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0.00%</td>
</tr>
<tr>
<td>866</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>0.00%</td>
</tr>
<tr>
<td>868</td>
<td>11</td>
<td>4</td>
<td>7</td>
<td>36.36%</td>
</tr>
<tr>
<td>870</td>
<td>32</td>
<td>18</td>
<td>14</td>
<td>56.25%</td>
</tr>
<tr>
<td>872</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0.00%</td>
</tr>
<tr>
<td>874</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>876</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>80.00%</td>
</tr>
<tr>
<td>878</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>75.00%</td>
</tr>
<tr>
<td>880</td>
<td>30</td>
<td>16</td>
<td>14</td>
<td>53.33%</td>
</tr>
<tr>
<td>882</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>25.00%</td>
</tr>
<tr>
<td>884</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>886</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>33.33%</td>
</tr>
<tr>
<td>888</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>66.67%</td>
</tr>
<tr>
<td>890</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.00%</td>
</tr>
<tr>
<td>892</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.00%</td>
</tr>
<tr>
<td>N/A</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.00%</td>
</tr>
</tbody>
</table>
Observations

- Bolus of recalls in cardiovascular (21 CFR 870) and general hospital and personal use (21 CFR 880 – a more “catch-all” category)
  - Higher rate of premarket issues than average
  - More complex devices
- Lesser concentrations in clinical chemistry and anesthesiology
- Scattering of recalls across other categories
  - No other significant patterns
Observations

- Remarkable few Class I orthopedic recalls
  - Implantable, chronic devices
- No ob/gyn recalls
  - High risk, high profile devices
- Remarkably few Class I recalls for radiology devices
  - High profile products
- Does this data support the need for a fourth device classification?
## Analyzing Recalls by Medical Specialty Demonstrates Same Pattern

<table>
<thead>
<tr>
<th>Medical Specialty</th>
<th>Total</th>
<th>Recalled for Pre-Market Issues</th>
<th>Recalled for Post-Market Issues</th>
<th>% Recalled for Pre-Market Issues to Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiology</td>
<td>11</td>
<td>3</td>
<td>8</td>
<td>27.27%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>33</td>
<td>18</td>
<td>15</td>
<td>54.55%</td>
</tr>
<tr>
<td>Clinical Chemistry</td>
<td>8</td>
<td>2</td>
<td>6</td>
<td>25.00%</td>
</tr>
<tr>
<td>Dental</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0.00%</td>
</tr>
<tr>
<td>Gastroenterology / Urology</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>100.00%</td>
</tr>
<tr>
<td>General &amp; Plastic Surgery</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>60.00%</td>
</tr>
<tr>
<td>General Hospital</td>
<td>30</td>
<td>17</td>
<td>13</td>
<td>56.67%</td>
</tr>
<tr>
<td>Hematology</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0.00%</td>
</tr>
<tr>
<td>Microbiology</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0.00%</td>
</tr>
<tr>
<td>Neurology</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>25.00%</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>25.00%</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>66.67%</td>
</tr>
<tr>
<td>Physical Medicine</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.00%</td>
</tr>
<tr>
<td>Radiology</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.00%</td>
</tr>
<tr>
<td>N/A</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.00%</td>
</tr>
</tbody>
</table>
Recalls by Medical Specialty, Percentage of Recalls for Pre-Market Issues

n=112

- Recalled for Post-Market Issues
- Recalled for Pre-Market Issues

<table>
<thead>
<tr>
<th>Medical Specialty</th>
<th>Post-Market</th>
<th>Pre-Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiology</td>
<td>37.27%</td>
<td>54.55%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>25%</td>
<td>100%</td>
</tr>
<tr>
<td>Clinical Chemistry</td>
<td>6%</td>
<td>25%</td>
</tr>
<tr>
<td>Dermatology/Oncology</td>
<td>100%</td>
<td>60%</td>
</tr>
<tr>
<td>General Hospital</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Hematology</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Microbiology</td>
<td>0%</td>
<td>25%</td>
</tr>
<tr>
<td>Neurology</td>
<td>0%</td>
<td>25%</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>25%</td>
<td>66.67%</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Physical Medicine</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Radiology</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medical Speciality
## Looking by specific device type shows concentrations

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Number of Recalls Within the Device Category</th>
<th>Number of Recalls for Pre-Market Issues</th>
<th>Percentage of Recalls for Pre-Market Issues</th>
<th>Percentage of Category Recalls to Total Recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>AED</td>
<td>12</td>
<td>6</td>
<td>50.0%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>11</td>
<td>3</td>
<td>27.3%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Blood Glucose System</td>
<td>3</td>
<td>2</td>
<td>66.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>9</td>
<td>5</td>
<td>55.6%</td>
<td>7.6%</td>
</tr>
<tr>
<td>Catheter</td>
<td>11</td>
<td>5</td>
<td>45.5%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Clinical Chemistry</td>
<td>5</td>
<td>0</td>
<td>0.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Dental</td>
<td>2</td>
<td>0</td>
<td>0.0%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Gastroenterology/Urology</td>
<td>4</td>
<td>4</td>
<td>100.0%</td>
<td>3.4%</td>
</tr>
<tr>
<td>General and Plastic Surgery</td>
<td>5</td>
<td>3</td>
<td>60.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>General Hospital</td>
<td>7</td>
<td>6</td>
<td>85.7%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Glucose Test Strips</td>
<td>5</td>
<td>0</td>
<td>0.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Hematology</td>
<td>2</td>
<td>0</td>
<td>0.0%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Infusion Pump</td>
<td>21</td>
<td>11</td>
<td>52.4%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Microbiology</td>
<td>3</td>
<td>0</td>
<td>0.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Neurology</td>
<td>3</td>
<td>0</td>
<td>0.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>4</td>
<td>1</td>
<td>25.0%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>3</td>
<td>2</td>
<td>66.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>5</td>
<td>3</td>
<td>60.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Physical Medicine Devices</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Radiology</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Sham Device</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>
Looking by specific device type shows concentrations

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Number of Recalls Within the Device Category</th>
<th>Number of Recalls for Pre-Market Issues</th>
<th>Percentage of Recalls for Pre-Market Issues</th>
<th>Percentage of Category Recalls to Total Recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>AED</td>
<td>12</td>
<td>6</td>
<td>50.0%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>11</td>
<td>3</td>
<td>27.3%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Blood Glucose System</td>
<td>3</td>
<td>2</td>
<td>66.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>9</td>
<td>5</td>
<td>55.6%</td>
<td>7.6%</td>
</tr>
<tr>
<td>Catheter</td>
<td>11</td>
<td>5</td>
<td>45.5%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Clinical Chemistry</td>
<td>5</td>
<td>0</td>
<td>0.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Dental</td>
<td>2</td>
<td>0</td>
<td>0.0%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Gastroenterology/Urology</td>
<td>4</td>
<td>4</td>
<td>100.0%</td>
<td>3.4%</td>
</tr>
<tr>
<td>General and Plastic Surgery</td>
<td>5</td>
<td>3</td>
<td>60.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>General Hospital</td>
<td>7</td>
<td>6</td>
<td>85.7%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Glucose Test Strips</td>
<td>5</td>
<td>0</td>
<td>0.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Hematology</td>
<td>2</td>
<td>0</td>
<td>0.0%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Infusion Pump</td>
<td>21</td>
<td>11</td>
<td>52.4%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Microbiology</td>
<td>3</td>
<td>0</td>
<td>0.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Neurology</td>
<td>3</td>
<td>0</td>
<td>0.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>4</td>
<td>1</td>
<td>25.0%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>3</td>
<td>2</td>
<td>66.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>5</td>
<td>3</td>
<td>60.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Physical Medicine Devices</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Radiology</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Sham Device</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>
Observations

- Two product types – AEDs and infusion pumps – account for 28% of all recalls
- Five product types account for 54.2% of all recalls
- Are product type specific guidances, special controls, etc. the appropriate response?
  - FDA’s current infusion pump initiative is consistent with this data
  - Note, however, the somewhat higher rate of recalls for abbreviated 510(k)s
- Detailed root cause investigation of these product types may be warranted
Excluding AEDs and infusion pumps doesn’t change the ratio of premarket issues.
22% of products are implantable

Data is essentially what would be expected

Recalls of Implantable vs. Non-Implantable Devices
(Excluding counterfeit products, n = 112)
3rd Party Review System not Linked to Recalls

Third Party Review

- % of 510(k)s Reviewed by Third Parties: 8%
- Total % of Third Party Reviewed Products Recalled: 3.4%
- % of Third Party Review Products Recalled for Pre-Market Issues: 1.1%
Conclusions and Open Questions
Introductory Thoughts

- Opinions are mine alone
- Research did not address other key issues
  - Patient access/autonomy
  - Innovation
  - Cost
  - Administrative issues
- Strong desire to make changes based on data
  - “Ready, fire, aim” never works
  - Changes can have a negative effect
  - Avoid policy by anecdote
- No one can deny that there have been at least some meaningful safety recalls
Key Conclusions

- Based on Class I (safety) recalls, FDA has an excellent record
  - ~99.8% of product submissions did not experience a Class I recall in a 5 year period

- Is ~99.8% “correct” decisions a mark of success or failure?
  - It can never be -0-
  - Personally, I’m fairly impressed

- Importance of QSR
  - Probably much more important than additional human testing
Other Conclusions

öst Majority (55%) of recalls are due to post-market issues
öst Issues exist with certain product types (AEDs and infusion pumps)
  ─ Product specific “rules” may be the answer
  ─ Up classification?
  ─ Ongoing review need of recall patterns
öst Benefit of ongoing review of recalls
  ─ Early identification and intervention for problem product types
Other Conclusions

- Additional human testing pre clearance would seem to be of limited value
  - Few undiscovered clinical issues
  - Different than pharma issues
  - Role of human factors

- Design controls, bench testing and preclinical studies would appear to be more effective and more ethical

- Hard to determine whether pre-clearance inspections would add meaningful data
  - Additional issue regarding resources and time

- Implantable devices seem to operate as predicted
Other Conclusions

- PMA and 510(k) systems seem to yield similar results
- Many product types have few or no recalls
  - Concentration in AEDs and infusion pumps
- Hard to define a logical “4th class” of devices based on safety needs
  - Orthopedics is often the example but very few recalls of orthopedic products
- Data supports importance of QSR systems
  - Design controls
  - Manufacturing controls
- Third party review system seems to work
Open Questions

- What role, if any, did post market surveillance have in identifying recall needs
  - What aspects of post market surveillance have the greatest impact?

- What are the true root causes of these safety recalls?
  - What lessons for submissions drive AEDs and infusion pumps recalls
  - Human factors?
  - Complexity?

- Potential impact of 510(k) changes
  - FDA resources and time
  - Will added burden of changes have a proportional benefit on safety
  - Impact on access
Open Questions

- Date relationship between events
- What parts of submissions make a difference?
  - E.g. does the manufacturing section of a PMA improve safety decisions?
- What role did multiple or split predicates have in recall situations?
- Hard to link a premarket issue to the first 510(k) or specific PMA/sPMA
  - Additional detail here would be interesting
  - Are we (FDA, industry, HCPs) learning from past events?
Questions or Comments?