

**Written Statement**

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**U.S. House of Representatives Energy and Commerce Committee**

**Subcommittee on Health**

**Medical Device Safety: An Overview of FDA's Authority and a Review of Safety Data**

**February 15, 2012**

Good morning, my name is Ralph F. Hall. I appreciate this opportunity to speak to this committee on these important medical device matters affecting patients, physicians, innovation and jobs. I am here to discuss FDA's medical device regulatory system including, specifically CDRH's post-market authorities and its recall authority and practices. In addition, I will review research I have done into the safety of 510(k) products. I am here speaking in my personal capacity and not on behalf of the University of Minnesota or any other entity.

**Background and Disclosures**

To start, I serve as Professor of Practice at the University of Minnesota Law School where I concentrate my teaching, research and writing in the area of FDA law and compliance matters. In addition, I am part time Counsel at the law firm of Faegre Baker Daniels where I work with clients on a variety of FDA matters and also provide counsel to a national 510(k) coalition. Finally, I serve as CEO at MR3 Medical LLC. – a four person start-up medical device company

working on a new technology for cardiac rhythm devices generally regulated under the PMA process.

The research that is the focus of many of my comments was funded by the Ewing Marion Kauffman Foundation, a private nonpartisan foundation based in Kansas City, MO. Their generous support made this research possible. The Kauffman Foundation has given me complete academic freedom to pursue this research.<sup>1</sup>

### **Overview:**

While medical device regulation can appear to be obtuse and convoluted, there are core themes and policies that can be readily discerned.

- 1) The system created by FDA and Congress rarely has just a single regulatory control point or tool to protect public health. In almost all situations, FDA has multiple tools it can use to ensure that only products with a reasonable assurance of safety and effectiveness (the statutory standard)<sup>2</sup> are permitted onto the market or permitted to remain on the market.
- 2) It is critical to separate questions of FDA's authority from questions about FDA's implementation of its authority. My comments focus on the agency's authority.
- 3) FDA has clear statutory authority under the 510(k) system to assess the safety and effectiveness of products under review.

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<sup>1</sup> I want to thank Amanda Maccoux, Mark Jones, Chris Walker and Ron Song - the research assistants at the University of Minnesota Law School who spent long hours doing the detailed data collection and coding required for the first study. Their talents, hard work and dedication are vital to this research and I appreciate all that they did. Chris Walker continues his strong support as he is conducting a detailed data review for recalls posted in 2010..

<sup>2</sup> 21 U.S.C. §393(b).

- 4) FDA has a substantial number of post market tools currently available to it. These tools, while not perfect, give CDRH significant authority to identify post market product issues and to compel corrective action.
- 5) Overall FDA has done well in providing the reasonable assurance that medical devices are safe and effective before they are approved or cleared. The majority of Class I recalls (the high risk situations) involve post market issues. The most powerful tool to improve this safety record is an emphasis on quality systems (so-called "QSR" systems) rather than changes to pre-market authorities.

### **Safety and effectiveness**

FDA has the explicit statutory mandate to provide a reasonable assurance that medical devices are safe and effective for their intended use. What can be confusing is that FDA uses different means to achieve this universal goal. This reasonable assurance of safety and effectiveness for Class I devices<sup>3</sup> is provided through the implementation of "general controls". A medical device is in Class I if these "general controls" "are sufficient to provide reasonable assurance of the safety and effectiveness of the device".<sup>4</sup>

Class II devices use both general controls and "special controls" to provide the reasonable assurance of safety and effectiveness.<sup>5</sup> These special controls can include clinical trials, specific bench testing, post market obligations and patient registries as some of the tools available to FDA to meet the statutory objective of safety and effectiveness. The 510(k) system has the explicit statutory authority to address safety and effectiveness issues and to keep unsafe products

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<sup>3</sup> Congress has created three risk based device classes. Class I devices are the lowest risk devices. Class II devices pose medium risk and, obviously, Class III devices present the highest risk. See 21 U.S.C. §360c for an overview of the classification system and processes.

<sup>4</sup> 21 U.S.C. §360c(a)(1)(A)(i).

<sup>5</sup> 21 U.S.C. §360c(a)(1)(B).

off the market. Class II products generally go through the 510(k) system for premarket clearance (there are some exceptions not relevant to this discussion).

CDRH has explicit authority to create special controls for life supporting or sustaining Class II devices to ensure that these products have a reasonable assurance of safety or effectiveness. The statute states:

For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.<sup>6</sup>

Class III devices are those high risk devices for which general controls and special controls are not adequate. These products use the PMA process to assess safety and effectiveness.

I want to make two key conclusions. First, no matter the device classification, CDRH is charged with providing a reasonable assurance of safety and effectiveness for the intended use. No medical device bypasses this requirement. What changes is the means (or tools) CDRH uses to meet this objective. Second, all devices – like all drugs – have some risk. The challenge to CDRH, physicians and patients is to ensure that the benefit outweighs the risk.

### **Post-Market Authorities**

In addition to the premarket control systems outlined above, FDA has a variety of post market authorities. Whether it uses them in the way Congress desires is a different question. The post market systems include information collection processes, information analysis mechanisms and corrective action systems.

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<sup>6</sup> 21 U.S.C. §360c(a)(1)(B)

These authorities can be categorized as either general (or universal) requirements applicable to all medical devices or requirements specific to a particular product type or specific product use. The first group is applicable to all devices; the second are applicable to defined subgroups. The agency uses all of these tools detailed below to implement a systemic post market control and information system.

### **Universal Post-Market Requirements**

The following post market legal/regulatory structures generally apply to all medical devices.

#### **1. MDR Reporting**

Pursuant to 21 C.F.R. § 803 (and related authorizing statutes such as 21 U.S.C. § 360i(a) and (b)), medical device manufacturers are required to submit any reports of deaths or serious injuries allegedly associated with the device and, in addition, are required to report device malfunctions which could, if such a malfunction were to occur in the future, cause death or serious injury. Failure to submit MDR reports can (and often do) lead to serious civil and criminal enforcement actions.

The regulatory definition of “serious injury” includes a wide variety of events including events in which medical intervention prevented an actual serious injury. For example, a product issue that extends the time of the operation by ten minutes would be “serious injury” under 21 C.F.R. § 803 even if there was no other patient impact. Stated differently, the regulatory definition of “serious injury” is much broader than what the lay person or physician might consider serious.

MDRs are required to be submitted within specified time frames even if the allegations are unproven or open to debate. Causation need not be established and an investigation need not be completed before the MDR must be submitted.

Approximately 180-200,000 MDRs are reported each year.

Properly implemented, the MDR system provides an ongoing assessment of product performance in real world situations and operates as an “early warning system” for unknown safety issues or changes in the frequency or severity of known risks.

## 2. Recall Reporting

Under 21 C.F.R. § 806 (and related statutes and guidance), companies are obligated to report to FDA within ten days any field action (technically, either a correction or removal action) related to product issues or regulatory matters.

These recall reports, subsequent recall effectiveness checks conducted by FDA and recall close outs processes provide FDA with information about field performance issues and to ensure that field performance issues related to that product or similar products are properly addressed.

As discussed in more detail below, FDA has the explicit statutory authority to mandate a recall.<sup>7</sup>

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<sup>7</sup> 21 U.S.C. §360h(a) and (e).

### 3. MedSun

The MDR system is a “passive” data collection system in that it relies on third parties to submit reports. To complement this “passive” system, CDRH has implemented (and is currently upgrading) the MedSun program. The program actively collects product performance data from approximately 350 hospitals covering different geographies and types of patient base (urban and rural, small and large, academic teaching centers and non-academic centers, etc.). CDRH has special relations with these institutions and has trained these institutions to actively report product issues.

The MedSun system provides enhanced field surveillance and the collection of more data in a structured, organized fashion.

In a related program, CDRH is working to implement MDEpiNet.<sup>8</sup> This system links together 10 major academic networks in order to bolster post market and field information collection and analysis.

### 4. QSR Systems

A critical element in CDRH’s post-market safety and surveillance systems are the Quality System Regulations (or QSRs) generally set forth in 21 C.F.R. § 820. These require, among other obligations, each company to collect and analyze all product complaints (i.e. post market information) and related internal product quality information. All such issues must be investigated to determine root cause and appropriate reporting (often MDR filings) must take place. The company has

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<sup>8</sup> <http://www.accessdata.fda.gov/FDATrack/track-proj?program=cdrh&id=CDRH-OSB-MDEpiNet>

an obligation to look not just at events in isolation but to trend events and look for commonality of issues across product lines. This event trending is a key tool to identify signals of issues and to understand any appropriate corrective action.

Properly implemented, these QSR processes (and related manufacturing and product development and testing systems), are robust tools to identify and analyze product performance. FDA routinely inspects these processes and, in fact, audits of these "CAPA" systems are part of the QSIT inspection system.

## 5. Inspections

FDA has the authority to inspect any medical device manufacturer. These inspections routinely cover QSR systems, compliant files, complaint investigations, root cause analysis, event trending, product modifications and recall activity. Inspectors have access to all relevant documentation and to individuals responsible for these various activities. Such inspections can be either "routine" or "for cause" if FDA suspects or has knowledge of some product performance issue. A failure or refusal to supply relevant information or documents or supplying false information can be a criminal offense.

## 6. Product Tracking

Post-market surveillance (and recalls as discussed below) is intended to link products to events and identify specific products. This is no small challenge given the literally billions of devices on the market that are used in a wide variety of settings outside the knowledge or control of the manufacturer by users or

consumers over which FDA has little if any regulatory authority. In addition, multiple devices are used in a single therapeutic setting and are often serving an ancillary role to the more obvious therapy delivery. There may be literally hundreds of devices used in a cardiac surgical procedure.

FDA's unique device identification (UDI) program should significantly improve the agency's ability to track devices and link specific devices to events. The agency is in the process of developing the UDI system as mandated by Congress in 2007.

In addition, FDA can, for implantable and high risk devices, impose specific device tracking requirements under 21 U.S.C. § 360i(e) (FDCA § 519(e)).

#### 7. Reports of Product Modifications or Changes

Under both the PMA and 510(k) systems, companies are also obligated to report to CDRH product modifications made to address field issues (whether safety or effectiveness issues). This process provides CDRH another view into product performance and can trigger inquiries about related products or systems. Product modifications that must be reported include physical changes to the device and also changes in the labeling such as new warnings or instructions for use.

#### **Specific Post-market Systems or Obligations**

For certain products, more tailored or specific post-market surveillance may be appropriate.

These are in addition to, not in lieu of, the general or universal post-market obligations described

above. CDRH has a wide variety of statutory authorities by which it can impose such tailored post-market surveillance obligations.

#### 1. Conditions of Approval

PMA product approvals include mandatory “conditions of approval” (see 21 C.F.R. § 814.82(a)(2)). These vary between product types but can include enhanced post-market surveillance, post-market testing, increased reporting, patient registries, etc. These post-market obligations can be tailored to the particular needs of the patients and products themselves thus allowing for more focused and relevant post-market surveillance.

#### 2. Special Controls

In an analogous way, Class II products can be subjected to special controls under 21 U.S.C. § 360c(a)(1)(B) (FDCA § 513(a)(1)(B)). These special controls can require any number of post-market obligations including patient registries, dissemination of product use guidelines, post-market surveillance plans, etc. In addition to these specifically enumerated tools, the FDA can mandate “other appropriate actions as the Secretary deems necessary to provide such assurance [of safety and efficacy].”

#### 3. Section 522 Orders

In 1997, Congress added 21 U.S.C. § 360l (FDCA § 522). Under Section 522, FDA may order manufacturers of Class II or Class III products which are implantable products, life sustaining products or products for which a failure

“would be reasonably likely to have serious adverse health consequences” to conduct post-market surveillance studies. These orders can be imposed as part of a PMA (or sPMA) approval or applied to 510(k) products. FDA has the power to review the proposed post-market surveillance plan to ensure that it is adequate and is being implemented by qualified individuals and the power to review compliance to the Section 522 order.

Section 522 orders are in addition to, not in lieu of, other post-market authorities.

#### 4. International Controls and Information

In addition to these U.S. centric obligations, companies are obligated to report to FDA adverse events occurring or reported outside the U.S. and to include adverse event information from non-U.S. sources in many submissions. The various regulatory agencies also have information exchanges such that a product issue in one jurisdiction is reported to regulators in other countries. International or domestic information can trigger field actions in the United States, corrective actions by the manufacturer and detention or refusal of entry of imports.

### **Recall Overview**

FDA has a number of existing statutory mechanisms to address field issues. In a number of cases, these don't use the term “recall” but perform the functions of a recall.

#### 1. Voluntary Recalls

In the event that industry takes a voluntary field action to address a product or regulatory issue, the company is obligated to inform FDA under 21 C.F.R. Part 7

and 21 C.F.R. § 806 within 10 days. The agency oversees the field action and conducts recall effectiveness checks of varying intensity based on the seriousness of the risk.

## 2. Mandatory Recalls and Notifications

If the company refuses to take action, FDA has a variety of actions it can take generally under 21 USC §360h (FDCA §518). These include the right to mandate a public notification if the device in question “presents an unreasonable risk of substantial harm to the public health” and notification is necessary to eliminate that risk. §518(e) also gives FDA the authority to order a mandatory recall in situations of a risk of serious adverse health consequences.

## 3. Seizure and Detention Actions

FDA also has the well-established authority to conduct seizure and detention actions pursuant to 21 USC §§331 and 334. In a seizure action, the government can go into the company and into the market place (including distributors and stores) and take physical control of the product to prevent any further movement in interstate commerce. Violation of a seizure order is a standalone criminal violation.

## 4. Publicity

Under 21 U.S.C. § 375, FDA has the authority to publicize issues or products which present an imminent danger to health or gross consumer deception.

## 5. Repair, replacement and refund

Section 518(b) gives FDA the authority to order the company to provide repairs or placements of defective products. FDA can also order a monetary refund to consumers. FDA has additional power under court decisions such as *Lane Labs* to order restitution to consumers.

## 6. Banning and suspension of approvals

FDA also has the authority under FDCA §516 and 515(e) to ban further distribution of products or to suspend (temporarily or permanently) PMA approval.

As can be seen, FDA has substantial statutory authority to take (or mandate) actions to protect consumers from unsafe products in the market. It is hard to imagine some action that FDA should be able to take action relating to an unsafe product in the market for which it does not already have statutory authority.

The existence of such authority is a very different question from whether FDA, industry and physicians are appropriately using or complying with such authority.

### **Recall Suggestions**

There are, however, some ways in which the general recall process under 21 C.F.R. Part 7 and 21 C.F.R. § 806 could, in my opinion, be improved.

First, the term “recall” implies a physical removal or explants. That causes unnecessary patient anxiety and possibly unnecessary explants. It is also inaccurate. While in some cases a physical removal or explants may be the best medical course that is often not the case. Implying that the product should be physically removed can mislead patients. Of course one does not want to

dilute or hide the importance of the field action. Calling it something like a “Safety Alert” while reserving the term “recall” for those situations in which a physical removal is appropriate conveys the seriousness of the situation in an accurate, non-misleading fashion.

Second, I would strongly encourage the agency to immediately classify any recall reported to it so that the field notification can accurately state the seriousness of the situation. Assigning a classification six weeks after the physician notification occurs serves no physician or patient communication purpose and can mislead physicians and patients into thinking that there is a second recall when that is not the case.

Finally, having more objective criteria for classification of recalls would improve the communication value of the classification.

### **Medical Device Review Decisions – Study Summary**

The safety of medical devices is, of course, of prime importance to patients, physicians and other stakeholders. Rather than look at individual events, opinion or anecdote, I am interested in the performance of the system as a whole. It is critical to remember that all devices carry with them some risk.

With the aid of a number of research assistants, I studied the overall safety profile of medical devices approved or cleared by FDA from 2005-2009 by using Class I safety recall data.<sup>9</sup> This study<sup>10</sup> evaluated Class I (or high risk) recalls of all medical devices, regardless of whether they

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<sup>9</sup> We are currently in the process of analyzing 2010 recall data.

<sup>10</sup> An earlier version of this research into the safety of medicals devices through an analysis of safety recalls was presented to the Institute of Medicine committee reviewing the 510(k) system, reviewed with FDA.

were approved through the PMA system, cleared through the 510(k) process or were otherwise exempt.

The key conclusions from my research are as follows:

7. Overall, 510(k) regulated medical devices have an excellent safety profile. Over 99.5%<sup>11</sup> of 510(k) submissions assessed during this study period did not result in a Class I safety recall. Over 99.7% of 510(k) submissions did not result in a Class I recall for any reason relevant to the 510(k) premarket system.
8. Products approved through the PMA system also have an excellent safety record. Again, greater than 99.5% of PMA or sPMA submissions do not result in a Class I safety recall during the study period.
9. Very few (less than 9%), Class I recalls during the study period involve possible undiscovered clinical risks. As such, increased preapproval clinical testing would not have any meaningful impact on reducing the number of Class I recalls.
10. The majority (approximately 55%) of all Class I recalls involve problems or issues that arose after market release and could not be affected by premarket approval systems or requirements. For example, a manufacturing mistake made three years after FDA approval or clearance may trigger a Class I recall. However, any premarket requirements such as clinical testing are irrelevant to preventing such a recall.
11. A very significant majority (over 90%) of all Class I recalls (including both premarket and post-market issues) are directly related to quality system issues (so-called QSR

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<sup>11</sup> All percentages have some margin of error given the relatively small data set.

systems<sup>12</sup>). Improved QSR systems will have the greatest effect in reducing the number of Class I recalls.

12. My study did identify a bolus of Class I recalls in two device types – automatic external defibrillators (AEDs) and infusion pumps. Any changes to the premarket review process should be targeted to demonstrate problems rather than applied in some random, shotgun way. In fact, following the initial public discussion of this data, CDRH has instituted two initiatives – one directed to infusion pumps and the other to AEDs.
13. Finally, one should not confuse classification for premarket review processes with recall classification. These are very different things and serve very different purposes.

## **Study Background**

The need for the research that I will describe goes back several years when a number of stakeholders started to question the robustness of the 510(k) system. I was and am familiar with the numerous issues relating to delays in submission reviews and changing data requirements. I was, however, struck by the belief among some that the 510(k) system did not assess or consider product safety in making clearance decisions and that there was some major issue with the safety of products being cleared by the 510(k). First, it is critical to note that FDA does consider safety when deciding whether to clear a 510(k) submission. Second, some stakeholders were advocating making major changes in the 510(k) system to address presumed safety problems. I was particularly struck by the fact that there was no good, objective data to support or refute the

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<sup>12</sup> QSR requirements are intended to provide “cradle to grave” product quality in a closed loop, learning system. QSRs include design input and processes, design validation, product testing, manufacturing controls, process controls, change controls, management review and post-market assessments. See, generally, 21 C.F.R. § 820.

assertion that the 510(k) system needed to be changed because of these presumed safety issues and, if some changes were warranted, the s.

In fact, at an early public meeting held by FDA to discuss making major changes to the 510(k) system, I commented that this was a “ready, fire, aim” exercise in which various interest groups were advocating major changes without any understanding of the actual performance of the system and any issues with the system. It struck me then and now that data, not opinion, should drive policy changes.

Given my concerns over the lack of hard data, I commenced a study (with the able assistance of four research assistants) assessing the safety performance of FDA approval processes. To my knowledge, this was the first study designed to systemically assess the safety performance of the 510(k) system. This study was funded by the private, nonpartisan Kauffman Foundation. I am solely responsible for the study and its results.

### **Study Methodology**

This study assessed the overall safety profile of medical devices approved or cleared by FDA from 2005-2009 by using Class I safety recall data.

Class I safety recalls were chosen as the measure of safety as these recalls involve any medical device problem posing any significant risk of serious health consequences to patients and also correctly exclude risks considered as part of the approval or review process. Class II recalls involve generally remote risks to patients and Class III recalls involve minimal or no risk to patients. FDA, not industry, is responsible for assigning the recall classification. Note that the Class of recall assigned by FDA is independent of the product’s device classification.

Using FDA databases, we identified all Class I recalls posted by FDA on public databases during 2005-2009. We first combined all duplicate recalls into one data set of unique or stand alone recalls. (FDA may have several recall announcements and thus there may be multiple data entries for the same issue because of different package configurations, brand names or product sizes).

118 unique recalls were identified. We then coded each recall for a number of factors including regulatory pathway, medical specialty, whether implantable and three letter product code. We also coded each recall with one of thirteen reasons for recalls. Generally speaking, these thirteen recall reasons can be combined into three broad groupings of premarket issues (*i.e.*, something that could, at least theoretically, have been discovered during a premarket review process), post-market issues and miscellaneous (counterfeit and “quack” products). We used FDA websites and publicly available information for this coding.

All data was entered into a standard Excel spreadsheet following quality control.

This study must be assessed in light of the following factors<sup>13</sup>:

1. We relied entirely upon publicly available data.
2. While companies are obligated to report recalls, there may be situations in which the company failed to meet this obligation. We believe that any such missing recalls would tend to be small in number because of the penalties for non-compliance and the variety of

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<sup>13</sup> We considered other methodologies; including reviewing adverse event reports (generally referred to as Medical Device Reports or MDR reports) and also tried to assess number of products involved in each recall. In these cases, the data is hopelessly inaccurate and incomplete, inaccurately counts actual events as compared to the risk of a malfunction or is not related to the binary decision to approve or not approve the submission.

information sources that would alert FDA and the public to any undisclosed recall.

Importantly, there is no reason to believe that the distribution of the causes of such recalls would be different than the data we had.

3. We reviewed Class I recalls and not Class II recalls. (FDA defines a Class II recall as a situation in which the problem “might cause a temporary health problem, or pose only a slight threat of a serious nature.) We believe that Class I recalls represent all recalls with any meaningful risk to patients and so represent a valid safety picture. Class I recalls represent the majority of actual patient risk and it seems that FDA (the entity doing the classification) tends to err in the direction of more serious recall classifications. Risks as low as 1/20,000 have been classified as Class I recalls thus demonstrating the breadth of risks captured by Class I recalls.
4. Finally we did not assess any effects of various regulatory systems or actions on patient access to new products, innovation or the economy in general.

We also determined the percentage of 510(k) submissions that resulted in a subsequent Class I recall. The numerator for this calculation is the number of recalls. The denominator is the number of submissions. The denominator for this calculation is a close estimate as there is no direct connection between the date of the submission and the subsequent recall. For example, a recall for a design defect might occur within a month after market release while a recall for a manufacturing error or packaging mistake could occur literally years after approval or clearance.

We determined an annualized number of submissions by taking the average number of submissions for a ten-year period (2000-2009) and annualizing that number. We used this

number for all percentage calculations. Those percentages, however, are approximations due to this data challenge.

### Study Results and Data

Initially, we looked at the reasons for recalls for these 118 Class I recalls. It must be remembered that all devices carry risk and that Congress has balanced patient access to new technology with premarket processes by creating the standard that there must be “reasonable assurance” of product safety before the product should be marketed. We determined the reason for the recall by examining FDA’s public databases and also reviewing publically available information including physician notification letters and SEC filings. I was responsible for all decisions relating to the reason for recall. I blindly recoded 10% of the recalls and had a complete match with the initial determination of the reason for the recall.

The following table shows the number of recalls by regulatory pathway and the reason for recall. Reasons for recall in blue are those related, at least potentially, to premarket review processes. The others are recall reasons that are completely unrelated to any premarket process.

Primary Reason for Recall	PMA	510K	Class 1	Other or Unknown	TOTAL
Manufacturing	6	31	2	1	40
Labeling Error	0	4	0	0	4
<b>Design Issue</b>	6	25	1	0	32
<b>Software Design</b>	1	9	0	0	10
Software Manuf. Failure	0	2	0	0	2
Supplier Issue	2	5	0	0	7
<b>Failure to Identify Clinical Risk</b>	0	0	0	0	0

<b>Failure to Warn/Inadequate Instructions</b>	0	8	0	0	<b>8</b>
Missing Parts	0	0	0	0	<b>0</b>
Sterilization	1	4	2	0	<b>7</b>
Regulatory Violation	0	1	1	0	<b>2</b>
Packaging/Handling	0	0	0	0	<b>0</b>
Other (Counterfeit, Sham)	0	6	0	0	<b>6</b>

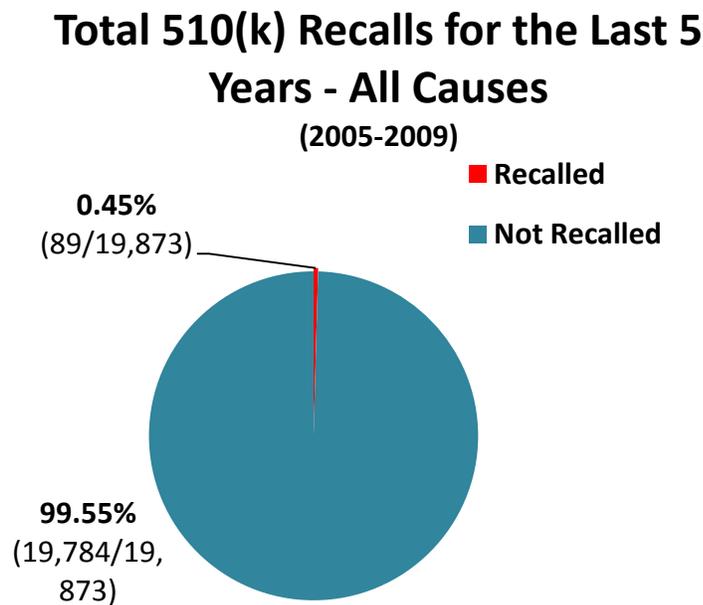
As shown below, the majority of all recalls (approximately 55%) are for post-market issues. For these recalls, no change in the premarket 510(k) or PMA process would affect the recall occurrence or frequency.

	<b>Total Recalls</b>	<b>Recalls for Pre-Market Issues</b>	<b>Recalled for Post-Market Issues</b>	<b>Recalled for Other Issues</b>	<b>Percent of Recalls to Total Recalls</b>
<b>Class I or u/k</b>	7	1 (14.2%)	6 (85.7%)	0 (0%)	5.9%
<b>510(k)</b>	95	43 (45.3%)	46 (48.4%)	6 (6.3%)	80.5%
<b>PMA</b>	16	7 (43.8%)	9 (56.3%)	0 (0%)	13.56%
<b>TOTAL</b>	<b>118</b>	<b>51</b>	<b>61</b>	<b>6</b>	<b>118</b>

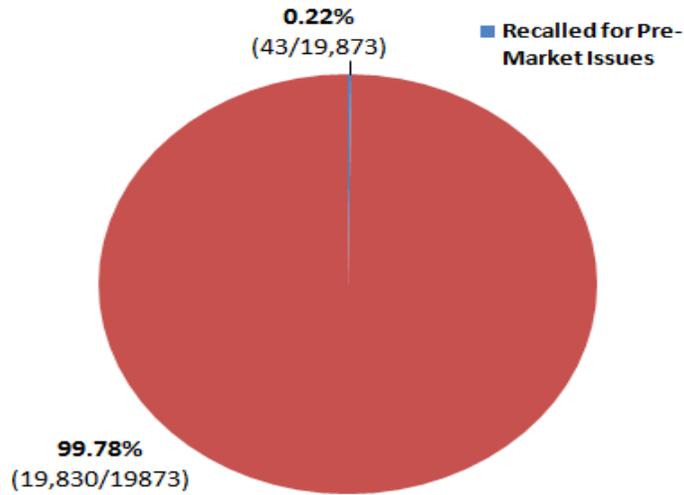
As seen below, a very small percentage of 510(k) submissions led to a Class I recall during our study period. The first chart shows the ratio of 510(k) submissions to all Class I recalls and the second chart shows the ratio of 510(k) submissions to Class I recalls related to any theoretical premarket issue.

This data shows that CDRH and the submission sponsors have done an admirable job in identifying potential device risks, particularly clinical risks, prior to the approval or clearance decision. These risks can then be explicitly balanced against benefits as part of that premarket decision. Very few, if any, recalls in the device world are related to undiscovered clinical issues.

Based on this data, approximately 99.55% of all 510(k) submissions did not result in a Class I recall for any issue during the study period. More importantly for assessing the 510(k) process, approximately 99.78% of all 510(k) submissions did not result in a Class I recall for any reason related to the premarket process. Stated differently, the maximum theoretical impact of any change in the 510(k) system would be on 0.22% of all 510(k) submissions. This data also demonstrates that additional premarket clinical testing would be ineffective in reducing Class I safety recalls.



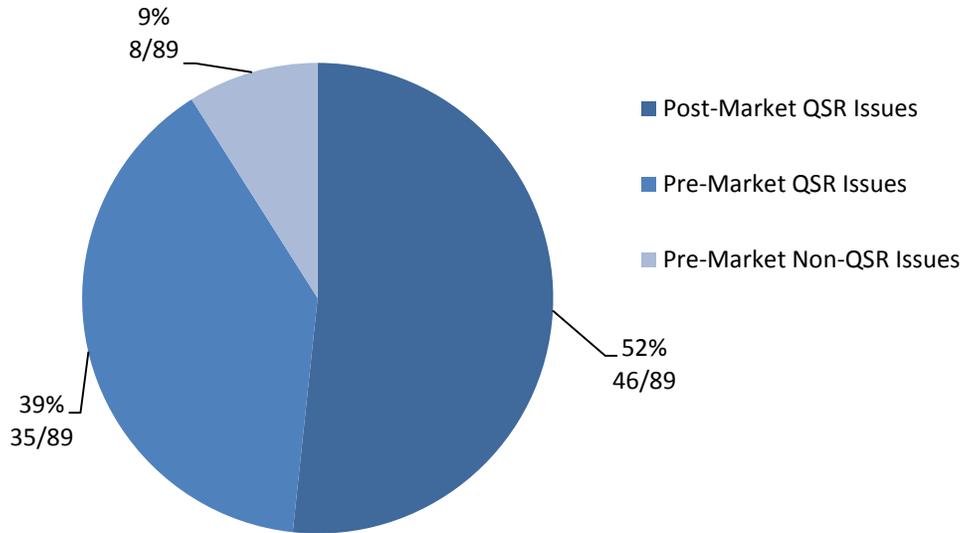
## Total 510(k) Recalls for the Last 5 years – Premarket issues



<b>Total 510(k) Submissions in 10 years</b>	<b>39,747</b>
<b>Average Submissions in 5 year time period</b>	<b>19,873</b>
<b>Total 510(k) Recalls for 2005-2009</b>	<b>89</b>
<b>Total 510(k) Recalls for Pre-Market Issues for 2005-2009</b>	<b>43</b>

The number of recalls related to premarket issues is most relevant in assessing whether the 510(k) system is adequately addressing patient safety during the review process. This data demonstrates that post-market issues, not premarket processes, should be the focus to improve patient safety.

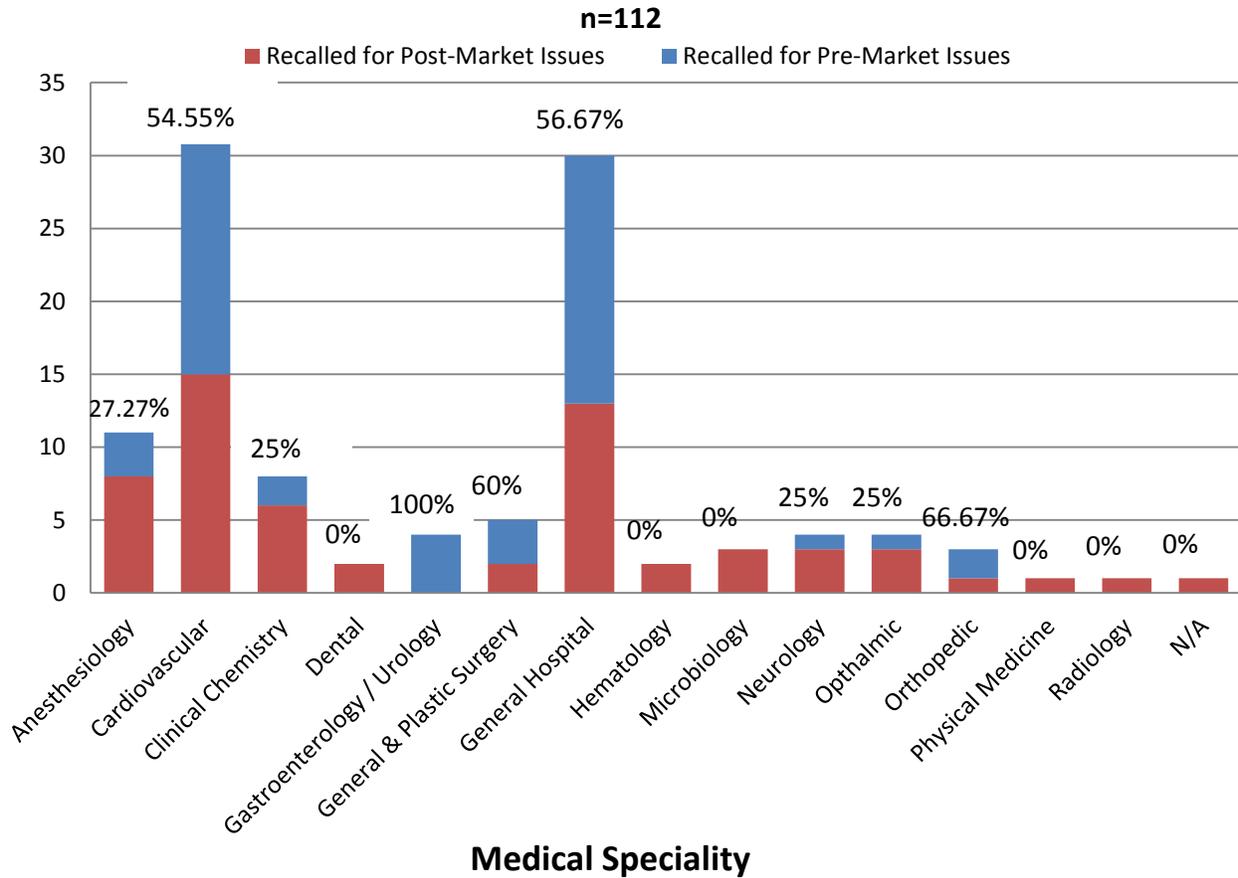
This conclusion is reinforced when we reviewed the role of quality systems in recalls. As shown below, over 90% of all Class I safety recalls are related to quality system issues and not to other factors such as a lack of clinical trials.



Clearly, this data demonstrates that all stakeholders should concentrate on QSR systems such as design control and bench testing — not the 510(k) submission system — as the most effective way to provide greater patient safety.

We also did sub-analysis by product type and medical specialty. Such analysis can be used to identify concentrations of issues for further investigation by FDA, industry and other stakeholders. As seen below, Class I recalls are concentrated in several product types.

## Recalls by Medical Speciality, Percentage of Recalls for Pre-Market Issues



Further analysis indicated that automatic external defibrillators (AEDs) and infusion pumps accounted for 28% of all Class I recalls and accounted for a substantial part of the bolus or recalls seen in the cardiovascular and general hospital categories. FDA has now triggered new regulatory initiatives for both AEDs and infusion pumps.

This data also shows remarkably few Class I recalls for a number of product areas, including some product types that have been recently agued demonstrating flaws with the 510(k) system, such as orthopedics, radiology and OB/GYN.

We also assessed the data to see whether implantable products or submissions that went through the third party review process had any concentration of Class I recalls. Our analysis showed that Class I recalls for implantable devices almost exactly matched the expected percentage of recalls and that there were fewer recalls for submissions reviewed under the 510(k) third party review system than might be expected.

### **Study Conclusion**

This study demonstrates that very few 510(k) medical device submissions — less than 0.5% — become the subject of a Class I safety recall. Even in this small number of Class I recalls, the majority of Class I recalls involve post-market issues such as manufacturing mistakes, and are focused around two product categories (cardiovascular and general hospital). These recalls involve quality system issues, not premarket issues. Overall, in excess of 90% of all recalls appear to involve quality system issues.

Our study shows that FDA has a very positive safety record in its 510(k) clearance decisions.

### **Overall Conclusion**

Overall, products approved or cleared by FDA have very good safety records. Of course, all stakeholders should always be striving to improve on this already good record. Improvements in QSR (quality systems) offer the greatest impact.

FDA also currently has substantial post-market surveillance authority and recall authority. It is difficult to imagine actions that FDA may want to take when faced with a serious public health issue for which it lacks authority. Implementation and compliance by all stakeholders may well be the most fruitful area of focus.

Again, I appreciate the opportunity to present to the committee and would be happy to answer any questions.