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## Five Year Review of Class I Medical Device Recalls: 2004-2008

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# Five Year Review of Class I Medical Device Recalls: 2004-2008

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## I. INTRODUCTION AND GOALS

Medical device manufacturers—as are all manufacturers of prescription products—are regulated by a variety of laws codified in Title 21, Chapter 9 of the U.S. Code and implemented by U.S. Food and Drug Administration (FDA). One statutory obligation is to monitor the safety of a prescription product and, based on this review, determine whether a product might have to be recalled.

Recalls of medical devices have a widespread impact on all the participants involved. For the companies that manufacture and distribute medical devices, a recall can have an appreciable and sudden impact on its operations, the public image (goodwill), and the value of the company. Medical professionals must also deal with the effect of recalls as they are challenged with health decisions for their patients and choices of treatment. Lastly, patients are also affected by medical device recalls whether the device is implanted or used externally on a regular basis to monitor or maintain their health.

By way of summary, a manufacturer of any prescription product may voluntarily initiate a recall “because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.”<sup>1</sup> The Regulatory Procedures Manual, which provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters, states that “[f]irms may also initiate a recall following notification of a problem by FDA or a state agency, in response to a formal request by FDA, or as ordered by FDA.”<sup>2</sup> While FDA does not have the authority to order a recall of a medicine, it does have this power for medical devices.<sup>3</sup> FDA’s website also contains numerous resources to guide manufacturers in the medical device recall process.<sup>4</sup>

If, in the language of the statute, “a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health”<sup>5</sup> a regulatory trigger is pulled.<sup>6</sup> If a manufacturer of a medical device, concludes

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<sup>1</sup> 21 CFR § 7.40.

<sup>2</sup> Available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProcedures-Manual/UCM074312.pdf> (Chapter 7, last accessed Aug. 7, 2009).

<sup>3</sup> Section 518(e) of the FDCA and 21 CFR 5.411.

<sup>4</sup> Medical Device Recall Webpage, <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm> (last accessed 8-8-09); Investigations Operations Manual, <http://www.fda.gov/ICECI/Inspections/IOM/default.htm> (Last accessed Aug. 10, 2009).

<sup>5</sup> 21 USC § 360h (a).

<sup>6</sup> Note that this is the same language as Section 350h (a) [the section governing the voluntary recall of all prescription products, with the exception that 360h (e) adds the risk of death as a criterion for evaluation.

that its product does not meet a material specification, is violative of the Federal Food, Drug, and Cosmetics Act (FDCA), or poses an unreasonable risk of harm to the patient,<sup>7</sup> it should consider voluntarily recalling the device.

On the other hand, if FDA finds that a firm is in violation of the FDCA, it may issue a Warning Letter. According to the Regulatory Procedures Manual, it is FDA's "practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action."<sup>8</sup> Warning letters are "the agency's principal means of achieving prompt voluntary compliance" with the FDCA. However, "FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action."<sup>9</sup> If a device "presents an unreasonable risk of substantial harm to the public health" FDA may, under 21 USC § 360h(a), also order a notification of healthcare professionals, patients and others when this is the most effective way of dealing with the risk and the company has taken no action to recall the device. FDA, however, is also given authority to order the recall of a medical device if the agency concludes that "there is a serious health hazard and a firm does not initiate a voluntary recall."<sup>10</sup> This authority is permitted by statute only for such prescription products as devices,<sup>11</sup> biological products,<sup>12</sup> and human tissue intended for transplantation.<sup>13</sup>

While FDA makes a variety of information about recalls and warning letters available online, the agency does not present a synthesis and analysis of this information. The authors previously presented a compilation and analysis of information on Class I recalls for three fiscal years (FY 2004-2006).<sup>14</sup> Class I recalls are those with the highest risk of health hazard, in that there is a reasonable chance that the medical device will cause serious health problems or death.

In the current analysis, the authors have added two fiscal years of Class I recalls (through FY 2008), and have added an evaluation of warning letters to the analysis for all five fiscal years (FY 2003-2008). The authors have examined the relationship between the recalls that occurred during this period and warning letters issued that were deemed to be related to the recalled products. In addition, the authors have included reports in the lay press and medical literature to evaluate how the public might learn about recalls. The authors also examined whether these recalls led to any significant product liability activity by reviewing those cases that have been consolidated for coordination by the Judicial Panel on Multidistrict Litigation.<sup>15</sup>

## II. METHODOLOGY OF ANALYSIS

The methodology used to collect recall data builds upon that used in Villarraga et al., 2007.<sup>16</sup> Briefly, information on medical device Class I recalls for fiscal years

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<sup>7</sup> 21 CFR § 7.40(2005). Hall, Ralph F., *To Recall or Not to Recall, That is the Question: The Current Controversy Over Medical Device Recalls*, 7 MINN. J. L. SCI & TECH 161 (2005).

<sup>8</sup> Regulatory Procedures Manual, (Mar. 2009), Chapter 4 Advisory Actions, p. 4-1-4-2.

<sup>9</sup> Regulatory Procedures Manual, (Mar. 2009), Chapter 4 Advisory Actions, p. 4-2.

<sup>10</sup> FDA may issue a recall order to the manufacturer under 21 CFR § 810, Medical Device Recall Authority. CDRH, Ensuring the Safety of Marketed Medical Devices — CDRH's Medical Device Postmarket Safety Program (January 18, 2006) p.44; Regulatory Procedures Manual.

<sup>11</sup> Section 518(e) of the FDCA and 21 CFR § 810.13.

<sup>12</sup> 42 USC § 262.

<sup>13</sup> 42 USC 264 and 21 CFR § 1271.440.

<sup>14</sup> Villarraga et al., 2007, *Medical Device Recalls from 2004-2006: A Focus on Class I Recall*, FOOD & DRUG LAW J, Vol 62(3): 581-591.

<sup>15</sup> <http://www.jpml.uscourts.gov/>.

<sup>16</sup> See footnote 12.

2004 through 2008 (a fiscal year extends from October 1 to September 30) was extracted from the data in FDA Enforcement Reports.<sup>17</sup> The Enforcement Reports list all recall “actions.” An individual recall action may include one or more products or models. FDA assigns each individual recalled product or model in an action a unique identifier; for medical devices, this identifier begins with a “Z;” hence, they are referred to as “Z-numbers.” The last two digits of the Z-number correspond to the fiscal year in which the recall action took place.

Information about the recalling manufacturer, number of products (i.e., Z-numbers) in each action, reason for recall and the volume of product in commerce (typically expressed as the number of units) associated with each recall action was gathered from the Enforcement Reports. The same source was also mined for information about whether a recall action was voluntary or FDA initiated, and complete or ongoing.

The “Reason[s] for Recall” listed on the FDA Enforcement Report or from the Medical Device Recalls database for each recall action were analyzed and grouped into one of 11 categories, listed in Table 1. The authors established these categories after a thorough review of the text in the “Reason[s] for Recall.” The text available in the “Reason[s] for Recall” ranged from simple one-sentence explanations to detailed explanations spanning several sentences. Inferences or interpretations about the reasons for recall were not made. Only one category was assigned for each action. Examples of text associated with each category are provided in Table 1.

Other online searchable FDA databases (e.g., Medical Device Recalls, 510(k), premarket approval (PMA) and device listing databases)<sup>18</sup> were used to collect additional information. The intended use of each recalled device was gathered from the FDA Medical Device Recall Database. From this intended use, we categorized devices as external or internal, with internal devices further categorized as permanent or transient. Devices were defined as external if they were not inserted into the patient but used as an adjunct. Devices were defined as internal if part of or all of the device went into the patient; classification of permanent or transient depended on whether a device was meant to remain implanted or to be used for a predefined period of time and then removed (e.g., catheters or surgical tools).

The 510(k), PMA, manufacturer and user facility device experience database (MAUDE), or FDA Medical Device Listing databases were used to determine the device class (Class I, II, or III) and medical specialty. For those devices where device specialty and/or device class information could not be found in above listed databases, information from a comparable device was used.

In the present analysis, the FDA warning letters database<sup>19</sup> was also used to identify warning letters issued to companies that manufactured devices subject to a recall. Warning letters are not always directly related to recall actions; however, warning letters identify issues that may ultimately lead to (or have led to) a recall. The warning letters database was searched by company for all letters issued to those companies who had a Class I medical device recall in FY 2004-2008. Each of these letters was individually analyzed to determine whether the products or issues

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<sup>17</sup> Available at: <http://www.fda.gov/opacom/Enforce.html> (Last accessed Apr. 30, 09).

<sup>18</sup> Medical Device Recall database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm> (Last accessed Aug. 6, 2009); 510(k) database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf-PMN/pmn.cfm> (Last accessed Aug. 6, 2009); PMA database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> (Last accessed Aug. 6, 2009); Device Listing database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm> (Last accessed Aug. 6, 2009).

<sup>19</sup> Warning letters database: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (Last accessed Aug. 6, 2009).

identified in the letter were the same or similar to those in the recalls database. In some cases a warning letter identified a specific product by brand name; in other letters, only the product category was identified (e.g., catheters). Similarly, the degree to which the issues identified in the warning letters matched the reasons for recall varied. It was only through individual analysis that a letter was considered to be applicable to a recall within the database. Furthermore, the analysis also identified whether multiple warning letters were associated with one recall, or whether one warning letter was associated with multiple recalls.

Warning letters list the dates of FDA inspections (warning letters follow these inspections), general issues identified by FDA as reasons for issuing a warning letter, and dates of responses provided by the cited company. These dates were used to evaluate whether a warning letter occurred before or after a recall, and how long it took a company to respond to FDA after its first written notification of deficiencies (which was defined as the last date of inspection, when 483 forms are typically provided to a company). In addition, the general issues cited in warning letters were also analyzed. For these analyses, in cases where multiple warning letters could be assigned to a single recall action, the first warning letter was used.

To determine whether device manufacturers were publicly traded or privately held, internet resources including Google Finance, Hoovers.com,<sup>20</sup> or company websites (when available) were used. The company information was gathered based on the *current* status of the device manufacturing company or parent company and not on the status at the time the device was released to the market or recalled.

Last, a review of medical literature and lay press articles regarding medical device recalls, and a compilation of information about multidistrict litigations filed related to the recalled devices identified in this analysis was also conducted. Table 2 summarizes all of the analysis parameters and sources of information.

### III. RESULTS OF ANALYSIS

Table 3 lists the total number of Class I recall actions, recalled products, and recalled units by FY and cumulatively for FY 2003-2008.

Over the five-year period there were 111 Class I recall actions. FY 2007 showed a slight increase in Class I recall actions compared to FY 2006 but it was followed by a sharp decline in recall actions (about half) in FY 2008. Despite this decrease, the total number of recalled products almost tripled in FY 2008 compared to FY 2007. In terms of units recalled, FY 2007 had the greatest number of recalled units mainly due to the volume of contact lens solution units (more than 57 million) recalled that year.

Tables 4 and 5 itemize recall actions and recalled units, respectively, by reason for recall along with the cumulative totals for the five fiscal years. Figure 1 shows the top reasons for recall by actions and units for the five fiscal years. Mechanical reasons dominated the recall actions, whereas contamination dominated in the recalled units (ophthalmic contact lens solution).

The Enforcement Report data described only one recall action as "FDA initiated" (in FY 2004) out of the 111 recalls identified over the five-year period. In addition, one other recall action was listed as FDA requested. Only five recall actions were classified as "complete" at the time of the Enforcement Report issuance. The Enforcement Reports also contained information about the methods that each company was using to notify users of the recall action. These methods took the form of letters,

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<sup>20</sup> Gathered from: <http://finance.google.com> and <http://www.hoovers.com>.

emails, faxes, phone calls, website alerts, FDA Public Safety Alerts, or press releases. Twenty-five of the recall actions included a press release.

Across all fiscal years, the majority of recalls were from public companies (approx. 78 percent of both actions and products). Across all fiscal years, the majority of the recall actions (more than 70 percent) were for external devices. Only 18 percent were permanent internal devices, compared to 12 percent transient internal devices. The year-to-year distributions were consistent with this overall distribution. In terms of recalled products, only 54 percent were external devices, compared to 18 percent permanent internal devices and 28 percent transient internal devices. Figures 2a and 2b show the recall actions and products categorized by device class (Class I, II or III), shown cumulatively and per year. The majority of both recall actions and products recalled were Class II devices. The spike in Class III devices in FY 2008 was attributed to balloon catheters recalled (78 different products in one recall).

Figures 3a and 3b show the recall data for actions and units, respectively, categorized by medical specialty. Among the top three specialties in the recalls by actions were cardiovascular (e.g., implantable cardioverter-defibrillators (ICDs), automatic external defibrillators (AEDs)), general hospital (e.g., infusion pumps, patient lift), and clinical chemistry (e.g., blood glucose test strips, reagents). When examined by units, the top specialties represented were general hospital, clinical chemistry, and ophthalmic (e.g., contact lens solution).

Across all five fiscal years, there were 40 recall actions with associated warning letters (36 percent of all recalls). Fourteen of these actions had two warning letters associated with them, and one action had three warning letters associated with it. Thus, there were a total of 56 warning letters identified as being associated with the Class I recalls over the five fiscal years. For 14 of the recall actions with warning letters, the medical device firm started the recall before receiving the first warning letter. Based on the inspection date and company response date noted in the warning letters, it took an average of 22 days for medical device firms to respond to FDA following the last date of the inspection (first inspection if more than one noted). The warning letter subject matters included: failure to follow Current Good Manufacturing Practices (CGMP), adulterated products, misbranded products, medical device reporting and lack of premarket approval. Over 90 percent of the first warning letters (if more than one) cited adulterated products or issues with CGMP. The other warning letter subject areas that were cited less often (i.e., less than 20 percent of letters) were misbranding, medical device reporting, and lack of premarket approval. The reasons for warning letters we report here are consistent with comments regarding typical reasons for recall which were recently made by a former FDA Chief Counsel.<sup>21</sup>

Findings in the lay press and medical literature dealt mainly with the recalls that impacted the cardiovascular field, namely ICDs and AEDs. With respect to product liability issues, only four multidistrict litigation filings were associated with devices identified across all fiscal years (cardiovascular devices, ophthalmic contact lens solution, and hernia patches).

#### IV. DISCUSSION

The Investigations Operations Manual (IOM) from FDA, which serves as the primary resource on FDA inspection policy and procedures for field investigators

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<sup>21</sup> Medical Device Recalls Remain Serious Business, Edata Integrity Report. <http://www.edataintegrityreport.com/samplecopy/specialreports.html> (Last accessed Aug. 13, 2009).

and inspectors, cites manufacturing defects, labeling deficiencies, failure to meet premarketing requirements (PMA, 510(k)), packaging defects, adverse event reporting or other nonconformance problems as reasons for a medical device recall.<sup>22</sup> The 11 categories that the authors chose here as Reasons for Recall are very similar to these reasons, with slightly more specificity.

Compared to our previous analysis, the authors identified a new category for Reasons for Recall in this analysis: counterfeit medical devices. Vigilance about counterfeit medical devices has increased and the crime has imposed a significant burden on medical device manufacturers, as well as to all manufacturers of prescription products.<sup>23</sup> For example, a businessman in China was found guilty by a Chinese court for counterfeiting diabetic testing supplies and was fined and sentenced to prison. The use of these products by diabetic patients could have caused injury or death, though there are no known cases. The increased volume and sophistication of counterfeit medical devices have now created a major public health concern.<sup>24</sup> Not only does the crime create a significant risk of harm to the patient but also impacts earnings by the patent holder as well as intellectual property rights.<sup>25</sup>

Recalls have other effects. The ease of access to "bad news" about a prescription product that is available to both the public and to healthcare practitioners cannot be overlooked, particularly when a recall is concerned.<sup>26</sup> Public access to this type of information comes from multiple sources, including the lay press, FDA recall and warning letter communications, and Public Health Notifications. Reporting in the lay press on recalls or recall information gained through other sources has a direct effect of the consumer's (whether it is the health professional or the patient) perception of a medical device and the firm that manufactures it. The level of public scrutiny afforded a recall might cause healthcare practitioners to face decisions about what devices to prescribe, potentially changing devices already being prescribed, explaining to patients what a recall means to their health, or potentially having to operate to remove an implanted medical device. Patients, in turn, evaluate concerns about the health benefits of the use of devices that may have been recalled, and decisions about how to respond to a recall (i.e., by discontinuing use of a device or having a device removed). All of this affects the cost of medical care, if a recall changes treatment options available to patients or if a surgery must take place to remove a recalled medical device.

The U.S. Chamber of Commerce in "Pharmaceutical Liability Study," has confirmed that access to negative information about prescription products makes physicians hesitant to prescribe them and patients to take them.<sup>27</sup> While in the context of the effect of pharmaceutical product liability litigation, the Chamber's findings are instructive as to the potential impact of a recall on a prescription product. The report noted that many doctors feel that information provided to patients (such as

<sup>22</sup> <http://www.fda.gov/ICECI/Inspections/IOM/ucm122546.htm#7.2.3> (last accessed Aug. 9, 09).

<sup>23</sup> Stearn, Douglas W., *Detering the Importation of Counterfeit Pharmaceutical Products*, 59 FOOD & DRUG L.J. 537-562 (2004).

<sup>24</sup> Bruderlin-Nelson, Christe S., (2007), *Chinese counterfeit devices elevate health concerns*, IVD TECHNOLOGY accessed from <http://www.devicelink.com/ivdt/archive/07/11/004.html> (Last accessed Aug. 9, 09).

<sup>25</sup> Bunker, Amy M., *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health*, 89 J. Pat. & Trademark Office Soc. 493 (2007).

<sup>26</sup> FDA provides a number of on-line resources to identify information about recalls. For example, a searchable database for device recalls is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>.

<sup>27</sup> *Chamber Study Shows Rx Lawsuits Affect Behaviors*, <http://www.uschamber.com/press/releases/2003/july/03-125.htm> See bottom of article for link to download the study.

patient packet inserts) is more complicated than necessary as a result of product liability litigation. Further doctors surveyed for the report said that their patients have stopped or refused to take prescribed medications because they discovered the drug might be involved in product liability litigation. While recalls of medical devices are obviously in the public interest, public reporting of a recall may elicit undue alarm or caution from patients (similar to those effects proven out in the Chamber's study).

For example, the availability of warning letters, recall information<sup>28</sup> and Public Health Notifications<sup>29</sup> is often used to create news feeds in blogs and in daily news updates on trends in medical devices, both of which can have an impact on a company's public image. Warning letters can also be used by competitors in a way that is not positive for the company.

The new analysis of warning letters in this study sheds light on the issues medical device firms are facing. The majority of the warning letters reviewed here cited issues including failure to comply with current good manufacturing practices, adulteration, issues regarding compliance and quality of medical devices or the quality system regulation. With the new administration at FDA, there appears to be the intent to speed up inspections and issuance of warning letters.<sup>30</sup> FDA Commissioner Margaret Hamburg recently indicated that FDA also intends to take aggressive action when direct patient harm is likely. Warning letters will no longer be required to be reviewed by the agency's top lawyer before being mailed.

The authors found a sharp increase in Class I recall actions in FY 2007 followed by the evident decline in FY 2008 compared to the previous fiscal years. This decline requires further exploration in light of new expectations at FDA. Classification of more device recalls by FDA at levels of lower risk (Class II or Class III) could be a reason for the lower number of Class I recalls in FY 2008, but it is not completely clear if that is the reason for the decline in Class I recalls in FY 2008.

With all this in mind, the establishment of Unique Device Identifiers (UDI) could potentially enhance the management of medical device recalls. The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes language related to the establishment of a Unique Device Identification System. This new system, when implemented, will require: 1) the label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices; 2) the unique identifier to be able to identify the device through distribution and use; 3) the unique identifier

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<sup>28</sup> On Sept. 30, 2009 FDA launched an on-line video to educate the public about recalls: *FDA 101: Product Recalls* <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm182929.htm> "When an FDA-regulated product is either defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public." FDA's Resource for Health Care Professionals on Device Recalls, Alerts, and other Safety Information is at <http://www.fda.gov/MedicalDevices/Safety/default.htm>. FDA Patient Safety News, a video update of safety issues, can be found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm>. Alerts and notices about safety issues involving medical devices are located at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm>.

<sup>29</sup> As FDA notes; "A Public Health Notification is an important message from the FDA's Center for Devices and Radiological Health (CDRH) to the healthcare community describing a risk associated with the use of a medical device and providing recommendations to avoid or reduce the risk." A Public Health Notification is an important message from the CDRH to the healthcare community describing a risk associated with the use of a medical device and providing recommendations to avoid or reduce the risk.

<sup>30</sup> Heavey, S., *Update 2—US FDA chief vows to speed up inspections, warnings*, (Aug. 6, 2009), accessed from <http://www.reuters.com/article/rbssHealthcareNews/idUSN0642179520090806>. (Last accessed Aug. 9, 2009).

to include the lot or serial number if specified by FDA.<sup>31</sup> A public workshop was held recently to discuss this topic,<sup>32</sup> and it appears that proposed regulation may be issued this year.<sup>33</sup> The industry-wide UDI system could bring about more efficient recalls. For instance, it could narrow the scope of recalls (i.e., fewer products), which invariably would result in significant savings to the recalling firm and less impact to the device user. Also, UDIs could help hospitals and healthcare facilities manage their responses to products recalls. FDA will oversee a public database where all UDI information will be stored. With this system in place, the agency and companies will have better control over all products.

#### IV. CONCLUSION

This analysis showed that there were 111 Class I recalls over the last five fiscal years. A new category of reasons for recall, counterfeit, was identified which has added an additional burden to both medical device manufacturers and end-users. Lay press and medical literature are means by which information on medical device recalls reaches patients and healthcare providers. This analysis also showed that issues leading to a medical device recall are often also identified in warning letters issued to firms following inspections.

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<sup>31</sup> Available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm> (Last accessed Aug. 9, 2009).

<sup>32</sup> Available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm111135.htm> (Last accessed Aug. 9, 2009).

<sup>33</sup> [THE SILVER SHEET], Vol 13, No. (June 6, 2009).

## TABLES AND FIGURES

*Table 1.* Reasons for recall chosen to categorize the information in the Medical Device Recall Database or the FDA Enforcement Report. The terms are listed, along with a general definition, and descriptive text from selected recalls.

<i>Reason Category</i>	<i>Example "Reason for Recall"</i>
Contamination	"The product is contaminated with Burkholderia cepacia (formally known as Pseudomonas cepacia), based on the Texas Health Department analysis and also firm's analysis."
Counterfeit	"The product is reported to be counterfeit."
Electrical	"The pumps may experience inadvertent power off, external communications port failures and electronic pump failure codes."
Labeling	"The original labeling for the device is inadequate because it instructs users to route the blood tubing sets through both channels of the two channel clips."
Manufacturing	"Some of the cards were stamped with an incorrect card code causing the system to read and report the cards incorrectly."
Mechanical	"Excessive wear of the hanger bar bolt, that connects the lift arm to the sling spreader bar, may cause the bolt to snap allowing the patient to fall."
Physiological implications	"Complaints of vessel erosion when using this product"
Regulatory	"Device marketed without 510k clearance..."
Sensor	"An in-vitro diagnostic kit reagent may cause false negative results in patients tested for sexually transmitted infections."
Software	"Software has the potential to match the patient with a different patient's test results."
User interface	"User may inadvertently change Units of Measure from mg/dL to mmol/L and the blood glucose results could be misinterpreted. This may lead to under treatment and potential for hyperglycemia."

Table 2: Analysis parameters and sources of information

<i>Sources</i>	<i>Analysis parameters</i>
Enforcement Report	Recall actions Products ("Z"-numbers) recalled Units recalled Firm- or FDA-initiated Recall is complete or ongoing
Reason for Recall from Enforcement Report	"Reason for Recall" text to determine category in Table 1
Medical Device Recalls Database 510(k) Database PMA Database Device Listing Database	Internal/external device Device class Medical Specialty
Internet resources Warning Letters	Public/private company Warning letter issued before or after recall Company response time Issues identified in warning letters
Search of Medical Literature	Instances of medical device recalls mentioned in medical literature
Search of Lay Press	Instances of medical device recalls mentioned in lay press
US Judicial Panel on Multidistrict Litigation	Multidistrict litigations filed for device recalls in this analysis

Table 3: Number of recall actions, recalled products, and recalled units in Class I Medical Device Recalls for FY 2004-2008.

	<i>Actions</i>	<i>Products</i>	<i>Units</i>
2004	23	32	1,882,991
2005	26	75	8,518,244
2006	21	76	18,097,161
2007	27	45	57,728,476
2008	14	131	727,219
<b>TOTALS</b>	111	359	86,954,091

Table 4: Number of Recall Actions in each Reason for Recall Category,  
FY 2004-2008

	2004	2005	2006	2007	2008	TOTAL
<b>Software</b>	5	2	0	5	1	13
<b>Mechanical</b>	10	8	8	6	8	40
<b>Manufacturing</b>	3	0	1	0	1	5
<b>Electrical</b>	2	7	4	1	1	15
<b>Sensor</b>	1	2	2	2	0	7
<b>Contamination</b>	1	0	3	3	1	8
<b>User interface</b>	1	3	0	1	0	5
<b>Physiological implications</b>	0	1	1	1	1	4
<b>Labeling</b>	0	2	2	0	0	4
<b>Regulatory</b>	0	1	0	0	1	2
<b>Counterfeit</b>	0	0	0	8	0	8
<b>TOTAL</b>	23	26	21	27	14	111

Table 5: Number of Units Recalled in each Reason for Recall Category,  
FY 2004-2008

	2004	2005	2006	2007	2008	TOTAL
<b>Software</b>	624	678	0	48,930	249	50,481
<b>Mechanical</b>	1,760,958	1,058,807	14,349,346	54,455	418,480	17,642,046
<b>Manufacturing</b>	79,632	0	18,000	0	203,277	300,909
<b>Electrical</b>	16,499	338,352	352,436	292,108	1,795	1,001,190
<b>Sensor</b>	6,692	2,499	2,436	14,504	0	26,131
<b>Contamination</b>	14,120	0	3,357,537	57,265,814	618	60,638,089
<b>User interface</b>	4,466	6,006,460	0	2,484	0	6,013,410
<b>Physiological implications</b>	0	36,340	12,234	102	102,792	151,468
<b>Labeling</b>	0	591,748	5,172	0	0	596,920
<b>Regulatory</b>	0	483,360	0	0	8	483,368
<b>Counterfeit</b>	0	0	0	50,079	0	50,079
<b>TOTAL</b>	1,882,991	8,518,244	18,097,161	57,728,476	727,219	86,954,091

Figure 1. Distribution of reasons for recall for all fiscal years. The data is presented for total actions and units. Categories are defined in Table 1.

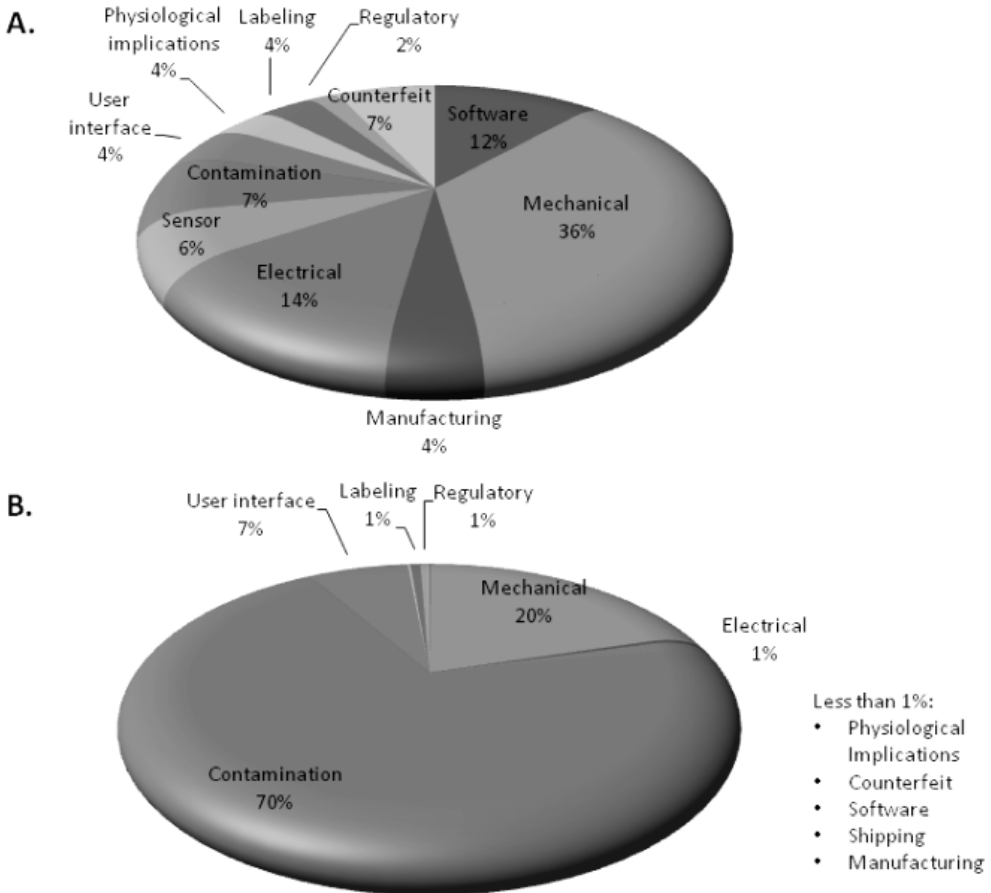
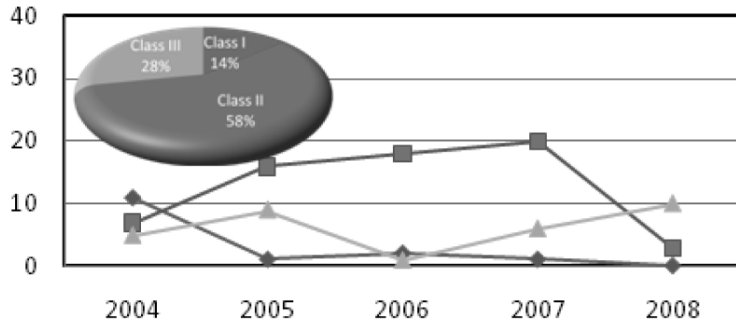


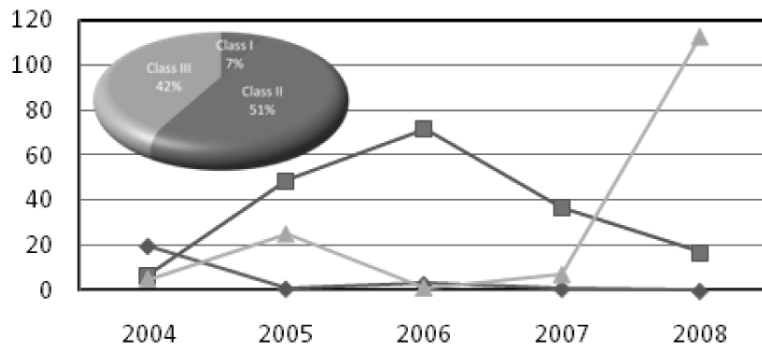
Figure 2. Distribution of devices recalled by device class. A. Device class by recalled actions (cumulative and per year). B. Device class by recalled products (cumulative and per year).

**A.**



	2004	2005	2006	2007	2008
◆ Class I	11	1	2	1	0
■ Class II	7	16	18	20	3
▲ Class III	5	9	1	6	10

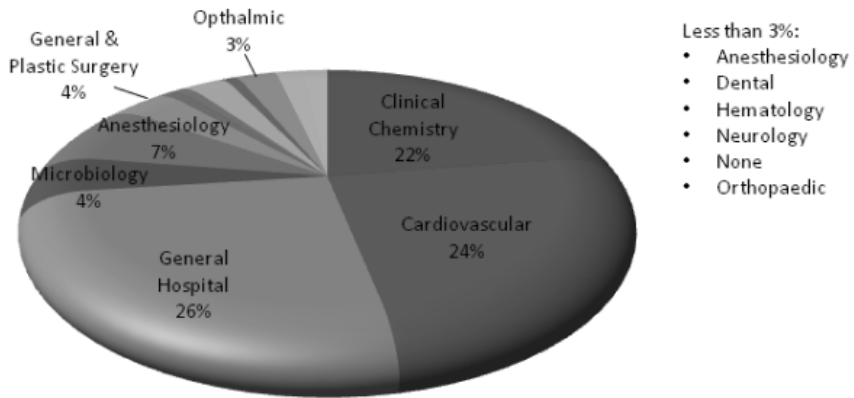
**B.**



	2004	2005	2006	2007	2008
◆ Class I	20	1	3	1	0
■ Class II	7	49	72	37	17
▲ Class III	5	25	1	7	113

Figure 3: Medical Specialties across all fiscal years for A. Recall Actions and B. Units Recalled.

A.



B.

