AdvaMed
Advanced Medical Technology Association

"A Delicate Balance: FDA and the Reform of the Medical Device Approval Process"

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My name is David Nexon, and I am Senior Executive Vice President of the Advanced Medical Technology Association (AdvaMed).

Thank you Chairman Kohl, Ranking Member Corker and Members of the Committee, for the opportunity to testify on this important topic. I would also like to especially thank you, Chairman Kohl, for your leadership on the Physician Payment Sunshine Act and for the opportunity you provided our industry to work with you to assure that the bill provided the public with the information it needed while enabling companies to continue to innovate.

AdvaMed is the world's leading trade association representing manufacturers of medical devices and diagnostics. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

The U.S. Medical Technology Industry

The medical technology industry is an American success story. Our industry employs more than 400,000 workers nationwide, including over 14,000 in the state of Wisconsin, making Wisconsin one of the top 10 states with the largest medical technology industry employment. And, if indirect employment is included, the employment impact is substantially higher. Typically, for every worker our industry directly employs, another four workers are employed by businesses supplying components and services to our industry and our employees.[1]

Other states represented by members of this Committee also have significant levels of medical technology employment, including Florida, Pennsylvania, and New York, which are all in the top 10 states with the largest medical technology industry employment.[2]

Our industry is heavily skewed toward small companies—the kind of companies that begin with a doctor, and engineer, and an idea to improve patient care. Almost two-thirds of the 7,000 medical technology firms in the U.S. have fewer than 20 employees. A high proportion of the breakthrough products in our industry come from these small, often venture-capital funded companies.[3]

And whether the firm is large or small, success in our industry comes only from innovation—the creation of diagnostics, treatments and cures that extend and enhance lives. Our industry's investment in research and development is more than twice the national average. Our product life-cycle is only 18-24 months.

The jobs our industry provides are good jobs—the kinds of jobs that allow employees to live the American dream. Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment.[4]

While the number of manufacturing jobs was plummeting across the larger economy, even before the current recession, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4%, adding 73,000 jobs.[5] During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4% for manufacturing as a whole.[6]

Our industry is so competitive that price increases have averaged only one-quarter the rate of other medical goods and services and just one-half the general CPI for almost 20 years.[7]

With $33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports.[8] Notably, unlike virtually every other sector of U.S. manufacturing, medical technology has consistently enjoyed a favorable balance of trade. With the aging of both U.S. and foreign populations, the projected explosive growth of large middle class populations demanding modern health care in developing countries like China and India, and the accelerating pace of biomedical discovery, the potential for growth of our industry is great.

While we are very proud of our contributions to the U.S. economy, we are even more proud of our contributions to improving patient care. For patients, medical progress has been remarkable. Between 1980 and 2000, medical progress added more than three years to life expectancy. The death rate from heart disease was cut in half; the death rate from stroke was cut by one-third, and the death rate from breast cancer was cut 20%.[9]

While we are proud of the progress we have made in improving patient care and see immense future opportunities to provide jobs and contribute to long-term economic growth, we are also worried. Today, America is the world leader in medical technology. But the trends are not good. Ten years ago we were the unchallenged world leader. Today, we are the challenged world leader. In ten years, we may not be the world leader at all. As a recent PriceWaterhouse Coopers report showed, our lead is slipping on a number of dimensions of competitiveness.[10] As I will discuss in more detail later in my testimony, a key factor in our loss of competitiveness has been the sharp decline in the efficiency of FDA's performance in stimulating the development of safe and effective medical devices and clearing them promptly so that they can be available to patients.

We are very appreciative of the Committee's interest in the topic of the Food and Drug Administration's regulation of medical devices. Put simply, FDA is a critical partner in our companies' efforts to bring safe and effective medical devices to patients. Without a strong, effective, and efficient FDA, we can not have a strong and competitive industry. President Obama recently noted in a Wall Street Journal opinion piece that there is a need to improve FDA's process for approving medical devices, "to keep patients safer while getting innovative and life-saving products to market faster." The predictability and efficiency of FDA decision-making, as well as reasonable, risk-based standards of evidence to assure the safety and effectiveness of medical technology products, is essential to drive new innovations for patients and for the long-term success of the medical device industry.

We are pleased at the President's recognition of the need to improve FDA's performance, and we are pleased that that recognition is shared by the FDA leadership. There are a number of policy changes now in process that, if implemented effectively, could significantly improve FDA's ability to meet the needs of patients and industry—but much needs to be done to restore the level of performance to where it was just a few years ago—a level that was suboptimal even then.

FDA's 510(k) Process for Pre-Market Review

FDA clears products for marketing by one of two routes—the 510(k) process or the Pre-market Approval (PMA) process. The 510(k) process clears products based on their similarity to products that are already on the market and is not available to highest risk products. To be cleared under the 510(k) process, a product must be judged by FDA to be "substantially equivalent" to a product already on the market, and manufacturers must demonstrate that the product is as safe and effective as the marketed product. If it has different technological characteristics or a different intended use than the product already on the market, the device manufacturer must present data to show that the product does not "raise new questions of safety and effectiveness." The FDA has broad discretion to require any data that it thinks necessary to assure the substantial equivalence of the device, including clinical data. And the FDA is the ultimate arbiter of whether a company may utilize the 510(k) process as a route to market.

The 510(k) process is critical to a vibrant and successful device industry and to the process of medical innovation that provides better products for patients to address unmet clinical needs. In a typical year, 3,800-4,000 new products will be cleared for marketing through the 510(k) process. This compares to 30-40 products annually approved through the PMA process.

Of course, medical devices can be very complex and, like other medical treatments, involve a balancing of risks and benefits. Yet studies have shown that the 510(k) process has an exemplary record of protecting the public from unsafe devices. A recent study conducted by the Battelle Memorial Institute found that of the nearly 47,000 medical devices cleared by FDA through the 510(k) process and on the market since 1998, less than two-tenths of one percent were involved in a class I recall, the most serious level of recall. The Battelle study further noted that less than one-tenth of one percent of devices cleared via 510(k) since 1998 were recalled for design reasons, the type of issue likely to be observed during premarket review.[11]

Another study by Professor Ralph Hall of the University of Minnesota, who is here with us today, found that class I recalls accounted for just 0.45 percent of cleared 510(k) products over the five years studied.[12] A third study by Dr. William Maisel, formerly of Beth Israel Deaconess Medical and now here with us today in his current role at the FDA, looked at all classes of recalls - the vast majority of which have no impact on patient care - and also found the 510(k) recall rate to be very low - in the range of 1.0 to 1.5 percent.[13]

These three studies come to the same conclusion - that FDA's 510(k) process has a strong safety record. While we recognize that product recalls do occur and that one patient harmed is one too many, our companies are striving - everyday - to make their products safer for patients, and we know that FDA shares this same goal.

The PMA process also has an exemplary safety record. Both the Hall and Battelle studies examined recalls for PMA products as well as 510(k) products and found a very low recall rate. Our joint challenge, as we seek to improve this excellent safety record, is to make sure that we do not impose requirements that provide minimal public health benefits while limiting the development of new treatments and cures.

Recently, FDA has undergone a thorough review of the 510(k) process, and is in the early stages of implementing some of their recommended changes. The Institute of Medicine has also been asked to review the process and will be making recommendations this year as to any changes it thinks are necessary. The device industry welcomes this review, because we believe that every process can be improved and that public confidence in it can be increased. In this regard, we have contributed a number of ideas to the FDA and are pleased to have engaged in positive dialogue with FDA.

The FDA has benefitted from significant increases in resources in recent years –thanks in no small part to your leadership on the Appropriations Committee, Mr. Chairman -- and the premarket review process has been shown to have a strong safety record; yet troubling trends have emerged at the FDA that risk unduly delaying patient access to safe and effective products. These trends also increase uncertainty for companies and are negatively impacting investment in new treatments and diagnostics. For example:

- Average approval times for original PMAs have risen 75% just since 2007, to more than two years.[14]

- Our companies report that the time to get an Investigational Device Exemption (IDE) - the prerequisite to beginning the clinical trials that must be completed before a PMA application and some more complex 510(k) applications - have lengthened dramatically - to times that are often measured in years rather than months. And the time just to get a meeting to discuss an IDE can be six months or more.

- The average 510(k) decision time has risen 20 percent (97 days in 2002 vs. 116 days in 2008)[15]

- The number of days 510(k) submitters spend answering FDA requests for more data has nearly tripled (19 days in 2002 vs. 51 days in 2008)[16]

- The number of review cycles (the number of times FDA "stops the clock" on its review because it has decided to ask the manufacturer for more information) per 510(k) submission increased by one-third between 2002 and 2008 (1.4 per application in 2002 vs. 1.9 in 2008)[17]

- The percentage of 510(k)s withdrawn by sponsors has skyrocketed 89 percent from 2004 to 2009 (nine percent to 17 percent).[18] This increase is indicative of a lack of clarity and consistency in FDA's review standards.

Additionally, several recent studies have demonstrated the existence of a "device lag" or a delay in U.S. patient access to innovative medical technologies as compared to patients in other countries. These studies outline a disturbing pattern of delay and inefficiencies at FDA that delay patient access to new treatments and cures and erode U.S. global competitiveness in the development of medical technology. Studies have also shown that these delays and inefficiencies do not result in greater protection for patients.

Dr. Josh Makower, medical device entrepreneur and professor at Stanford University, found in a recent survey of 200 small companies that on average, innovative new devices are available to U.S. patients two full years later than patients in other countries.[19] In some cases, American patients wait as long as six years longer than patients elsewhere. This hurts patient health and U.S. competitiveness. Additionally, Dr. Makower's survey found that by strong majorities, companies reported that European regulatory authorities were more predictable and transparent than FDA. Almost half the companies reported that key FDA personnel responsible for reviewing their product changed during the course of the review, and one-third reported that appropriate staff was not present at meetings between the companies and FDA to discuss review issues. Companies are willing to work with the FDA and provide the data that are necessary for new product submissions, but it is unreasonable to expect a company to navigate rules that change in the middle of the game.

Similarly, the California Healthcare Institute, or CHI, recently released a report by the Boston Consulting Group called "Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry" where they identified similar problems at FDA. Boston Consulting Group, using a different industry sample, found that the average lag between European and U.S. approval of PMA products had grown from slightly more than a year in 2004 to almost four years by 2010.

As I stated earlier, we are pleased that the Administration and the FDA, from the President on down, have recognized that there is a serious problem that needs to be addressed. Some of the proposals included in the 510(k) and "New Science" reform plans are very constructive could, if implemented properly, help improve the situation. These include greater reviewer training, more product specific guidance documents, and new efforts to improve the consistency of review. We are also pleased that some of the original proposals that could have increased industry burdens and further slowed product approvals without providing safety improvements were dropped from FDA's 510(k) implementation plan.

We stand ready to work with FDA in addressing these challenges.

FDA's Post-Market Authority for Medical Devices

FDA's work on ensuring patient access to safe and effective medical devices, however, does not end once products are on the market. No premarket review system, no matter how rigorous, will be able to identify all the potential problems that can develop in the real world of care for large numbers of patients with unique characteristics and with a wide range of health care professionals.

FDA has many post-market tools at its disposal, and its post-market authorities under the Federal Food, Drug and Cosmetic Act (FD&C Act) are robust. These controls ensure that all devices, but especially higher risk devices, are adequately monitored once they reach the market, and subject to remedial measures, if necessary, to protect the public health. In several respects, postmarket controls were tailored to reflect device risk and therapeutic or diagnostic importance, so that complex devices like robotic surgical equipment and automatic implantable cardioverters/defibrillators are subject to more controls than those applied to simple devices like stainless steel scalpels.

The following includes a description of the FD&C Act's three integrated types of device postmarket controls that assure device safety and effectiveness:

1. comprehensive sources of clinical experience data;

2. methods of device location to support remediation efforts; and

3. remedies to ensure the continued availability of safe and effective devices.

It is important to note that all devices are subject to the FD&C Act's General Controls that ensure devices and device manufacturing facilities remain in compliance. Once a device reaches the market, numerous regulatory requirements kick in requiring device manufacturers to actively monitor the performance of their products and ensure that their devices and manufacturing facilities maintain compliance with the requirements of the FD&C Act. For example, all devices, no matter what their regulatory classification, are subject to the general controls of the FD&C Act, including registering device facilities with the U.S. Food and Drug Administration (FDA) so that the agency may locate and inspect them, listing with FDA devices in commercial distribution, and manufacturing devices in accordance with the good manufacturing practices identified in the Quality System Regulation (QSR).[20] As part of the QSR, most devices are required to be manufactured in accordance with design controls, including appropriately managing any design changes made to a marketed device,[21] an important part of ensuring safe and effective products.

The QSR also requires all device manufacturers to maintain complaint files on any alleged deficiencies related to a device's identity, quality, durability, reliability, safety, effectiveness, or performance.[22] Manufacturers evaluate these complaints as part of their quality system to determine, among other things, whether medical device reports (MDRs) for device malfunctions and serious adverse events must be reported to the agency; corrective or preventive actions, including manufacturing changes, must be initiated; or

recalls must be undertaken. Complaint and corrective and preventive action files are among the first things FDA investigators examine when they inspect a device manufacturer; review of these documents provides enormous insight into the quality of a device manufacturing facility and the products manufactured at the facility.

The FD&C Act requires device manufacturers (and others) to collect and report to FDA a large amount of useful postmarket information. The FD&C Act and FDA's regulations require adverse event reporting to the agency through MDRs, thus providing FDA valuable information upon which to assess product performance. Specifically, a manufacturer must submit an MDR when it becomes aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury. MDRs must also be submitted for device malfunctions where, if the malfunction were to recur, the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury.[23] In addition to manufacturers, the FD&C Act requires importers and user facilities, for example, hospitals, to submit adverse event information to the agency. FDA receives MDR information within 30 days of manufacturers becoming aware of reportable events, unless remedial action is necessary to protect the public health, and then the time to report is reduced to five days. Non-compliance with reporting requirements can result in significant remedial action, ranging from criminal prosecution to product seizures. According to the agency, in 2010, it received about 330,000 adverse events for all medical devices.[24] FDA uses these reports to target unsafe or ineffective devices.

Importantly, the FD&C Act requires mandatory reporting of certain corrections and removals of devices within 10 working days of initiating remedial actions.[25] Device manufacturers and importers must report to FDA corrections or removals if the action was taken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health. As a result, all health-related voluntary recalls must be reported to FDA.[26] These reporting requirements also encompass non-recall actions, *i.e.*, corrections and removals of non-violative devices taken to reduce a risk to health.[27] Again, the failure to comply with this reporting requirement would potentially subject violators to dire enforcement consequences.

FDA also has ample authority to require postmarket studies to generate specific information the agency deems necessary to protect the public health. For example, FDA may require a post-approval study as a condition of approval of a premarket approval application (PMA) for a class III device.[28] Post-approval studies can be either clinical or non-clinical studies, or both. FDA's website currently identifies 120 records of post-approval studies ordered since January 1, 2005, and their status. The agency also monitors postmarket performance of PMA devices through the manufacturers' submission of annual reports that, among other things, contain a summary of unpublished reports of data from clinical or non-clinical studies, reports in the scientific literature concerning the devices, and changes made to devices that do not implicate safety or effectiveness.[29] A failure to comply with a condition of approval could result in grounds to withdraw an approved PMA.

Also, FDA has the authority under the FD&C Act to order postmarket surveillance for class II and III devices where (1) the device's failure would be reasonably likely to have serious adverse health consequences, (2) the device is expected to have significant use in pediatric populations, (3) the device is intended to be implanted for more than one year, or (4) the device is life-sustaining or life-supporting and is used outside a device user facility.[30] This postmarket surveillance requirement may last for three years, unless the agency and the manufacturer agree to a longer period, or if no agreement is reached, after a determination by a dispute resolution panel prescribed by statute. As an exception, postmarket surveillance for pediatric devices may last longer than three years.

Congress originally provided FDA with mandatory and discretionary postmarket surveillance authority in 1990, but after determining the law was "so broadly worded that it is causing a great deal of uncertainty about those devices which are subject to this requirement," Congress amended the law in 1997 to grant FDA "broad discretion to implement postmarket surveillance."[31] Failure to comply with a postmarket surveillance order renders a device misbranded and is also a prohibited act under FD&C Act § 301(q). The agency's website currently identifies 39 postmarket surveillance studies.

For certain devices, FDA may impose additional postmarket requirements to ensure effective remedial actions. The FD&C Act gives FDA broad discretionary authority to require device tracking to ensure that manufacturers will be able to promptly locate devices in commercial distribution to facilitate patient or healthcare professional notifications or device recalls.[32] Specifically, the agency may order a manufacturer to track a class II or III device where (1) device failure would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted for more than one year, or (3) the device is life-sustaining or life-supporting and is used outside a device user facility. Like the postmarket surveillance provision, Congress fine-tuned FDA's tracking authority in 1997 by eliminating mandatory tracking for certain devices because here also the "statutory mandate [had] proven to be uncertain with regard to which devices require mandatory tracking."[33] Currently, approximately 17 types of devices are subject to tracking orders, including TMJ prostheses, automatic implantable cardioverter/defibrillators, and ventricular bypass (assist) devices used outside a device user facility. A manufacturer that fails to meet the requirements of a tracking order misbrands its device.

FD&C Act § 520(j) and FDA's regulations authorize additional traceability requirements for certain devices. Specifically, manufacturers of implants and life-supporting or life-sustaining devices that can be reasonably expected to result in a significant injury to users if they fail to perform when properly used, must have procedures for identifying with a control number each unit, lot, or batch of finished devices and, where appropriate, components.[34] The purpose of these requirements is to support and facilitate corrective actions. This requirement by regulation applies to all devices within the specified categories, and unlike tracking, does not require FDA action to impose the product identification requirement to specific devices.

Importantly, the FD&C Act provides the agency with extensive remedial authority. To address devices in commercial distribution, the statute empowers FDA with more

remedial measures for devices than for any other FDA regulated product. For example, the agency has mandatory recall authority when there is a reasonable probability that a device would cause serious, adverse health consequences or death.[35] This authority empowers FDA to order the immediate cessation of use and distribution of devices prior to a hearing. Within 10 days, the agency would hold an informal hearing to determine the correctness of its original action or the exercise of administrative injunctive authority and whether a recall is appropriate. A failure to comply with a mandatory recall order misbrands the device and, of course, is subject to FDA's enforcement authority.

FDA rarely needs to invoke this authority because the vast majority of device recalls are conducted under the agency's voluntary recall guidelines that apply to all products regulated by FDA.[36] However, the regulatory threat posed by this authority reinforces the agency's leverage to obtain voluntary device recalls.

In addition to this powerful recall tool, the law authorizes FDA to issue mandatory notification orders that require notification to healthcare providers, patients, or others when a device presents an unreasonable risk of substantial harm to the public health.[37] Failure to comply with a notification order results in a misbranded device. Additionally, under the FD&C Act, FDA may order a device manufacturer, importer, or distributor to repair a device, replace a device, or refund the purchase price of a device if the device presents an unreasonable risk of substantial harm and the device was not properly designed or manufactured with reference to the state of the art.[38] The FD&C Act also empowers the agency to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury.[39]

Importantly, FDA has powerful enforcement tools at its disposal, including criminal prosecution, device civil money penalties, injunctions, and device seizure.[40] Under the FD&C Act, and in support of device seizures or injunctions, FDA investigators can administratively detain devices based on a mere "reason to believe" that they are misbranded or adulterated.[41] Further, the FD&C Act empowers FDA to publicize information relating to "imminent danger to health or gross deception of the consumer,"[42] thus positioning the agency to leverage the vast amount of postmarket device information that the law directs to the agency.

The robustness of FDA's device postmarket authorities has long exceeded those for drugs. Recently, Congress updated drug postmarket authorities to make them more similar to those authorities long applied to devices, including tracking of prescription drugs[43] and the ability to order postmarket studies or clinical trials to assess serious risks related to the use of a drug.[44] However, the agency's postmarket drug controls still do not equal those for devices. For example, postmarket drug authorities do not include mandatory recall (including the device administrative injunctive component), reports of corrections or removals, or administrative detention. In sum, the FD&C Act includes more postmarket authorities for devices than drugs, and those comprehensive device authorities equip FDA to manage the device postmarket context.

Aside from the authorities listed above, FDA has a number of tools that are under development and will enhance their post-market abilities, including the implementation

of unique device identifiers, or UDI. The UDI system, particularly when coupled with electronic medical records and FDA's MedWatch program (Safety Information and Adverse Event Reporting), will provide FDA with the ability to track targeted patient outcomes for large patient populations on a real-time basis and can be an extremely valuable tool for device manufacturers anxious to improve their products and for FDA problem identification.

FDA is currently developing guidance on implementation of unique device identifiers, and AdvaMed is pleased to partner with FDA in this effort to develop a workable and effective tracking system.

Similarly, AdvaMed has been pleased to partner with FDA and other organizations as they have sought to develop and implement product-specific and patient outcomes-focused medical device registries, I'd like to focus for a minute on one particular example, which is our orthopedic sector's work on a national orthopedic registry.

AdvaMed's orthopedic sector is part of a collaborative initiative with orthopedic surgeons, hospitals, payers, patients, and other stakeholders to develop the American Joint Replacement Registry (AJRR). At the request of the AJRR Board of Directors, the sector has made a substantial and ongoing financial commitment to the AJRR, which has begun a pilot program, which is already collecting data in 15 hospitals before expanding nationwide. The AJRR's goal is to achieve over a 90% capture rate of all hip and knee joint replacements done in the U.S. by 2014. This registry is being thoughtfully developed by a multi-stakeholder governance board focused on the range of factors that impact patient outcomes after a joint replacement – including the implant itself, the skill and technique of the surgeon, and the facility in which the procedure takes place. The AJRR will generate data that can improve outcomes for hip and knee replacements and identify potential performance issues that require further investigation.

It is important to recognize, however, that registries are not a one-size fits all solution. They are costly and labor-intensive to operate. They require buy-in and willingness to devote substantial amounts of time from a large number of clinicians and hospital staff. In order to provide useful information, they must be designed to meet specific objectives and to collect data that relates directly to those objectives.

In summary, registries can play an important role in improving device safety and effectiveness under certain circumstances, but a more effective and less costly approach for most products is the use of UDI in conjunction with electronic medical records.

Conclusion

In conclusion, FDA's device regulatory systems must be thorough, timely and efficient in order to best serve both American patients and U.S. medical technology innovation.

AdvaMed and our member companies are supportive of a strong FDA so that it can fulfill its dual mission of patient safety and patient access to new treatments and cures.

I appreciate the Committee's interest in these issues and thank you for the opportunity to testify.

[1] The Lewin Group, "State Economic Impact of the Medical Technology Industry," June 7, 2010.
[2] *Ibid.*
[3] United States International Trade Commission, "Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets," March, 2007.
[4] *Ibid.*
[5] *Ibid.*
[6] *Ibid.*
[7] Donahoe, Gerald and King, Guy. "Estimates of Medical Device Spending in the U.S." May, 2009. Available from: http://www.advamed.org/NR/rdonlyres/6ADAAA5B-BA37-469E-817B-3D61DEC4E7C8/0/King2009FINALREPORT52909.pdf
[8] The Manufacturing Institute, "The Facts about Modern Manufacturing," 2009, p. 18; ITC data web.
[9] MEDTAP International, Inc. The Value of Investment in Health Care: Better care, Better Lives, 2004, Bethesda, MD: MEDTAP.
[10] PriceWaterhouseCoopers, "Medical Technology Innovation Scorecard: The race for global leadership." January 2011.
[11] The Battelle Memorial Institute, "510(k) Premarket Notification Evaluation," .Advanced Medical Technology Association, September, 2010.
[12] Hall, Ralph. "Using Recall Data to Assess the 510(k) Process." July 28, 2010. http://www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/510kProcess/2010-JUL-28/06%20Hall.pdf. April 11, 2011.
[13] Maisel, William. "Premarket Notification: Analysis of FDA Recall Data." July 28, 2010. http://www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/510kProcess/2010-JUL-28/05%20Maisel.pdf. April 11, 2011.
[14] The Boston Consulting Group, "Competitiveness and Regulation: the FDA and the Future of America's Biomedical Industry," California HealthCare Institute, February, 2011.
[15] FDA data.
[16] FDA data.
[17] FDA data
[18] FDA data.
[19] Makower, Josh. "FDA Impact on U.S. Medical Technology Innovation." Medical Device Manufacturers Association. November, 2010.
[20] Registration and listing are required per FD&C Act § 510 and the Quality System Regulation is found in 21 CFR Part 820.

[21] 21 CFR § 820.30(i).
[22] 21 CFR § 820.198.
[23] FD&C Act § 519(a).
[24] *See* Transcript of the Center for Devices and Radiological Health, Medical Devices Advisory Committee, Circulatory System Devices Panel at 39 (Jan. 25, 2011).
[25] FD&C Act § 519(g).
[26] A class I recall occurs when "there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." A class II recall occurs when "use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." A class III recall occurs when "use of, or exposure to, a violative product is not likely to cause adverse health consequences." 21 CFR § 7.3(m).
[27] Corrections and removals without health-related implications are not reportable to FDA, but records of such corrections and removals must be maintained by a device facility for inspection.
[28] 21 CFR § 814.82(a).
[29] 21 CFR § 814.84(b).
[30] FD&C Act § 522.
[31] S. Rep. No. 104-43 at 37 (1997).
[32] FD&C Act § 519(e).
[33] S. Rep. No. 104-43 at 36.
[34] 21 CFR § 820.65.
[35] FD&C Act § 518(e).
[36] 21 CFR Part 7.
[37] FD&C Act § 518(a).
[38] FD&C Act § 518(b).
[39] FD&C Act § 516.
[40] FD&C Act §§ 302, 303, and 304.
[41] FD&C Act § 304(g).
[42] FD&C Act § 705.
[43] FD&C Act § 505D(b).
[44] FD&C Act § 505-1.