Gil Frazier
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Editors

Medical Devices and the FDA

Regulation, User Fees and Tort Claims

BIOMEDICAL DEVICES AND THEIR APPLICATIONS

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PREFACE

Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical devices. They may be simple tools used during medical examinations, such as tongue depressors and thermometers, or high-tech life-saving implants like heart valves and coronary stents. The medical device market has been characterized as including eight industry sectors: surgical and medical instrument manufacturing, surgical appliance and supplies, in vitro diagnostic products (IVDs, or laboratory tests), electromedical and electrotherapeutic apparatus, irradiation apparatus, dental equipment and supplies, ophthalmic goods, and dental laboratories. This book explores FDA regulation of medical devices with a focus on the user fee program and tort claims.

Chapter 1 - Prior to and since the passage of the Medical Device Amendments of 1976, Congress has debated how best to ensure that consumers have access, as quickly as possible, to new and improved medical devices and, at the same time, prevent devices that are not safe and effective from entering or remaining on the market. Medical devices regulation is complex, in part, because of the wide variety of items that are categorized as medical devices; examples range from a simple tongue depressor to a life-sustaining heart valve. The regulation of medical devices can affect their cost, quality, and availability in the health care system.

In order to be legally marketed in the United States, many medical devices must be reviewed by the Food and Drug Administration (FDA), the agency responsible for protecting the public health by overseeing medical products, including devices. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. CDRH activities are funded through a combination of public money (i.e., direct FDA

appropriations from Congress) and private money (i.e., user fees collected from device manufacturers) which together comprise FDA's total. User fees account for 33% of FDA's total FY2011 program level and 15% of CDRH's program level, which is $378 million in FY2011 including $56 million in user fees. FDA's authority to collect user fees, originally authorized in 2002 (P.L. 107-250), has been reauthorized in five-year increments. It will expire on October 1, 2012, under the terms of the Medical Device User Fee Act of 2007 (MDUFA), Title II of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).

FDA requires all medical product manufacturers to register their facilities, list their devices with FDA, and follow general controls requirements. FDA classifies devices according to the risk they pose to consumers. Premarket review is required for moderate- and high-risk devices. There are two paths that manufacturers can use to bring such devices to market. One path consists of conducting clinical studies, submitting a *premarket approval* (PMA) application and requires evidence providing reasonable assurance that the device is safe and effective. The other path involves submitting a *510(k) notification* demonstrating that the device is *substantially equivalent* to a device already on the market (*a predicate device*) that does not require a PMA. The 510(k) process results in FDA clearance and tends to be much less expensive and less time-consuming than seeking FDA approval via PMA. Substantial equivalence is determined by comparing the performance characteristics of a new device with those of a predicate device; clinical data demonstrating safety and effectiveness are usually not required. Once approved or cleared for marketing, manufacturers must comply with regulations on manufacturing, labeling, surveillance, device tracking, and adverse event reporting.

Problems related to medical devices can have serious consequences for consumers. Defects in medical devices, such as artificial hips and pacemakers, have caused severe patient injuries and deaths. In 2006, FDA reported 116,086 device-related injuries, 96,485 malfunctions, and 2,830 deaths; an analysis by the National Research Center for Women & Families claims there were 4,556 device-related deaths in 2009. Reports published in 2009 through 2011—by the Government Accountability Office (GAO), the Department of Health and Human Services Office of the Inspector General and the Institute of Medicine—have voiced concerns about FDA's device review process. In 2009 and 2011 GAO included FDA's oversight of medical products on the GAO list of high-risk areas. FDA has conducted internal reviews as well and is implementing changes.

Chapter 2 - The Food and Drug Administration (FDA) is the agency responsible for the regulation of medical devices. These are a wide range of products that are used to diagnose, treat, monitor, or prevent a disease or condition in a patient. A company must obtain FDA's prior approval or clearance before marketing many medical devices in the United States. The Center for Devices and Radiological Health (CDRH) within FDA is primarily responsible for medical device review and regulation.

Congress first gave FDA the authority to collect user fees from medical device companies in the Medical Device User Fee and Modernization Act of 2002 (P.L. 107-250). The purpose of the user fee program is to help reduce the time in which FDA can review and make decisions on marketing applications. Lengthy review times affect the industry, which waits to market its products, and patients, who wait to use these products. The user fee law provides a revenue stream for FDA; in conjunction, the agency negotiates with industry to set *performance goals* for the premarket review of medical devices. Reauthorization of FDA's medical device user fees last occurred in 2007, just before the FDA's authority would expire, via the Medical Device User Fee Amendments of 2007 (MDUFA II). Current authority will expire on October 1, 2012.

On February 1, 2012, FDA announced that it had reached "an agreement in principle" with the medical device industry on proposed recommendations for the second reauthorization—referred to as MDUFA III. A draft MDUFA III package, composed of statutory language and the FDA-industry agreement on performance goals and procedures, was posted on the FDA website on March 14, 2012, and a public meeting describing the draft was held on March 28, 2012. The 30-day comment period on the draft ended April 16, 2012. Following review of the comments, FDA may revise the recommendation and then is to submit the final package to Congress.

Since medical device user fees were first collected in FY2003, they have comprised an increasing proportion of FDA's device budget. Medical device user fees have raised a number of concerns, prompting Congress to carefully consider issues such as which agency activities could use fees, how user fees can be kept from supplanting federal funding, and which companies should qualify as a small business and pay a reduced fee.

Congress is also considering reauthorization of the Prescription Drug User Fee Act (PDUFA) as well as new proposals for a Generic Drug User Fee Act and a Biosimilars User Fee Act. It is likely that these three will be combined with MDUFA III along with a variety of related and unrelated issues. Because of the importance of user fees to FDA's budget, PDUFA and MDUFA are

considered to be "must pass" legislation, and Congress has often in the past included language to address a range of other concerns. For example, MDUFA II included provisions about the extent to which FDA can delegate activities to third parties, a unique device identification system, and reporting requirements for devices linked to serious injuries or deaths. House and Senate committees are circulating discussion drafts that contain many proposals that would affect medical device regulation. FDA has indicated that some of these pending reforms could conflict with what was negotiated with industry in the MDUFA III proposal. Some reforms are of concern because they would require more agency resources; others were discussed during the user fee negotiations and were set aside. If MDUFA reauthorization does not occur by early summer, federal regulations require that reduction-in-force notices be sent out in July 2012, giving 60 days' advance notice to about 250 FDA employees that their employment under the MDUFA program would end September 30, 2012.

Chapter 3 - In *Riegel v. Medtronic, Inc.*, the United States Supreme Court held in an 8 to 1 decision that if the Food and Drug Administration (FDA) grants premarket approval (PMA) to a medical device, the device manufacturer is immune from certain suits under state tort law, due to an express preemption provision in the Medical Device Amendments of 1976 (MDA). This holding establishes that FDA PMA preempts claims such as strict liability, breach of implied warranty, and negligence in design, testing, manufacturing, labeling, distribution, sale, inspection, or marketing of the device to the extent that such state law claims are "different from, or in addition to" federal PMA requirements. However, the Supreme Court held that the MDA's express preemption provision did not prohibit state "claims premised on a violation of FDA regulation." The Court stated that such claims "'parallel,' rather than add to, federal requirements." Post-*Riegel*, the lower courts have come to differing conclusions when determining whether particular state law claims, such as manufacturing defect claims, "parallel" federal requirements, and thus are not preempted, or rather are state requirements "different from, or in addition to" federal requirements, and thus are preempted under *Riegel*.

The Supreme Court's decision has been a cause for concern for some Members of Congress who disagree with the ruling, as well as trial lawyers and patients. However, advocates of more limited tort liability, including the previous Administration, agree with the ruling. The decision has broad implications for consumers of Class III medical devices, who are prevented from suing device manufacturers on most state common law claims, as well as manufacturers, who are shielded from many suits if their device receives FDA

PMA. In the 111th Congress, bills were introduced—H.R. 1346, H.R. 4816, and S. 540—that would have overturned the Court's decision in *Riegel* by modifying the statute at issue. As of the date of this report, similar legislation has not been introduced in the 112th Congress.

This report will provide a brief overview of federal premarket regulation of medical devices. The report then provides an overview of federal preemption of state law, as well as arguments for and against federal preemption of state law tort claims with respect to medical devices. The report explains the Supreme Court's decision in *Riegel* and examines the concurring and dissenting opinions. Finally, the report analyzes the legal, procedural, policy, and legislative implications for Congress, consumers, and medical device manufacturers.

CONTENTS

Preface		**vii**
Chapter 1	FDA Regulation of Medical Devices *Judith A. Johnson*	**1**
Chapter 2	The FDA Medical Device User Fee Program *Judith A. Johnson*	**39**
Chapter 3	*Riegel v. Medtronic, Inc.*: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval *Vanessa K. Burrows*	**83**
Index		**121**

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Chapter 1

FDA REGULATION OF MEDICAL DEVICES*

Judith A. Johnson

On June 20, 2012, the House of Representatives passed, by voice vote and under suspension of the rules, S. 3187 (EAH), the Food and Drug Administration Safety and Innovation Act, as amended. This bill would reauthorize the FDA prescription drug and medical device user fee programs (which would otherwise expire on September 30, 2012), create new user fee programs for generic and biosimilar drug approvals, and make other revisions to other FDA drug and device approval processes. It reflects bicameral compromise on earlier versions of the bill (S. 3187 [ES], which passed the Senate on May 24, 2012, and H.R. 5651 [EH], which passed the House on May 30, 2012).

SUMMARY

Prior to and since the passage of the Medical Device Amendments of 1976, Congress has debated how best to ensure that consumers have access, as quickly as possible, to new and improved medical devices and, at the same time, prevent devices that are not safe and effective from entering or remaining on the market. Medical devices regulation is complex, in part,

* This is an edited, reformatted and augmented version of the Congressional Research Service Publication, CRS Report for Congress R42130, dated June 25, 2012.

because of the wide variety of items that are categorized as medical devices; examples range from a simple tongue depressor to a life-sustaining heart valve. The regulation of medical devices can affect their cost, quality, and availability in the health care system.

In order to be legally marketed in the United States, many medical devices must be reviewed by the Food and Drug Administration (FDA), the agency responsible for protecting the public health by overseeing medical products, including devices. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. CDRH activities are funded through a combination of public money (i.e., direct FDA appropriations from Congress) and private money (i.e., user fees collected from device manufacturers) which together comprise FDA's total. User fees account for 33% of FDA's total FY2011 program level and 15% of CDRH's program level, which is $378 million in FY2011 including $56 million in user fees. FDA's authority to collect user fees, originally authorized in 2002 (P.L. 107-250), has been reauthorized in five-year increments. It will expire on October 1, 2012, under the terms of the Medical Device User Fee Act of 2007 (MDUFA), Title II of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).

FDA requires all medical product manufacturers to register their facilities, list their devices with FDA, and follow general controls requirements. FDA classifies devices according to the risk they pose to consumers. Premarket review is required for moderate- and high-risk devices. There are two paths that manufacturers can use to bring such devices to market. One path consists of conducting clinical studies, submitting a *premarket approval* (PMA) application and requires evidence providing reasonable assurance that the device is safe and effective. The other path involves submitting a *510(k) notification* demonstrating that the device is *substantially equivalent* to a device already on the market (*a predicate device*) that does not require a PMA. The 510(k) process results in FDA clearance and tends to be much less expensive and less time-consuming than seeking FDA approval via PMA. Substantial equivalence is determined by comparing the performance characteristics of a new device with those of a predicate device; clinical data demonstrating safety and effectiveness are usually not required. Once approved or cleared for marketing, manufacturers must comply with regulations on manufacturing, labeling, surveillance, device tracking, and adverse event reporting.

Problems related to medical devices can have serious consequences for consumers. Defects in medical devices, such as artificial hips and pacemakers,

have caused severe patient injuries and deaths. In 2006, FDA reported 116,086 device-related injuries, 96,485 malfunctions, and 2,830 deaths; an analysis by the National Research Center for Women & Families claims there were 4,556 device-related deaths in 2009. Reports published in 2009 through 2011—by the Government Accountability Office (GAO), the Department of Health and Human Services Office of the Inspector General and the Institute of Medicine—have voiced concerns about FDA's device review process. In 2009 and 2011 GAO included FDA's oversight of medical products on the GAO list of high-risk areas. FDA has conducted internal reviews as well and is implementing changes.

INTRODUCTION

Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical devices. They may be simple tools used during medical examinations, such as tongue depressors and thermometers, or high-tech life-saving implants like heart valves and coronary stents. The medical device market has been characterized as including eight industry sectors: surgical and medical instrument manufacturing, surgical appliance and supplies, in vitro diagnostic products (IVDs, or laboratory tests), electromedical and electrotherapeutic apparatus, irradiation apparatus, dental equipment and supplies, ophthalmic goods, and dental laboratories.[1]

The federal agency primarily responsible for regulating medical devices is the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS). A manufacturer must receive FDA permission before its device can be legally marketed in the United States. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. Another center, the Center for Biologics Evaluation and Research (CBER), regulates devices associated with blood collection and processing procedures, cellular products and tissues.[2]

CDRH activities are funded through a combination of public money (i.e., direct FDA appropriations from Congress) and private money (i.e., user fees collected from device manufacturers) which together comprise FDA's total.[3] User fees may be used only to support product review activities, not other CDRH activities. User fees account for 33% of FDA's total FY2011 program level and 15% of CDRH's program level, which is $378 million in FY2011 including $56 million in user fees.[4] Congress has reauthorized in five-year increments FDA collection of medical device user fees; authority will expire

on October 1, 2012 under the terms of the Medical Device User Fee Act of 2007 (MDUFA), Title II of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).

Congress has historically been interested in balancing the goals of allowing consumers to have access, as quickly as possible, to new and improved medical devices with preventing devices that are not safe and effective from entering or remaining on the market. The goals of device availability and device safety may exert opposite pulls, with implications for consumers, the health care system, and the economy.

Investment in medical device development reportedly reached a high of $3.690 billion in 2007. Investment has slowed somewhat to $2.380 billion in 2010, and $1.510 billion in the first two quarters of 2011.[5] According to one report, the medical technology industry is a "vibrant and growing contributor to the U.S. economy, generating US$197 billion in revenue and employing over a half million workers in 2009 alone."[6] "Medical technology industry" includes "medical device, diagnostic, drug delivery and analytic/life science tool companies but excludes distributors and service providers" such as contract research or contract manufacturing organizations.[7] Another analysis found that "32 of the 46 medical technology companies with more than $1 billion in annual revenue are based in the United States."[8] Although the largest companies dominate the market for devices in terms of sales, it is often the small device companies that make a significant contribution to early innovation. Small companies may partner with larger companies to bring products to market if they lack access to the capital and resources to conduct clinical trials and navigate regulatory and reimbursement hurdles.

Manufacturers make decisions about pursuing new devices based in part on the cost of their development. Additional regulatory requirements may escalate these costs, while other incentives, such as tax breaks or market exclusivity extensions, may diminish them. If the device development cost is too high, the eventual result may be that consumers are denied access because new products are not developed or brought to market. Access problems have led to proposals for, and the enactment of, incentives to develop medical devices for rare diseases and pediatric populations. However, if the regulation and oversight of device development are not stringent enough, unsafe or ineffective products may reach the market and cause harm to consumers.

Problems related to medical devices can have serious consequences for consumers. Defects in medical devices, such as artificial hips, pacemakers, defibrillators, and stents, have caused severe patient injuries and deaths.[9] In 2006, FDA reported 116,086 device-related injuries, 96,485 malfunctions, and

2,830 deaths; a more recent independent analysis claims there were 4,556 device-related deaths in 2009.[10] Consequences such as these have raised questions as to whether adequate enforcement tools, resources, and processes are in place to ensure that marketed devices are safe. Reports by the Government Accountability Office (GAO), the Department of Health and Human Services Office of the Inspector General, and the Institute of Medicine (IOM) have voiced concerns about FDA's device review process.[11] In 2009 and in 2011 GAO included FDA's oversight of medical products on the GAO list of high-risk areas.[12]

This report provides a description of FDA's medical device review process divided into two parts: premarket requirements and postmarket requirements. **Appendix A** provides a brief history of laws governing medical device regulation and **Appendix B** provides a table of acronyms used in the report.

THE MEDICAL DEVICE REVIEW PROCESS: PREMARKET REQUIREMENTS

FDA requires all medical product manufacturers to register their facilities, list their devices with the agency, and follow general controls requirements.[13] FDA classifies devices according to the risk they pose to consumers. Many medical devices, such as plastic bandages and ice bags, present only minimal risk and can be legally marketed upon registration alone. These low-risk devices are deemed *exempt* from premarket review and manufacturers need not submit an application to FDA prior to marketing.[14] In contrast, most moderate- and high-risk devices must obtain the agency's permission prior to marketing. FDA grants this permission when a manufacturer meets regulatory premarket requirements and agrees to any necessary postmarket requirements which vary according to the risk that a device presents.[15]

PMA vs. 510(k)

There is a fundamental difference between the PMA and 510(k) pathways. In a PMA review, FDA determines if the device is reasonably safe and effective for its intended use. In a 510(k) review, FDA determines if the device is substantially equivalent to another device whose safety and effectiveness may never have been assessed.

There are two paths that manufacturers can use to bring their moderate- and high-risk devices to market with FDA's permission. One path consists of conducting clinical studies, submitting a *premarket approval* (PMA) application and requires evidence providing reasonable assurance that the device is safe and effective.[16] The PMA process is generally used for novel and high-risk devices and is typically lengthy and expensive. It results in a type of FDA permission called *approval.*

The other path involves submitting a *510(k) notification* demonstrating that the device is *substantially equivalent* to a device already on the market (*a predicate device*) that does not require a PMA.[17] The 510(k) process is unique to medical devices and results in FDA *clearance.* Substantial equivalence is determined by comparing the performance characteristics of a new device with those of a predicate device. To be considered substantially equivalent, the new device must have the same intended use and technological characteristics as the predicate; clinical data demonstrating safety and effectiveness are usually not required. The manufacturer selects the predicate device to compare with its new device. However, FDA has the ultimate discretion in determining whether a comparison is appropriate.

According to a 2009 GAO report, of the more than 50,000 devices that were listed by manufacturers with FDA from FY2003 through FY2007, about 67% were exempt from premarket review; the remainder entered the market via the 510(k) process (31%), the PMA process (1%) or via other means.[18]

Device Classification

Under the terms of the Medical Device Amendments of 1976 (MDA, P.L. 94-295), FDA classified all medical devices that were on the market at the time of enactment—the *preamendment* devices—into one of three classes. Congress provided definitions for the three classes—Class I, Class II, Class III—based on the risk (low-, moderate-, and high-risk respectively) to patients posed by the devices.[19] Examples of each class are listed in **Table 1**. Device classification determines the type of regulatory requirements that a manufacturer must follow. Regulatory requirements for each class are described below in more detail. *General controls*, the minimum regulations that apply to all FDA regulated medical devices, include five elements:[20]