COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE REGARDING THE INSTITUTE OF MEDICINE REPORT: "MEDICAL DEVICES AND THE PUBLIC'S HEALTH, THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS"

Docket No. FDA-2011-N-0556, 76 Fed. Reg. 45825 (August 1, 2011)

The Competitive Enterprise Institute (CEI) appreciates the opportunity to submit these comments regarding the Institute of Medicine report: "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years." CEI is a non-profit research and advocacy organization that studies the impact of regulation on the economy, public health and welfare, and consumer choice. For the past 25 years, CEI has been extensively involved in issues of drug, biologic, and medical device regulation, medical product labeling, and other public health and consumer protection issues.

The medical device industry has been a remarkable private enterprise success that has improved or extended the lives of millions of people. Unfortunately, the FDA's inconsistent and often unpredictable management of the device clearance and premarket approval processes has been increasingly burdensome for the industry, and it is leading to an exodus of pioneering research and development from the United States to other countries. CEI therefore commends the Food and Drug Administration (FDA) for attempting to study the shortcomings in its management of the 510(k) clearance process.

Unfortunately, the Institute of Medicine (IOM) committee tasked with this investigation abdicated its duty in performing this important task. The FDA asked the IOM (1) to investigate whether the current 510(k) clearance process "protect[s] patients optimally and promote[s] innovation in support of public health" and (2) to recommend changes that could help the agency better achieve those goals. The IOM committee fulfilled neither of those requests. Instead, it insisted that there is no way to determine whether substantially equivalent devices cleared through the 510(k) process are safe or effective, and it recommended eliminating the 510(k) clearance process altogether.

In large part, we believe that the IOM committee's failure is based on a misunderstanding regarding the design and purpose of the device classification system, as well as the sufficiency of the regulatory controls to which devices in each class are subject. In order to address some of these misunderstandings, CEI commissioned a report by a medical device regulation expert with substantial experience in both government and the private sector. That report is attached as an appendix to these comments, but its primary conclusions are included below.

The regulatory framework established by the Medical Device Amendments of 1976 was the product of a seven-year collaboration among health care professionals, consumer groups, manufacturers, federal and state government agencies, and Congress, all of whom had an interest in creating a regulatory process that could provide a reasonable assurance of safety and effectiveness without hampering the innovative and entrepreneurial nature of the device industry. The Department of Health, Education, and Welfare's Study Group on Medical Devices, which recommended the approach incorporated in the 1976 Amendments, recognized that most devices would not need to go through a comprehensive clinical testing and approval process in order to ensure their safety and effectiveness.

Under the provisions of the 1976 Amendments, devices that were intended for use in "supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or [whose use] presents a potential unreasonable risk of illness or injury," were assigned to Class III and would be subject to rigorous testing requirements and premarket approval (PMA). In addition, all genuinely novel devices that were unlike any others already on the market would automatically be assigned to Class III unless the FDA determined that they could be reassigned to Class I or II. However, most new devices incorporate only minor improvements to previously marketed ones and are not essential for supporting or sustaining human life or health. Consequently, the safety and effectiveness of new devices that were substantially equivalent to a Class I or II device already on the market could be ensured by imposing various regulatory controls, but would not require premarket approval.

The IOM report, however, misconstrues the fundamental underlying nature of the medical device classification system. The classification system created by the 1976 Amendments was intended to assign devices to the appropriate regulatory class and establish standards, or controls, for each class that would provide a reasonable assurance of safety and effectiveness. While many observers mistakenly equate the device classes with a measure of risk, the classification system is not primarily based on the inherent riskiness posed by the devices. The one exception is for the rare occurrence of a Class III device that does present a "potential unreasonable risk of illness or injury."

The purpose of the classification system is to ensure that devices are subject to regulatory requirements that are sufficient to provide a reasonable assurance of their safety and effectiveness, based on their intended use and complexity.[1] Class III devices are more important than Class II and Class I devices in supporting or sustaining human life or in preventing impairment of human health. Yet even for a Class III device, the FDA confirms by approving the PMA application that the product does not pose a "high risk," but in fact is reasonably safe and effective for its intended use.

With that classification system in mind, the 510(k) process was designed to ensure that new products were assigned to the correct class, so that the appropriate regulatory standards could be applied. It does not rely solely on a substantial equivalence

[1] Food and Drug Administration, "Medical Devices: Establishment Registration and Premarket Notification Procedures," *Federal Register*, Vol. 41, No. 173 (1976), p. 37,459.

determination in order to assure safety and efficacy, as additional regulatory controls and performance standards still apply to Class II devices both before and after marketing. Nor was the 510(k) process intended to establish an independent safety or efficacy review process akin to premarket approval, because the regulatory controls associated with the classification system were thought sufficient to provide a reasonable assurance of safety and effectiveness.

No comprehensive review has questioned the sufficiency of these regulatory controls. Nor is there any evidence indicating that the 510(k) process systematically allows unsafe devices on the market. Indeed, the IOM report itself acknowledges that there is no reason to believe that any devices currently on the market are unsafe or ineffective, and that "their use in clinical practice provides at least some level of confidence" in their safety and effectiveness.[2]

The regulatory framework established by the 1976 Amendments performed admirably during its first 15 years in operation. And nearly all the problematic medical devices marketed during that time were Class III devices that were subject to premarket approval. Nevertheless, the Safe Medical Devices Amendments of 1990 gave the agency additional authority to require manufacturers to submit clinical data to support a 510(k) clearance. It also required manufacturers to wait for the FDA to issue an order clearing substantially equivalent devices before they could be marketed.

The FDA has used this authority vigorously. In response to increased public scrutiny over the past two decades, the FDA has added new and more burdensome laboratory and clinical data requirements, and it has repeatedly requested additional information from manufacturers during the 510(k) review. As a consequence, the 510(k) process has been transformed from an informed notification into a far more rigorous premarket review, which many observers now describe as a "mini PMA."

Given these substantial powers, the IOM committee could have concluded, as a 1993 staff report issued by the House of Representatives Committee on Energy and Commerce did, that the FDA has adequate legal authority to ensure the safety and effectiveness of devices reviewed under both 510(k) and PMA submissions. That committee report found, however, that CDRH personnel often lacked proper training, failed to assess submitted data critically, and did not use expert advisory committees efficiently or effectively.[3]

Today, as in 1993, the FDA's weaknesses include "inadequate attention to warnings of likely problems, excessive delays and disorganization in the review and approval process, poor communication inside the FDA and between the industry and the

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[2] Institute of Medicine, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (Washington, D.C.: National Academies Press, 2011), p. 4-5.

[3] Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, *Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, Committee Print 103-N, 103d Congress, 1st Session, May 1993, pp. 2, 42-49.

FDA, and an inability to recognize and correct internal problems."[4] But the IOM committee did not appear to investigate what personnel or resource constraints contribute to mismanagement of the 510(k) clearance process, nor did it suggest how the FDA could make better use of the resources and powers it already has.

The IOM report was therefore wrong to suggest that eliminating the 510(k) clearance process is necessary to ensure the safety and effectiveness of new medical devices. On the contrary, improvements in the FDA's management of new medical device reviews should be sufficient to provide an adequate assurance of patient safety without adding to the already substantial burdens on device manufacturers.

Based on 35 years of practical experience with the regulatory framework created by the 1976 Amendments, the IOM report could easily have concluded that the 510(k) clearance process, as set forth in the statute and accompanying regulations, has been sufficient to ensure the safety and effectiveness of new medical devices. As a representative of the American Academy of Orthopedic Surgeons explained at a June 2010 IOM workshop, "the current 510(k) process, combined with Food and Drug Administration surveillance programs, provides the most favorable balance between benefits and risks. That balance is achieved through the 510(k) process's inherent flexibility, which maximizes the benefits of early access to new technology while minimizing the risks associated with innovation."[5]

Again, CEI appreciates the opportunity to comment on the IOM report. We encourage the agency to disregard the report's recommendations, and instead to consider internal managerial changes to improve the predictability and transparency of the 510(k) clearance process and better facilitate communication within the FDA and between the agency and manufacturers.

Respectfully submitted,

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[4] Ibid., p. III.
[5] Institute of Medicine, *Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation* (Washington, D.C.: National Academies Press, 2010), p. 53.

Stifling Medical Device Innovation

A Response to Critics of the FDA's 510(k) Clearance Process

By Larry R. Pilot, Esq.

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Executive Summary

The United States has long been the home to cutting-edge innovations in the medical device industry, a remarkable private enterprise success that has improved or extended the lives of millions of people. However, increasingly burdensome regulatory policy is driving pioneering research and development to Europe and to the rest of the world. Nevertheless, the U.S. Food and Drug Administration (FDA) and self-styled public health advocates are engaged in an assault on the primary regulatory pathway through which new products reach the market. This could lead to further erosion of U.S. leadership in this important field.

The primary law governing medical devices, enacted in 1976, established a flexible review process intended to tailor FDA oversight of new and improved devices to a level of regulatory control sufficient to provide a reasonable assurance of safety and effectiveness. Most new devices incorporate fairly modest changes or improvements on previously marketed ones. For that reason, an estimated 90 percent or more of the devices now on the market have been authorized for commercial sales through what is known as the 510(k) process. These products do not go through a full premarket approval, but they are nevertheless subject to numerous and burdensome legal requirements to ensure their safety and effectiveness.

While there have been a few examples of FDA mishandling the 510(k) process by inappropriately clearing devices that should have been subject to full premarket approval, there is no evidence that the 510(k) process itself systematically allows unsafe devices on the market. Nevertheless, the process has been made more strict and more comprehensive over the years through legislative changes and bureaucratic excess. Consequently, many 510(k)-cleared devices must now meet requirements similar to those for devices that go through the full premarket approval process. This has resulted in a lengthier and less predictable review process that hinders innovation.

The FDA recently proposed additional changes that would make the 510(k) review even more onerous, and a report from the Institute of Medicine (IOM) has called for scrapping the 510(k) process altogether. However, most criticisms of the 510(k) process are based on a misunderstanding of how it works and why it was designed the way it was.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act created a classification system for devices based largely on the nature of their intended use, the importance of those uses in sustaining or supporting the life or health of patients, and the sufficiency of various regulatory standards in providing a reasonable assurance of safety and effectiveness.

- **Class I** includes fairly simple products, such as tongue depressors.
- **Class II** includes somewhat more important devices, such as most artificial knee joints.
- **Class III** includes devices most important in supporting the life or health of patients, such as heart valves.

The 1976 Amendments also recognized that most devices would not need to surmount a comprehensive clinical testing and approval process to ensure their safety and effectiveness. Nearly all Class III devices would have to be rigorously tested and pass through the FDA's stringent premarket approval (PMA) process. And genuinely novel devices that are not substantially equivalent to other devices already on the market are automatically placed into Class III. Devices that contain only minor improvements to a previously marketed Class I or II device must comply with rigorous performance standards and other regulatory controls, but generally do not have to be reviewed through the comprehensive PMA process.

With that classification system in mind, the 510(k) review was designed to ensure that new products were assigned to the correct class. It was not intended to establish an independent safety or efficacy review process akin to premarket approval because the regulatory controls associated with the classification system itself are sufficient to provide a reasonable assurance of safety and effectiveness.

Many observers mistakenly equate the device classes with a measure of risk. However, the classification system is not based on the inherent riskiness posed by the devices, but on their complexity and function. Even for a Class III device, the FDA confirms by approving the PMA application that the product does not pose a "high risk," but in fact is reasonably safe and effective for its intended use.

Although most Class I devices are exempt from the 510(k) clearance requirement, essentially all Class II devices may not be marketed until the manufacturer submits a 510(k) notification providing a substantial amount of data from laboratory testing, bench trials, and comparative studies demonstrating substantial equivalence to a predicate device before they may be marketed. Clinical testing is not explicitly required by the statute, but the FDA has broad authority to demand clinical data before clearing a Class II device.

During the past 20 years, the FDA has become more aggressive in using this authority, and it has required more and more devices to go through the full PMA process. This has drawn out both 510(k) and PMA review times and has created an atmosphere of unpredictability and uncertainty about what will be necessary to get products to market. Yet, critics have increasingly called for even more legislative and regulatory burdens.

Much of the criticism has focused on a seemingly high number of medical device recalls. From 2005 through 2009, device manufacturers initiated a total of 3,510 recalls for products in all three classes. Without any further context, that number may seem to suggest deep flaws in the regulatory process. But it is essential to examine the data more closely and place those figures in the appropriate context.

In most cases, recalls involve manufacturing or packaging problems that occur after the FDA cleared or approved the device. And, in any event, many recalls involve technical violations of statutory or regulatory requirements that do not affect the safety or effectiveness of the devices in question. Of the recalls issued from 2005 to 2009, the FDA concluded that approximately 96 percent involved little or no risk of harm to patients. Only 131 recalls were considered "high-risk." Yet even among these, more than half involved infractions such as labeling errors, inadequate instructions, or manufacturing glitches that could not have been prevented by a more thorough FDA review. Roughly 87 percent of those high-risk recalls were of devices cleared through the 510(k) process. But the FDA cleared approximately 18,500 devices through the 510(k) process during the five-year study period, and approved just 150 through the PMA process. That means that fully approved devices were more than 30 times more likely to be recalled.

Arguably the most stinging safety criticism that can be made against the FDA is not that the 510(k) clearance process is flawed per se, but that the agency has mismanaged it by occasionally clearing devices that were not in fact substantially equivalent to predicate devices. Over the past decade, the FDA's response to the increased public scrutiny over such mishaps has been to add new and more burdensome laboratory and clinical data requirements, and to repeatedly request additional information from manufacturers during the 510(k) review. That response represents yet another form of FDA mismanagement.

In 2009, the FDA commissioned a study by the Institute of Medicine to investigate whether the 510(k) process sufficiently protect patients and promotes innovation, and to recommend changes that would help the agency better achieve those goals. Strangely, the IOM report, published in July 2011, acknowledges that its committee found no reason to believe that any devices on the market are unsafe or ineffective, but it still concluded that the 510(k) process should be scrapped.

Based on 35 years of practical experience with the 1976 Amendments, the IOM could easily have concluded that the 510(k) clearance process has been sufficient to protect patients. Rather than scrapping the entire process, a more effective approach to protecting consumers and promoting innovation is for Congress to engage in more vigorous oversight and investigation of the FDA's performance.

* The author thanks CEI Senior Fellow Gregory Conko for his assistance in preparing the manuscript for publication.

Introduction

The Medical Device Industry is a remarkable example of private enterprise success that has improved or extended the lives of millions of people.

The Medical Device Industry is a remarkable example of private enterprise success that has improved or extended the lives of millions of people. The United States has long been the home to the majority of cutting-edge innovations in the medical device industry. However, increasingly burdensome U.S. regulatory policy is driving pioneering research and development to Europe and to the rest of the world. The U.S. Food and Drug Administration (FDA) and many self-styled public health advocates are now engaged in an all-out assault on the primary regulatory pathway through which new products reach the market. This could lead to further erosion of U.S. leadership in this important field.

The FDA regulates not only sophisticated and cutting-edge medical technologies such as artificial heart valves and MRI machines, but simple devices as well—from tongue depressors and surgical drapes to IV fluid bags and contact lens solutions. The primary law governing medical devices is the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. The Amendments established a flexible review process intended to tailor the level of FDA oversight of new and improved devices to a level of regulatory control sufficient to provide reasonable assurance of safety and effectiveness.

The 1976 Amendments also recognized that many new devices incorporate fairly modest changes or improvements on previously marketed versions. If a new device had the same or similar technological characteristics as a device already on the market, and had the same intended use as that predicate device, the new one would be considered "substantially equivalent" and subject to less comprehensive premarket review. Most of these products do not go through a full premarket approval process that may require substantial clinical testing, but they are still subject to numerous and burdensome legal requirements to ensure their safety and effectiveness. An estimated 90 percent or more of all medical devices now on the market have been authorized for commercial sales through what is known as the "510(k) process," named for the section of the statute in which it is described.[1] Only those devices that are not substantially equivalent to older devices, as well as those that are important for supporting or sustaining the life or health of patients, are subject to the most stringent premarket approval (PMA) process.

While there have been a few examples of FDA mishandling the 510(k) process by inappropriately clearing certain devices that should have been subject to full PMA approval, there is no evidence indicating that the 510(k) process itself systematically allows unsafe devices on the market. Nevertheless, the process has been made more demanding and comprehensive over the years through legislative changes and excessive bureaucratic meddling. Consequently,

many 510(k)-cleared devices must now meet requirements similar to those for devices that go through full premarket approval. This has resulted in a lengthier and less predictable review process that hinders innovation, driving a substantial amount of medical device innovation overseas.

Critics of the 510(k) process, both within and outside the FDA, have increasingly called for changes that would make the pre-clearance review even more onerous. In August 2010[2] and January 2011,[3] the FDA's Center for Devices and Radiological Health (CDRH) released two internally prepared reports recommending a number of proposals to beef up the 510(k) process, including the creation of a new category for devices that would require even more safety and effectiveness data before they could be cleared for marketing. FDA mis-management and the 510(k) process itself have also been the subject of repeated criticism by the U.S. Government Accountability Office during the past several years. And the FDA commissioned a $2 million dollar study by the Institute of Medicine (IOM) to make recommendations about CDRH management of the 510(k) process. The IOM report, published in July 2011, recommended eliminating 510(k) clearance altogether, in favor of new legislation that would subject essentially all medical devices to a more extensive premarket review.[4]

Many 510(k)-cleared devices must now meet requirements similar to those for devices that go through full premarket approval. This has resulted in a lengthier and less predictable review process.

With growing calls for a reformation of medical device regulation, it is worth reviewing its origins and understanding why it was designed as it is.

The Birth of Device Regulation

The Federal Food, Drug, and Cosmetic Act of 1938 broadly defined the term "device," but there was no requirement for any premarket review of medical devices for commercial distribution until May 28, 1976, when the Medical Device Amendments of 1976 became effective. That law was the product of a seven-year collaboration among health care professionals, consumer groups, manufacturers, federal and state government agencies, and Congress, all of whom had an interest in creating a regulatory process that could provide a reasonable assurance of safety and effectiveness without hampering the innovative and entrepreneurial nature of the device industry.

The resulting law created a classification system for devices based largely on the nature of their intended use, the importance of those uses in sustaining or supporting the life or health of patients, and the sufficiency of various regulatory standards in providing a reasonable assurance of safety and effectiveness.[5] Briefly, the classes break down as follows:

- **Class I.** Fairly simple products, such as tongue depressors.
- **Class II.** Somewhat more important devices, such as most artificial knee joints.

- **Class III.** Devices most important in supporting the life or health of patients, such as heart valves.

While many observers mistakenly equate the device classes with a measure of risk, the classification system is not, and never has been, based on the inherent riskiness posed by the devices.

The objective was to establish regulatory standards, or controls, for each class that would provide a reasonable assurance of safety and effectiveness, with each higher class being subject to greater controls and an increasing level of scrutiny.

The 1976 Act also recognized that most devices would not need to go through a comprehensive clinical testing and approval process in order to ensure their safety and effectiveness. Nearly all Class III devices would have to be rigorously tested and pass through the FDA's stringent PMA process. Genuinely novel devices that were not substantially equivalent to other devices already on the market would automatically be placed into Class III, unless the agency determined that the products could be reclassified into Class I or II. However, devices that contained only minor improvements to a previously marketed Class I or II predicate device, or to a small number of Class III devices, would have to comply with rigorous performance standards and other regulatory controls, but generally would not have to be reviewed through the comprehensive PMA process.

With that classification system in mind, Section 510(k) of the Medical Device Amendments was included to ensure that "manufacturers do not intentionally or unintentionally circumvent the automatic classification into Class III … of devices that are not substantially equivalent to previously marketed devices."[6] Device developers were required to give the FDA a 90-day advance notice of their plans to market a new device in order to provide the agency with an opportunity to determine whether the device:

- Was substantially equivalent to a predicate device;
- Required a PMA application; or
- Could be reclassified into Class I or Class II.

Section 510(k) was not intended to establish an independent safety or efficacy review process akin to premarket approval because the regulatory controls associated with the classification system itself were thought to be adequate to provide a reasonable assurance of safety and effectiveness.

Importantly, while many observers—including journalists, Members of Congress, and even some in the public health community—mistakenly equate the device classes with a measure of risk, the classification system is not, and never has been, based on the inherent riskiness posed by the devices. The purpose of the classification system is to ensure that devices are subject to regulatory requirements that provide a reasonable assurance of their safety as well as

effectiveness, based on their intended use and complexity.[7] Class III devices are more important than Class II and Class I devices in supporting or sustaining human life or in preventing impairment of human health. Yet even for a Class III device, the FDA confirms by approving the PMA application that the product does not pose a "high risk," but in fact is reasonably safe and effective for its intended use.

Because Class III devices are used in supporting or sustaining the life or health of patients, a manufacturer's failure to comply with applicable regulatory controls could indeed pose serious safety concerns. So, once the manufacturer of a Class III device provides valid scientific data demonstrating safety and efficacy, it must still be manufactured with a high degree of precision and sophistication to ensure that it works as intended. It is worth noting, though, that Class III also includes such devices as extended-wear contact lenses and many diagnostic tests, which are not risky per se.

The unfortunate tendency to confuse device classification with a measure of riskiness has profound consequences for the future of medical device regulation. Critics of the 510(k) process rely on perpetuating this misunderstanding in order to claim that the clearance process is insufficient to protect patient health. An understanding of how the classification system actually works makes clear why most criticisms of the 510(k) process are fundamentally flawed.

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The Classification System

Even before enactment of the Medical Device Amendments, the FDA had identified approximately 1,800 distinct types of devices organized into 16 medical specialties—ranging from cardiac pacemakers to hip prostheses to intraocular lenses, and many others. The agency also convened expert advisory committees for each specialty area, which were authorized to review devices and recommend the appropriate classification applicable to each distinct device type. The advisory committees conducted their work with full public participation, and their classification recommendations were published in the *Federal Register* and subject to notice-and-comment rulemaking.

The criteria for classification were based on the level of compliance with regulatory controls that would be sufficient to provide a reasonable assurance of the safety and effectiveness of the devices. That is, if compliance with the regulatory controls associated with Class I was sufficient to provide a reasonable assurance that a particular device type would be safe and effective, the device would be placed into Class I. If compliance with Class I regulatory controls was considered insufficient, the device would be placed into Class II or Class III as appropriate.

Class I devices include relatively simple products such as surgical gloves, elastic bandages, and hand-held surgical instruments. For these devices, compliance with what the statute calls General Controls—more than a score of very specific legal requirements, such as facility registration, periodic reporting to the FDA, and adherence to Good Manufacturing Practices—are sufficient to provide a reasonable assurance of safety and effectiveness. Most Class I devices are exempt from the 510(k) notification and clearance process and may be marketed once the manufacturer registers and lists them with the FDA. Under the Food, Drug, and Cosmetic Act, though a few dozen Class I device types, such as blood bank equipment, are subject to 510(k) notification because their use is of special importance in preventing impairment of human health.[8]

Class II devices are those for which General Controls alone are thought to be insufficient to assure safety and effectiveness. Powered wheelchairs, infusion pumps, and most artificial joints fall into this class. They must comply with all the controls applicable to Class I devices and also meet specific performance standards. In 1990, the Act was further amended to also subject Class II devices to various Special Controls, such as special labeling, clinical data requirements, and post-market surveillance, among others.

While most Class I devices are exempt from the 510(k) process, essentially all Class II devices may not be marketed until the manufacturer submits a 510(k) notification providing a substantial amount of data from laboratory testing, bench trials,[9] and comparative data demonstrating substantial equivalence to a predicate device. Although clinical testing is not explicitly required by the statute, "substantial equivalence sometimes can be evaluated only in the clinic," according to David Feigal, former director of the FDA's Center for Devices and Radiological Health.[10] Therefore, in many cases, Class II device manufacturers must also present clinical testing data that support a substantial equivalence determination, as well as safety and effectiveness claims. In addition, since 1990, each Class II device must be "cleared" by an order from the FDA before it can be distributed commercially. Manufacturers of Class II devices also must be inspected by the FDA every two years.

Class III devices are those explicitly intended for a use in "supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, *or* presents a potential unreasonable risk of illness or injury."[11] Devices such as implantable pacemakers and artificial heart valves fall into Class III. They are subject to both the General Controls governing Class I and the Special Controls governing Class II devices. And nearly all Class III devices must go through a rigorous FDA premarket approval process

that typically involves extensive clinical testing as well as prior inspection of facilities for compliance with good manufacturing practice requirements.[12]

Initially, substantially equivalent improvements to Class III device types that were on the market before enactment of the 1976 Amendments could be cleared through the 510(k) process. However, the statute gave FDA authority to reclassify these Pre-Amendment device types into Class I or II where appropriate, and to promulgate regulations requiring full PMA approval for the others. By 2009, all but 25 Pre-Amendment Devices had been reclassified or subject to PMA approval. In April of that year, the FDA initiated a plan to evaluate those remaining device types, so this grandfathered exemption is likely to end within the near future.[13]

Again, it is important to recognize—as the passage quoted above from the Food, Drug, and Cosmetic Act shows—that the class into which a device is categorized is not based on the riskiness of the device. The one exception is for the very rare occurrence of a Class III device that does present a "potential unreasonable risk of illness or injury." The fact that the nature of medical device classification is so poorly understood has led many observers to suggest that the framework established by the 1976 Amendments is not up to the task of ensuring the safety of important medical products. Nevertheless, the framework has performed admirably—although with occasional shortcomings caused by unpredictable performance by the FDA.

The fact that the nature of medical device classification is so poorly understood has led many observers to suggest that the framework established by the 1976 Amendments is not up to the task of ensuring the safety of important medical products.

Legislative History

After passage of the Food, Drug, and Cosmetic Act in 1938 and the Drug Amendments of 1962, the drug approval process became more complicated, causing delays that often deprived health care practitioners and their patients of beneficial treatment options that were available in other countries.[14] However, the medical device industry faced little regulation, and hundreds of small medical device businesses were established by creative physicians, engineers, and other specialists to investigate and ultimately manufacture novel devices that could help in the treatment of patients.

These products included life supporting valves and pacemakers, orthopedic implants, intraocular lenses, kidney dialysis and heart-lung machines, and a wide variety of diagnostic products to mention just a few. Although the Food, Drug, and Cosmetic Act could have been interpreted to subject some medical devices to the same approval process applicable to drugs,[15] these remarkable innovations occurred, with very few exceptions, without any input or oversight from the FDA or other federal regulatory agencies. Despite the lack of intense

regulatory oversight—or perhaps because of it—the device industry had a remarkable and successful history of introducing safe products that delivered countless benefits for patient health.

Improvements in medical devices and many other technologies tend to occur in small incremental steps, which lead to vast improvements over time.

It was not until the mid-1960s that the FDA began to stretch its interpretation of the Food, Drug, and Cosmetic Act, in an attempt to bring a very small number of devices under its New Drug approval process. At the same time, Presidents Kennedy, Johnson, and Nixon and several members of Congress joined FDA officials in calling for more rigorous oversight of the medical device industry.[16] There was broad agreement among physicians and device makers that the design, manufacture, clinical evaluation, use, and performance of devices were separate and distinct from the development and use of drugs. Still, many of them feared that the FDA would further expand its application of the drug approval laws to devices or that Congress would enact a new device law comparable to the one applied to drugs. President Nixon allayed some of those fears in 1969, when he directed the Department of Health, Education, and Welfare (which then housed the FDA) to convene a committee of experts to make recommendations on how medical device regulation should be structured.[17]

That Study Group on Medical Devices, chaired by the then-director of the National Heart and Lung Institute, Theodore Cooper, M.D., rejected proposals to regulate medical devices the same as drugs. The Cooper Committee recognized that, "[A] predictable increase in the complexity and sophistication of medical devices requires action now to prevent the emergence of even more serious and complex problems in the foreseeable future."[18] However, it recommended a more nuanced approach that would tailor device regulation to match the variability in the characteristics of individual products.

Because there were broad differences in the complexity of various devices, the committee concluded that the "type, quality, and quantity of evidence required" to demonstrate device safety and efficacy "were different from those required for drugs."[19] Furthermore, most devices operate by simple, mechanical processes, so their performance is much easier to predict than that of drugs, which are metabolized by the body in complex biochemical reactions. Importantly, the Cooper Committee also realized that the vast majority of improvements in the medical device industry represent incremental tweaks to previously marketed products that do not significantly alter their safety but may improve effectiveness.

Improvements in medical devices and many other technologies tend to occur in small incremental steps, which lead to vast improvements over time. As the National Research Council has observed, "[T]he cumulative effect of numerous minor incremental innovations can sometimes be more transforming and have more economic impact than a few radical innovations or 'technological

breakthroughs'."[20] In recognition of this fact, the most significant regulatory pathway for medical device advancement allows manufacturers to make minor alterations to certain previously marketed products without a need to surmount the hurdles of the FDA's comprehensive, expensive, and burdensome premarket approval process. As Stanford University medical professor and device industry investor Josh Makower points out, medical device development "is and must be iterative. The 510(k) process encourages multiple iterations, which can have a revolutionary effect on patient care."[21]

As Stanford University medical professor Josh Makower points out, medical device development "is and must be iterative. The 510(k) process encourages multiple iterations, which can have a revolutionary effect on patient care."

Premarket Notification and the 1990 Amendments

Truly innovative medical devices that are not substantially equivalent to a predicate device, along with nearly all Class III devices, must generally be tested for safety and effectiveness and reviewed by the FDA through its PMA process. The statute does not specify the types and extent of information necessary to support PMA device applications. However, the FDA almost always requires manufacturers to submit data from extensive laboratory analysis and bench trials, results of animal studies and clinical trials on human patients, and all other published and unpublished scientific research on the devices. Because seeking approval for a PMA application is so onerous, Congress and the FDA were concerned that manufacturers might intentionally or unintentionally circumvent the PMA process by incorrectly categorizing products as substantially equivalent to a predicate device. To prevent that from occurring, the 1976 Amendments established the 510(k) premarket notification process through which the FDA could identify those devices for which it determined a PMA application was mandatory.[22]

The 510(k) process requires manufacturers to notify the FDA of their intent to market a new product and submit data demonstrating its equivalence to the predicate device. The objective of the 510(k) notification is to give the agency an opportunity to determine whether the device may be marketed without completing the more comprehensive PMA approval process. Before 1990, the statute required no explicit clearance for substantially equivalent devices, and manufacturers who submitted 510(k) notifications could begin commercial distribution on the 91st day after submission, irrespective of whether the FDA responded or the nature of any response.

Following enactment of the 1976 Amendments, the number of 510(k) notifications rose steadily, reaching an average of over 5,000 submissions each year by the late 1980s, and peaking at just over 7,000 in 1989.[23] The FDA determined that the vast majority were substantially equivalent to a predicate device, and there was no evidence suggesting that any 510(k) device caused a

problem that would have been prevented if the FDA had the authority to demand additional information or testing. Although hearings held in 1990 by the House Energy and Commerce Committee considered problems associated with several medical devices—with one entire hearing focused on the failure of the Bjork-Shiley mechanical heart valve—most of these were Class III devices that were PMA approved, not the Class II devices that comprise the vast majority of 510(k) clearances.[24] Nevertheless, members of Congress worried that an FDA substantial equivalence determination was not the same as a determination that a device was safe and effective, and they were determined to beef up the 510(k) requirements. Congress enacted the Safe Medical Devices Amendments of 1990 to address this and several other concerns.

The need to wait for the FDA to issue a clearance order has drawn out the 510(k) process and added a substantial amount of uncertainty for all filers.

Today, device manufacturers are subject to new requirements for device tracking, reporting of any correction or removal of a device from the market, post-market surveillance, mandatory device recalls, pre-production device validation, and fines for violations of the Act.[25] In many cases, the stringency of these and other requirements exceed those that are applicable to new drugs. However, a major change in the 510(k) process was arguably the most important feature of the 1990 Amendments. Congress gave the FDA new authority over 510(k) notifications, transforming the process into what has come to be known as a "mini-PMA."[26]

The Mini-PMA

Under the terms of the 1990 Amendments, manufacturers may not begin marketing a 510(k) device until the FDA issues a clearance order authorizing commercial distribution. Just as under the prior law, the FDA may confirm that the new product is substantially equivalent to a legally marketed predicate device and clear it for marketing, or it could conclude that the product is not substantially equivalent and subject the device to premarket approval. But the need to wait for the FDA to issue a clearance order has drawn out the 510(k) process and added a substantial amount of uncertainty for all filers, even though only about 5 percent of the devices submitted through 510(k) notifications are determined not to be substantially equivalent.[27]

The 1990 Amendments also authorize the FDA to require manufacturers to submit clinical data to support a 510(k) clearance order. As a consequence, the 510(k) process has been transformed from an informed notification into a far more rigorous premarket review. During the past 20 years, the FDA has become more aggressive in using its authority to demand additional information from manufacturers and in requiring more and more devices to go through the full PMA process. This in turn, has drawn out both the 510(k) and PMA review

times and has, according to attorney and food and drug law expert Ellen Flannery, created an "atmosphere of unpredictability and uncertainty in which innovators have no clear idea of what the agency requires or expects of new submissions."[28]

This simple, but unfortunate regulatory delay was not introduced because of any mishaps related to 510(k) device notifications, but it has become the principal complaint of those who must wait for the issuance of an order. Some of these delays may extend beyond a year or more before an order is issued or the submitter abandons the review process.[29] Nevertheless, supporters of these burdensome regulatory hurdles have presented no evidence that either the FDA review process or the delays caused by sometimes repeated agency requests for more and more information actually improve the safety or effectiveness of the devices presented to the agency.

Delays, combined with increasingly burdensome data requirements, often make it impractical for device manufacturers to bring many new products to market in the United States.

The creativity of the domestic device industry has been severely damaged by the FDA's poor administration of law and regulations applicable to the 510(k) process. Increasingly, as a result of questionable regulatory burdens and costly FDA delays for issuance of PMA approvals or 510(k) clearance orders, more new devices are now being developed and marketed in other countries where regulatory requirements are more balanced. A recent study by the consulting firm Emergo Group examined 510(k) process review times for the years 2006 and 2010. The average time for review in 2006 was 96 days, but it had ballooned to 132 days by 2010.[30] While a six-month to one-year FDA review delay may not seem particularly burdensome in an industry such as pharmaceuticals, where one-year-plus review cycles are common, it can be devastating in the medical device industry. The typical product life-cycle for a new medical device is just 18 to 24 months, meaning that most devices are replaced by a new or improved product within two years.[31]

These delays, combined with increasingly burdensome data requirements, often make it impractical for device manufacturers to bring many new products to market in the United States. Roughly 80 percent of device manufacturers are small, capital-starved businesses with fewer than 50 employees, yet the cost of bringing a new medical device to market through the 510(k) clearance process amounts to an average of some $73 million.[32] In contrast, the European Medicines Evaluation Agency takes only half the time on average as the FDA does to review new medical devices.[33] Many small and medium sized manufacturers have responded by moving research facilities overseas and by marketing new devices first in Europe or Asia.

Since 1976, more than 150,000 different types of useful devices have become available to health care professionals and consumers through the 510(k) substantial equivalence process,[34] which is based on the understanding that

compliance with the Class I and Class II regulatory controls are sufficient to provide a reasonable assurance of safety and effectiveness. The 35-year success of the 510(k) process supports claims that less FDA interference, rather than more, is the best alternative. At present, the FDA's regulatory powers over medical devices are so excessive that the agency has rarely—or never—even applied some of them. For example, while the FDA does not have the authority to mandate the recall of approved human drugs, it does have authority to mandate the recall of devices.[35] However, the agency has not used this authority, relying instead on voluntary recalls initiated by manufacturers on their own or at the FDA's request. Yet, critics increasingly call for even more legislative or regulatory burdens.

In most cases, the underlying reason for a recall could not have been prevented by a more thorough review.

The Recall Process

Since the early 1970s, much of the criticism of the 510(k) process and of the FDA's overall performance in medical device regulation has focused on a relatively small number of problems with 510(k) cleared devices and on the number of cleared devices that have been subject to recalls. From 2005 to 2009, medical device manufacturers initiated a total of 3,510 recalls for devices in all three classes, an average of just over 700 per year.[36] Without any further context, an observer might be led to believe that so many recalls is evidence of hopeless flaws in the regulatory process. But in order to determine how serious an issue this number of recalls may be, it is essential to examine the data more closely and place those figures in the appropriate context.

In most cases, the underlying reason for a recall could not have been prevented by a more thorough review. And, in any event, many recalls involve technical violations of statutory or regulatory requirements that do not affect the safety or effectiveness of the devices in question. Indeed, very few recalls actually involve the physical removal of the device from the patient-user or owner. Most involve a field correction or examination, labeling modification, or other action that the FDA believes would remedy the possible violation. Thus, "recall" is a term of art for which the FDA definition in the applicable regulation "means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery."[37]

In contrast to the statutory device classification system, the determination of classification for recalls is risk-related. Class III recalls involve violations that pose minimal or no risk. Class II recalls generally involve violations that pose only remote risks to patients. And only Class I recalls involve problems

that pose any significant risk of serious health consequences to patients.[38] Although they share the same nomenclature, it is worth recognizing that the classification of recalls bears no relation to the product's device classification.

Of the 3,510 total recalls issued for devices from 2005 to 2009, the vast majority—approximately 83 percent—where in Class II, meaning that the probability of serious adverse health consequences was remote.[39] Only 131—approximately 4 percent—were Class I, or "high-risk" recalls that might pose some potential for serious patient harm. Even among these, many involved infractions such as labeling errors or inadequate instructions, rather than a flaw in the device itself. Nevertheless, two recent studies have singled out 510(k)-cleared devices as being especially susceptible to recalls, suggesting in turn that the process must be overhauled to incorporate a more comprehensive safety review.

A June 2011 Government Accountability Office (GAO) report discusses the role of recalls and touches on a possible connection between 510(k) clearance and device recalls.[40] Although the report provides some useful information about the recall of devices and FDA's performance, its criticism of lax regulatory oversight is premised on out-of-context reporting on the number of 510(k) recalls. It notes that 87 percent of recalls during the 2005-2009 period were of devices cleared through the 510(k) process, 8 percent were of devices approved through the PMA or PMA supplement process, and 6 percent involved devices for which some components were cleared through the 510(k) process and others through the PMA process.

Similarly, a February 2011 article published in the *Archives of Internal Medicine*,[41] attempted to establish a relationship between 510(k) clearance and subsequent Class I recalls. The authors—Diana Zuckerman, Paul Brown, and Steven Nissen—examined the same 2005-2009 time period, identified 113 Class I recalls and found that 80—or 71 percent—of the recalled devices were cleared through the 510(k) process. Just 21—or 19 percent—of the recalled devices were approved through the PMA process. From this, they concluded that, "[R]eform of the regulatory process is needed to ensure the safety of medical devices."

This simplistic "analysis" illustrates the lengths to which critics will go to support preconceived outcomes and recommendations. A useful analysis of the recall data that can support any conclusions about the safety or soundness of the 510(k) process needs to consider denominators along with numerators.

From 2005 through 2009, the FDA cleared approximately 18,500 devices through the 510(k) process and approved just 150 through the PMA process. During that five-year period, 21 of the PMA-approved devices were the subject of a Class I recall, for a ratio of one Class I recall for every seven approvals.

Arguably the most stinging safety criticism that could be made against the FDA is that the agency has mismanaged it by occasionally clearing devices that were not in fact substantially equivalent to predicate devices.

By comparison, only 80 devices that were 510(k)-cleared were subject to a Class I recall, for a ratio of one Class I recall for approximately 231 devices cleared through the 510(k) process. Contrary to Zuckerman, Brown, and Nissen's poorly reasoned conclusions, one might actually infer that the 510(k) review process is *more* effective than the PMA process in avoiding Class I recalls. Yet a thorough analysis of the 510(k) process should not end there.

A separate review conducted by University of Minnesota law professor Ralph Hall found that more than half of the Class I recalls initiated for 510(k) cleared devices during the 2005-2009 period involved manufacturing defects, rather than defective designs, or similar failures that occurred *after* the clearance process.[42] Frequent reasons for Class I recalls include labeling errors, sterilization problems, and even the presence of counterfeit devices being passed off by a third party as the lawfully marketed products. In these and other "post-clearance" cases, the problems leading to the recall could not have been prevented by a more stringent FDA review.[43] As Hall notes, a manufacturing glitch that arises a year or more after FDA clearance could necessitate a recall, as could a packaging mistake or misprinted label. In these cases, increasing or decreasing the premarket oversight requirements would be incapable of preventing the manufacturing mistake or the need for a recall.

FDA Mismanagement of the 510(k) Process

Arguably the most stinging safety criticism that could be made against the FDA is not that the 510(k) clearance process is flawed per se, but that the agency has mismanaged it by occasionally clearing devices that were not in fact substantially equivalent to predicate devices. In one recent high-profile case, the agency sought in October 2010 to rescind the 510(k) clearance of a surgical patch for injured knees that was granted two years earlier after an investigation revealed that the FDA grossly mismanaged the clearance, which may have been tainted by political pressure.[44] The FDA had twice rejected 510(k) notifications for the device on the grounds that it was not substantially equivalent to the claimed predicates. The agency later cleared the device after persistent lobbying by four Democratic congressmen—Sens. Robert Menendez and Frank Lautenberg and Reps. Frank Pallone and Steven Rothman—all from New Jersey, where the manufacturer, ReGen Biologics, is headquartered.[45]

Over the past decade, the FDA's response to the increased public scrutiny over mishaps like this and others, has been to add new and more burdensome laboratory and clinical data requirements, and to repeatedly request additional information from manufacturers during the 510(k) review. In the 1970s, 510(k) notifications were often just a few pages long; today they average more than

360 pages, with some stretching to 500 pages or more.[46] The FDA's more demanding approach, combined with increasing regulatory burdens, is lengthening FDA review times and raising development costs. According to Paul Citron, an engineer and retired device industry executive, "The paradox is that the FDA's current regulatory approach may be causing unnecessary patient suffering and death by virtue of the regulatory delay imposed by its requirements."[47] This kind of response represents yet another form of FDA mismanagement.

The FDA's more demanding approach, combined with increasing regulatory burdens, is lengthening FDA review times and raising development costs.

Congress and the GAO have repeatedly grilled the FDA for its clearance or approval of products like the ReGen Biologics knee patch, but neither has conducted a serious review of problems within the agency since 1993, when the House Energy and Commerce Committee conducted a series of hearings on the performance of the FDA's Center for Devices and Radiological Health (CDRH). A staff report published following that extensive investigation found that FDA weaknesses included "inadequate attention to warnings of likely problems, excessive delays and disorganization in the review and approval process, poor communication inside the FDA and between the industry and the FDA, and an inability to and correct internal problems."[48] The report concluded that the CDRH had adequate legal authority to ensure the safety and effectiveness of devices reviewed under both the 510(k) and PMA processes. The report found, however, that CDRH personnel often lacked proper training, failed to assess submitted data critically, and did not use expert advisory committees efficiently or effectively.

Since that time, the CDRH staff has been increased, and the Medical Device User Fee and Modernization Act of 2002 has boosted the Center's financial resources considerably, even as the annual number of 510(k) submissions has fallen from an average of over 6,000 in the early 1990s to around 4,000 during the past decade.[49] In addition, the Food and Drug Administration Modernization Act of 1997 requires the CDRH to use the "least burdensome" means of demonstrating substantial equivalence and to develop guidance documents clarifying when a 510(k) clearance is appropriate.[50] Despite all this, the FDA's performance in managing the 510(k) and PMA review process has continued to deteriorate. Delays in the CDRH review of 510(k) notifications are endemic, and the entire process is riddled with confusion, unpredictability, and a lack of transparency. It is long past time for Congress to conduct a follow-up evaluation of CDRH management. Presumably, the Institute of Medicine study was intended to provide exactly that sort of investigation, but it did nothing of the sort.

Strangely, the Institute of Medicine report acknowledges that its committee found no reason to believe that any devices on the market are unsafe or ineffective, and that "their use in clinical practice provides at least some level

of confidence," yet it still concluded the 510(k) process should be scrapped entirely.[51] At their root, many of the criticisms of the clearance process seem to be based on nothing more than a belief that a full evaluation through the PMA process is the only way to prevent unsafe products from reaching the market. Furthermore, this two-million dollar, nearly two-year project did not even answer the two simple questions that were principal to its mission:

1. Does the current 510(k) clearance process protect patients optimally and promote innovation in support of public health?
2. If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) clearance process optimally?

Many of the criticisms of the clearance process seem to be based on nothing more than a belief that a full evaluation through the PMA process is the only way to prevent unsafe products from reaching the market.

The IOM committee responsible for writing the report simply declined to answer the first question, arguing that, because most devices already on the market had not gone through a full PMA process with extensive clinical analysis, there is no way to determine whether substantially equivalent devices are safe or effective. In effect, this amounts to a claim that we cannot know whether a device is safe and effective unless the FDA has said that it is. The committee argued that only by subjecting Class II devices to a more comprehensive regulatory approval process could the public be confident "that safe and effective medical devices are being made available in a timely manner."[52]

In making this claim, however, the IOM committee ignored the substantial negative effect that the FDA's existing "mini-PMA" process is already having on medical device innovation. It further ignored the judgment of Congress, the Cooper Committee, and the expert advisory committees charged with designing the device classification system, all of which concluded that the regulatory controls associated with various device classes are sufficient to provide a reasonable assurance of safety and effectiveness.

After the IOM committee decided it could not answer the first question, it chose not to answer the second. Instead of suggesting ways that the 510(k) clearance process could be improved, the committee recommended that the process be eliminated and "replaced with an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle."[53] The committee chose not to be more specific, though, indicating that it did "not believe that available information is adequate to inform the design of an appropriate framework."[54]

Based on 35 years of practical experience with the 1976 Amendments, the IOM report could easily have concluded that the 510(k) clearance process,

as set forth in the statute and accompanying regulations, has been sufficient to protect patients. As a representative of the American Academy of Orthopedic Surgeons explained at a June 2010 IOM workshop, "[T]he current 510(k) process, combined with Food and Drug Administration surveillance programs, provides the most favorable balance between benefits and risks. That balance is achieved through the 510(k) process's inherent flexibility, which maximizes the benefits of early access to new technology while minimizing the risks associated with innovation."[55]

Rather than scrapping the entire 510(k) process, a more effective approach to achieving the goals of protecting consumers and promoting innovation is for Congress to engage in more vigorous oversight and investigation of the FDA's performance and suggest a possible approach that would enable the agency to keep up with developments in this important and highly innovative industry. Fortunately, the FDA rejected the IOM's proposal to eliminate the 510(k) system. It nevertheless re-committed itself to making changes to the clearance process that it had already initiated in the fall of 2010.[56]

Conclusion

For decades, patients have reaped substantial benefits from the continuing improvements and innovations delivered by America's nimble and innovative medical device industry. Congress enacted the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act in the expectation that FDA oversight would not disrupt the dynamic and successful progress of the then-lightly regulated device sector—an expectation shared by the medical community and the medical device industry. This optimism has turned to pessimism among supporters of the 510(k) process. Meanwhile, critics have been increasingly more aggressive in their quest for legislative and regulatory policy changes, which would impose even greater burdens than those that exist today.

The Medical Device Amendments of 1976 is a good law that has been poorly managed by the FDA. Today, the FDA's mismanagement is the object of increasing criticism from both supporters and detractors of the 510(k) process. Criticisms by the Government Accountability Office, Institute of Medicine, the FDA itself, and others have helped to broaden our understanding of what has gone wrong with device regulation and how it can be improved, but there is no substitute for a fair and balanced independent audit of the FDA's performance. The time is right for Congress to accept the challenge to carefully examine the structure and management of the FDA, and to assure greater accountability.

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Pilot was honored with the FDA's Award of Merit in 1977 for his contributions to the development of the agency's medical device programs. Upon his departure from the FDA in 1979, he began practicing law, and his clients included dozens of small and large medical device firms as well as the Medical Device Manufacturers Association. In 2008, Larry Pilot retired as a partner with the firm of McKenna, Long & Aldridge, but he continues to advise medical device industry clients and contribute to scholarship and analysis on device regulation.

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