Recent scandals such as the debacle over safety issues surrounding the prescription anti-inflammatory drug, Vioxx, as well as other medications, have strongly suggested that FDA has recently enjoyed an uncomfortably-close relationship with the pharmaceutical industry it must regulate. Another major public health safety issue which is just as important and which, until recently has received relatively little media attention, concerns the manner in which FDA approves and regulates medical devices, particularly those high-risk devices posing the greatest potential safety risks to patients. Serious controversy is now swirling around the relationship of FDA to the medical device industry and whether the agency’s current regulatory framework is equipped to handle the level of new medical device technologies entering the thirty-five year old medical device approval process.

Two recent developments strongly suggest that these concerns are going to be addressed. First, The New York Times published a letter sent by nine scientists working at the Center for Devices and Radiological Health (CDRH) at FDA to President Obama charging that senior FDA officials had allegedly acted illegally by approving medical devices for marketing which had been unanimously rejected as being unsafe by scientific reviewers. Such a direct complaint to the White House is typically unusual by FDA medical officers who will often stay within FDA’s hierarchy of authority or contact pertinent officials in the Department of Health and Human Services. The second was the publication by the U.S. Government Accountability Office on medical devices which highlighted potential deficiencies in the manner in which FDA approves high-risk medical devices for marketing in the U.S.

The Current Regulatory Framework for Medical Device Marketing and Approval

The current regulatory framework for medical device approval was established in the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA). The MDA was an innovative piece of legislation resulting from

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6 Id.
the public health debacle surrounding women’s safety issues resulting from use of the Dalkon Shield intrauterine contraceptive device. The 1976 MDA contained a three-class classification system for medical devices.\(^9\) Class I devices pose the lowest risk to consumers’ health, do not require FDA approval for marketing, and include devices such as tongue depressors.\(^{10}\) Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents.\(^{11}\) Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery.\(^{12}\)

The 1976 MDA also contained two different routes for FDA to get new medical devices to market.\(^{13}\) Class III devices already on the market prior to passage of the MDA were exempt from the requirement to submit a marketing application and would serve as “predicate devices” to which newer, but similar devices could be compared. New Class III medical devices seeking FDA approval (after passage of the MDA on May 28, 1976), could be approved, i.e. “cleared,” for marketing via an abbreviated process called a 510(k) clearance if they could demonstrate that the new device was substantially equivalent to a pre-existing predicate medical device.\(^{14}\) If substantial equivalence could be demonstrated, the manufacturer was not required to submit any new clinical trial data on the device’s effectiveness and safety and could rely on old data.\(^{15}\) If no predicate device existed, the manufacturer was required to submit a Pre-marketing Application (PMA) requiring new safety and efficacy data.\(^{16}\) The PMA process is more expensive, takes longer to complete, and is more complicated from both an administrative and medical point of view.\(^{17}\)

**Issue #1: Lack of Original Data on Some High-Risk Class III Devices**

In an era of limited agency resources and only incremental changes to new medical devices, there were some unexpected consequences to the manufacturer’s option to select the 510(k) clearance mechanism:\(^{18}\) (1) CDRH has favored it because it is faster and less


\(^{10}\) 21 C.F.R. § 860.3; see also U.S. Food & Drug Admin., Medical Devices: Device Classification Panels, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm (last visited June 2, 2009).

\(^{11}\) Id.

\(^{12}\) Id.

\(^{13}\) Id.


\(^{15}\) Id.

\(^{16}\) Id.

\(^{17}\) Id.

\(^{18}\) Bruce Patsner, Riegel v. Medtronic, Inc, Revisiting Pre-emption for Medical Devices, J. LAW, MED. &
labor-intensive; (2) sponsors have favored it because it is faster and they only need demonstrate that a new device is substantially equivalent to a pre-existing one; and (3) the 510(k) clearances have become more complicated as the newer devices began to resemble preexisting predicate devices less and less, and the predicate devices to which they were being compared were no longer even the “gold standard” for that particular class of devices.

Congress acknowledged this potential problem in 1990 when it enacted the Safe Medical Devices Act. This amendment to the FDCA mandated that all currently and newly marketed Class III medical devices that could not be reclassified as Class I or II devices would ultimately undergo the more rigorous PMA process, regardless of whether they had “cleared” for marketing via the 510(k) mechanism. The 1990 Act was a major effort to correct inappropriate over-reliance on 510(k) clearance for Class III medical device marketing. Unfortunately, despite this Congressional mandate, for almost two decades FDA has failed to “call” for PMAs for 27 types of Class III medical devices which have been allowed to be marketed via 510(k) clearance. The end result was that some potentially dangerous devices were marketed without submission of any original safety or efficacy data to FDA for review. It is only with the publication of the GAO Report and some adverse media attention directed at CDRH that FDA announced it has begun to review the safety and effectiveness of older medical devices. But, there is a second issue which was raised by the controversy over the failure to call for PMAs for existing Class III devices.

Issue #2: Should the Current Medical Device Approval Process Be Overhauled?

The GAO Report’s criticism of FDA’s continued reliance on the 1976 MDA review and approval process for high-risk (e.g. class III) medical devices was more than just a formal reminder that the medical devices division of FDA has not lived up to the administrative burden placed on it by the Medical Device Safety Act of 1990. More pointedly, the GAO noted that the high-risk Class III medical devices should essentially always be approved for marketing via the PMA process, even if an abbreviated marketing mechanism (i.e., 510(k) clearance) were available. This may be true from a public health point of view. It also might be preferable from a liability point of view as well, given the fact that manufacturers are entitled to federal preemption protection against tort claims in civil suits in state courts only if their product was approved for marketing by FDA via a PMA as a result of the recent Riegel v. Medtronic, Inc., decision.

21 Id.
22 Rebecca Voelker, More Safety Data Sought for High-Risk Devices, 301 JAMA 1867 (2009).
These two facts notwithstanding, the only way for all Class III medical devices to be required to reach U.S. markets only via a PMA would be for Congress to amend the FDCA. This would be reasonable only if sufficient data exists to demonstrate that the bifurcated marketing mechanisms originally set forth in the 1976 MDA are no longer a viable regulatory framework for high-risk Class III medical devices. What is not clear is whether the adverse publicity CDRH is encountering regarding the appropriate level of safety and efficacy data for high-risk medical devices in the media\textsuperscript{25} and peer-review medical literature\textsuperscript{26} is the result of: (1) a medical device approval matrix that has now become outmoded; (2) a simple lack of sufficient medical and administrative personnel to reverse the tendency to employ 510(k) clearance instead of PMA whenever remotely feasible; (3) a political problem in which otherwise competent negative medical reviews about safety problems for high-risk devices are simply being ignored or over-ridden by superior FDA officials who have decided to make industry-favorable approval decisions despite safety concerns; or some combination of these. What is clear is that overall manner FDA is handling safety issues for prescription medical devices is going to come under the same level of Congressional and public scrutiny, and skepticism, that its handling of prescription drug safety issues has. Although that may not bode well for some in industry and FDA, it may be a welcome signal to the new FDA Commissioner\textsuperscript{27} and a real benefit to consumers in this country.


