



June 22, 2009

Subcommittee on Health Examines Medical Device Safety

On June 18, 2009, the Subcommittee on Health of the House Committee on Energy and Commerce held a hearing to examine whether the current processes for medical device approval sufficiently protected users of medical devices. Specifically, most of the hearing was dedicated to exploring the adequacy of the 510(k) process, which requires a device manufacturer to notify the FDA before it markets a device and to establish that the device is “substantially equivalent” to a legally marketed “predicate” device that did not require the more stringent premarket approval (PMA) process.

In January 2009, the Government Accountability Office (GAO) reported that two dozen class III devices continue to be cleared for the U.S. market through the 510(k) process, despite the fact that the Safe Medical Devices Act of 1990 (SMDA) required the Food and Drug Administration (FDA) to reexamine these devices and either reclassify them as class I or class II, or allow them to remain in class III but obtain FDA approval through the rigorous PMA process. The GAO report is accessible by clicking [here](#).

Members and witnesses at the hearing debated two central issues during the hearing: (1) whether more devices, particularly those in class II, should be evaluated through the PMA process; and (2) whether or not the 510(k) process should be revised to require more science-based data.

Brief Summary of Witness Testimony

Dr. Marcia Crosse, GAO

- FDA has not ensured that all class III devices are approved through the PMA process.
- FDA additionally faces large challenges in post-market surveillance of devices. Strong post-market surveillance of these devices that have been approved through this “least

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burdensome” approach is vital.

- FDA has failed to conduct required inspections on manufacturing establishments.
- FDA’s oversight of medical devices is already on the GAO’s list of high-risk issues that merit Congressional monitoring.

Dr. Peter Lurie, Public Citizen

- Three problems plague FDA’s device approval process:
 - (1) the approval standard for medical devices is lower than the approval standard for drugs;
 - (2) FDA uses a permissive interpretation of the “same intended use” standard of the 510(k) process; and
 - (3) the 1990 amendments to the Food, Drug, and Cosmetic Act allow new devices to have “different technological characteristics” from their predicates as long as no new issues of safety or effectiveness are raised, which allows the use of the 510(k) pathway by dissimilar devices that otherwise would have been reviewed by the PMA process.
- These problems underscore the fact that the 510(k) process itself is not the problem, but rather that considerations regarding “same intended use” and “different technological characteristics” are too weakly applied.
- These problems must be rectified by modifications of FDA practice, regulation and legislation.

Dr. William Maisel, Medical Device Safety Institute

- The fact that potentially dangerous devices like Automated External Defibrillators continue to be cleared via the 510(k) pathway, despite the SMDA, highlights FDA’s lack of resources and staff.
- The 510(k) process runs deeper than simple reclassification of class III 510(k) devices. The FDA relies too heavily on the device industry to make determinations regarding the need for a 510(k) submission.
- Even the more stringent PMA process can sometimes fall short in adequately protecting patients. When large numbers of patients are rapidly exposed to a newly-approved product, risks are heightened and the FDA needs stronger post-market surveillance capabilities to obtain follow-up safety data.
- In contrast with approved drugs that remain on the market for decades, the device product life cycle



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is short and rapid device innovations can render prior devices obsolete. Because the short product life cycle contributes to a lesser track record of safety, the FDA must promote and enforce a higher standard, especially for high-risk devices.

Philip Phillips, Former Director of CDRH

- The 510(k) process is adequate and provides FDA with an appropriate means for classification of devices.
- FDA should develop special controls for every device in class II rather than requiring the PMA process for such devices.
- Any suggestion of a “revitalization” of the medical device reclassification system is inappropriate, because it must be “vitalized” first.

Statement from AdvaMed

In a statement submitted to the hearing record, Stephen J. Ubl, the president and CEO of the Advanced Medical Technology Association (AdvaMed), commented that the FDA system for oversight of medical devices had served the public well for over 30 years. He emphasized that it is important that the FDA regulatory system continue to ensure that patients have timely access to life-sustaining and life-enhancing innovations.

FDA was not Formally Represented as a Witness at the Hearing

The general consensus among most Subcommittee Members was to allow the new leadership at FDA the opportunity to address the problems highlighted in the GAO report before any legislative intervention is considered. That prompted Members on both sides of the aisle to express dissatisfaction with the FDA’s absence, raising the prospect of a future hearing. “Where is the FDA today?” asked Representative Mike Burgess, a Texas Republican. Burgess continued, “Only last year, former FDA Commissioner von Eschenbach told this Committee ‘the 510(k) process is out of control.’ Did the 510(k) process improve when President Obama took the helm, or is there still a problem? We need to hear from the Commissioner of the FDA to determine gaps in the regulatory process.”

Implications for Medical Device Manufacturers

- **Preemption.** The hearing may stimulate further attention on medical device preemption and the status of H.R. 1346, the Medical Device Safety Act of 2009. In *Riegel v. Medtronic*, 129 S.Ct. 999 (2008), the Supreme Court held that the express preemption clause of Medical Device Act bars common-law state tort claims against manufacturers whose devices underwent PMA approval. H.R. 1346 is intended to modify the Medical Device Act with the intent of ensuring a common-law state tort cause of action against manufacturers of any device, regardless of whether the device



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underwent PMA approval or 510(k) clearance. In his opening statement, Representative Bruce Braley (D-IO) stated, “FDA approval is not enough to guarantee every device is safe, which is why H.R. 1346 must be passed immediately to clarify the intent of Congress to preserve a cause of action against [device] manufacturers.” Yesterday’s hearing highlighted the perceived shortcomings of the device approval process and further focused Congressional attention on H.R. 1346.

- **Legislative activities.** While the general consensus at the hearing appeared to be that legislation is not necessary yet, Subcommittee Members are still considering the prospect. “What we’re trying to do here is to see if there is need for legislation to fix the concerns you’ve raised,” said Chairman Pallone before questioning the witnesses. “Chairman Dingell, Congressman Stupak, and myself have a bill written that addresses these issues as well as inspection issues and lack of FDA resources.” Chairman Dingell’s comprehensive legislation to overhaul the Food, Drug, and Cosmetics Act did not move last Congress, but last week, the Subcommittee approved food safety provisions from that bill. The Subcommittee may still decide to move on the device provisions of former Chairmen Dingell’s legislation following this hearing.
- **Further Congressional attention on the 510(k) process.** Finally, in the final minutes of the hearing, Representative Burgess made a comment during his questioning to suggest that the 510(k) debate may get louder. While questioning Dr. Maisel, Burgess analogized the perceived shortcomings of the 510(k) process with Chairman Waxman’s recent attempts to create an abbreviated pathway for the approval of follow-on biologics. Representative Burgess’s comments may presage further rehashing of the 510(k) process in the debate over follow-on biologics and the pitfalls of an abbreviated approval process.

King & Spalding will continue to monitor the activities of the Energy and Commerce Committee. Please contact us with any questions or if we can assist with targeted analysis of Committee action or related activities.

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