

Can the Innovation Watchdog Innovate? FDA's Recent Proposals to Streamline the Medical Device Clearance Process

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In the first few months of 2011, the FDA's Center for Devices and Radiological Health ("CDRH") has issued a number of proposed actions and initiatives designed to clarify and streamline the process for bringing new medical devices to market. This paper describes some of these proposals and industry's reaction to them, and briefly analyzes the likelihood that the proposals will bring about any significant changes.

Impetus for the Proposals

The FDA in general, and CDRH in particular, have been under pressure from both the medical device industry and politicians to streamline the medical device approval process. In August of 2010, CDRH published a list of proposals designed to tighten the rules for premarket approval of devices and increase the Center's authority to require post-approval studies. The result was a backlash of lobbying and criticism by the industry, arguing that the process needed to be less, not more, stringent.¹

Politicians have also been advocating for change. In February 2011, Representative Joe Pitts (R-Pa.) publicly criticized the overly-stringent and time-consuming device approval process.² Pitts focused primarily on the potential effect of over-regulation on the economy, describing the United States as "the world leader in medical innovation" and expressing concern that "we are quickly losing this lead." Pitts argued that as cost and time required for approval have increased, manufacturers have turned elsewhere, particularly Europe, to develop and market their devices.

President Obama also joined in the chorus. In an article published in the *Wall Street Journal*, the President pointed out that, while regulations are important, those rules sometimes get out of balance, "placing unreasonable burdens on business—burdens that have stifled innovation and have had a chilling effect on growth and jobs."³ The President promised a "government-wide review of the rules already on the books to remove outdated regulations that stifle job creation and make our economy less competitive."⁴ The President specifically alluded to forthcoming changes in the medical device approval process.

The Proposed Changes

¹ Alicia Mundy, Melanie Torttman & Jon Kamp, *U.S. Backs Down on Work Noise, Medical Devices*, WALL ST. J., Jan. 20, 2011, http://online.wsj.com/article/SB10001424052748703951704576092051613167570.html?mod=rss_whats_news_us_business.

² Joe Pitts, *Keeping American Jobs in America*, CONGRESS BLOG (Feb. 15, 2011 1:20 PM), <http://thehill.com/blogs/congress-blog/economy-a-budget/144199-keeping-american-jobs-in-america>.

³ Barack Obama, *Toward a 21st-Century Regulatory System*, WALL ST. J., Jan. 18, 2011, <http://online.wsj.com/article/SB10001424052748703396604576088272112103698.html>.

⁴ *Id.*

Modifications to the 510(k) premarket notification process

The first set of changes announced on January 19, 2011,⁵ focus on streamlining the 510(k) premarket notification process. The 510(k) process, by which the majority of medical devices are cleared for marketing in the United States,⁶ provides a less stringent clearance process than the traditional premarket approval (“PMA”) process. It is generally open to lower-risk devices classified as “Class I” and “Class II” devices, and to certain “Class III” devices that are “substantially equivalent” to devices already on the market (the “predicate device”).⁷

The 510(k) process is typically both faster and less expensive than the PMA process. Manufacturers submitting devices for 510(k) clearance are usually not required to submit clinical data to establish the safety and efficacy of their products.⁸ Rather, CDRH bases its decisions primarily on comparison to the predicate device and, in some cases, on data from performance tests.⁹ The result is that manufacturers are able to submit devices to the FDA for approval sooner and the FDA is able to respond more quickly.¹⁰ The process is also significantly less expensive for both the FDA and the manufacturer.¹¹

While the 510(k) process is less onerous than the PMA process, both the medical device industry and the FDA have raised concerns that, recently, “the 510(k) program had become less predictable, consistent, and transparent...”¹² In an August 2010 report, the FDA noted that there was substantial ambiguity in certain critical terms, such as “substantial equivalence.” This ambiguity made the process less predictable for industry and resulted in “inconsistency in CDRH’s ...decision making.”¹³ Additionally, the FDA acknowledged that “manufacturers lack clear guidance as to when clinical information

⁵ News Release: Food & Drug Admin., *FDA to Improve Most Common Review Path for Medical Devices* (Jan. 19, 2011) (available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm>).

⁶ See *FDA Announces Changes To Medical Device 510(k) Approval Process*, MEDICAL DEVICE NEWS AND INSIGHTS (Jan. 19, 2011), <http://www.mdci.com/blog/2011/01/fda-announces-changes-to-medical-device-510k-approval-process/>. (“90% of medical devices approved between 2003 and 2007 used this regulatory path [the 510(k) process].”).

⁷ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-190, *MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS* 12 (2009).

⁸ *Id.* at 14.

⁹ *Id.*

¹⁰ The FDA’s goal is to respond to 510(k) submissions within 90 days and premarket approval submissions within 180 days. *Id.* at 15.

¹¹ In 2005, “the estimated average cost for the agency to review a 510(k) submission was about \$18,200, while the estimate for a PMA submission was about \$870,000.... [For applicants], the standard fee for 510(k) submissions is \$3,693, while the standard fee for original PMA submissions is \$200,725.” *Id.* at 15-16.

¹² Jeffrey Shuren, Remarks at MassMEDIC FDA Update Conference, (Dec. 1, 2010) available at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm235567.htm>.

¹³ 510(k) WORKING GROUP, FOOD & DRUG ADMIN., *PRELIMINARY REPORT AND RECOMMENDATIONS* 42 (2010) available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf>.

will be requested, and they may not learn of the need to conduct a study until after they have submitted their 510(k) for review.”¹⁴

Most of the proposals announced by CDRH in January seem designed to address these basic concerns. Many of the proposed actions involve clarifying specific regulations and procedures for the benefit of both CDRH staff and industry. For example, CDRH proposed publishing guidance regarding when clinical data was necessary to support a submission and what sorts of modifications to a medical device require a new submission.¹⁵

Additionally, CDRH proposed steps to improve both the consistency and the scientific quality of decisions by CDRH staff. Recognizing that staff may not always have the experience or expertise to deal with specific technological issues, the plan reaffirmed the Center’s desire to create a “Center Science Council” comprised of senior CDRH scientific experts and experienced review staff.¹⁶ This Council would create guidelines for, audit the decisions of, and serve as a resource to FDA staff.¹⁷ A similar proposal was to create a “network of external experts” to provide outside expertise to FDA staff when necessary.¹⁸

Innovation Initiative

Less than a month after publishing its plan to streamline the 510(k) review process, the CDRH announced three goals to create a more significant “Innovation Initiative.”¹⁹

First, it will help accelerate the development and regulatory evaluation of innovative devices that have the potential to transform an area of health care and address an unmet medical need. Second, it will strengthen the U.S. research infrastructure. Finally, it will help the FDA better prepare for and respond to transformative technologies and scientific breakthroughs.²⁰

Whereas the 510(k) plan focused on streamlining the process for devices that were substantially similar to devices already on the market, the Innovation Initiative looks to the other end of the spectrum, focusing on “pioneering” devices for which there is no predicate.²¹ Unlike the Class I and Class II devices eligible for the streamlined 510(k)

¹⁴ *Id.* at 77

¹⁵ CENTER FOR DEVICES & RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., PLAN OF ACTION FOR IMPLEMENTATION OF 510(k) AND SCIENCE RECOMMENDATIONS 2 (Jan. 2011) available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>.

¹⁶ News Release, *supra* note 5; CENTER FOR DEVICES & RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., CDRH INNOVATION INITIATIVE 10 (Feb. 2011) available at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHInnovation/ucm242067.htm>.

¹⁷ CDRH, *supra* note 15, at 3.

¹⁸ *Id.*

¹⁹ Shuren, *supra* note 12.

²⁰ *Id.*

²¹ CDRH, *supra* note 16, at 7

process, the devices affected by the Initiative will be primarily Class III devices subject to the more stringent and onerous PMA process.²²

The primary rationale behind the Initiative seems to be that novel devices currently face a significant disadvantage in the PMA process. “[T]ransformative innovative devices typically present new scientific and regulatory challenges.”²³ New technology based on new science faces delays in review.²⁴ In fact, even though many such products are already eligible for an expedited review process, CDRH has acknowledged that such “expedited review times are typically longer than standard review times..., primarily due to the unique regulatory and scientific challenges presented by [innovative] devices.”²⁵

The Innovation Initiative seeks to correct for this disadvantage by creating a special pathway for novel devices. The pathway would have a number of features designed to expedite the review process. One such measure is to ensure that CDRH is involved earlier in the process of developing a product. Delays often occur in the approval of novel devices because CDRH is caught off guard by a submission involving novel scientific concepts about which the Center does not have sufficient expertise. Presumably, by getting CDRH involved earlier in the process, the Center will recognize its need for additional expertise early on and prepare accordingly.²⁶

Additionally, the Center Science Council created by the 510(k) plan discussed above would be closely involved in the review of devices admitted into the Innovation Pathway. The primary review team for a device would regularly report to the Center Science Council to quickly resolve scientific and technical issues that arise.²⁷

How Have The Proposals Been Received by Industry?

As one might expect, the response of the medical device industry to these proposals has been ambivalent. Industry representatives have expressed gratitude that CDRH seems to understand the difficulties caused by the stringent review process, but have also stated that the proposals are not broad enough.

Industry commenters seem to be particularly supportive of the idea of a Center Science Council designed to increase quality and consistency of decision making. A number of commenters have expressed enthusiasm at the idea of working with such a council on a regular basis.²⁸ Commenters also expressed concern, however, that such a council could hinder efficiency if it was implemented simply as an extra layer of review.²⁹

²² *Id.* at 10

²³ *Id.* at 7

²⁴ *Id.* at 16

²⁵ *Id.* at 8

²⁶ *Id.* at 10-11

²⁷ *Id.* at 11

²⁸ *See, e.g.* ADVANCED MEDICAL TECHNOLOGY ASS’N, public comments to regulatory Docket No. FDA-2010-N-0348, at 52 (Oct. 4, 2010) (hereinafter “AdvaMed Comments”) *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0348-0059.1>; MEDICAL IMAGING & TECHNOLOGY ALLIANCE, public comments to regulatory Docket No. FDA-2010-N-0348, at 13 (Oct. 4,

At a public meeting about the Innovation Initiative held on March 15, 2011,³⁰ several commenters questioned the decision to limit the Innovation Pathway to novel technologies. Some of the most important medical devices, they suggested, may not be as “super-innovative” or “exciting” as others, but could nevertheless have major effects on patient care.³¹ Tom Fitzsimons of the University of Pennsylvania pointed out that, although “people like shiny new things,” such a focus could be the “wrong direction” for CDRH.³² Sharon Segal, vice president at AdvaMed, opined that, “while we support the goals of the Innovation Initiative, we believe that early and consistent interaction ... should be available to all innovative products.”³³

A number of commenters implied that the appropriate criteria for admission to the pathway should not simply be the novelty of the idea, but the nature of the “risk-reward equation” that developers and investors face in deciding whether to invest in a new product. Products that provide major benefits, but only affect small numbers of individuals, face difficulty in getting to market. One participant pointed out that it is difficult to get investors to invest heavily in a project with a potential patient base of only 50,000—no matter how helpful that project might be to those patients.³⁴ Thus, commenters suggested that such devices may benefit from a regulatory scheme that provides “a different kind of risk-benefit calculus ... in certain types of situations.”³⁵

Perhaps the biggest concern of commenters, however, was that neither the 510(k) plan nor the Innovation Initiative focused on what they perceived as the critical issue—that the FDA has grown too risk adverse, preferring to deny approvals to medical devices that could have major positive impacts rather than risk a major negative impact. One commenter complained, “I think there’s a concept here that, if the FDA brands a product for approval, everything’s supposed to be perfect about it.”³⁶ Such an emphasis on perfection is likely to lead to products being obsolete before they can be brought to market. Especially with products that focus on unmet needs of specific patients, “we ought to have a different paradigm for thinking about risk and benefit.”³⁷ Thus, rather than focus on trying to create a faster pathway for certain products, CDRH may need to fundamentally reconsider its basic risk-benefit calculus.

2010) (hereinafter “MITA Comments”) *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0348-0054>.

²⁹ See e.g. AdvaMed Comments, *supra* note 28 at 52; MITA Comments, *supra* note 28 at 13-14.

³⁰ Public Workshop – Center for Devices and Radiological Health’s Innovation Initiative (Mar. 15, 2011) (hereinafter “Workshop”) video *available at* <http://www.fda.gov/MedicalDevices/NewsEvents/Workshops/Conferences/ucm241095.htm>.

³¹ *Id.*

³² *Id.*

³³ *AdvaMed Cool to FDA’s New Medical Device Innovation Initiative*, MEDICAL DESIGN, Mar. 21, 2011, <http://medicaldesign.com/engineering-prototyping/regulatory/advamed-fda-medical-device-innovation-0321/>.

³⁴ Jonathan Kuniholm, comments at Workshop, *supra* note 30; see also Tim Wright, in panel discussion, *id.*

³⁵ Jonathan Leff, in panel discussion, *id.*

³⁶ Rick Kuntz, in panel discussion, *id.*

³⁷ Jonathan Leff, in panel discussion, *id.*

Are These Changes Likely to Create Significant Improvements?

Whether the proposed changes will result in significant improvements in the efficiency of the approval process for either 510(k) submissions or for new innovations will depend largely on how they are implemented. The Innovation Initiative is still in its earliest stages of seeking public comment. The 510(k) plan is somewhat further along, but the proposals are still vague.³⁸

Ultimately, the 510(k) plan is likely to have little impact. The majority of the proposals focus on “clarifying” current standards and offering more guidance. While such guidance could no doubt be helpful, a frequent complaint is that the FDA relies too much on informal guidance and not enough on more formal measures such as rulemaking.³⁹

Perhaps the most significant aspect of the plan is the creation of the Center Science Council. A number of commenters have expressed enthusiasm about the potential for such a council.⁴⁰ If the council is successfully created and utilized, it could improve the efficiency, quality, and consistency of the agency’s decision making process. This would require CDRH to determine when, how, and in what role the Council would engage in the decision making process. A Council that is structured primarily as an extra layer of review—to audit and possibly overturn decisions of FDA staff—would likely do little to improve the process and could impede it. On the other hand, the Council can hardly be expected to be involved early on and regularly in each submission. For the Council to be effective, CDRH will need to determine how the Council can utilize its limited resources effectively to influence the approval process in a timely manner.

The Innovation Initiative seems likely to create more significant changes than the 510(k) plan. Unlike the 510(k) plan’s primary focus on clarification and guidance, the Initiative contains procedural and structural changes designed to significantly impact the process. Details are still very unclear, however. Furthermore, the Initiative will necessarily be limited in scope, as CDRH is attempting to implement it with no additional funding.⁴¹ One of the key issues CDRH will have to decide is what sort of devices to allow into the exclusive pathway. While the Center’s original plan focused on the novelty of the scientific issues raised, industry commenters strongly emphasized that other factors, such as the likely risk-benefit calculus of potential investors in a device, should be considered.

Ultimately, both the 510(k) plan and the Innovation Initiative have the potential to improve both the quality and the effectiveness of the medical device approval process—although such improvement is likely to be small even in the best of scenarios. Whether

³⁸ See generally CDRH, *supra* note 15.

³⁹ See, e.g. MITA Comments, *supra* note 28, at 2 (arguing that guidance is often insufficient, and that on sensitive issues, “it is important for the Agency to instead opt for more stringent and public processes....”).

⁴⁰ See generally panel discussion, Workshop, *supra* note 30.

⁴¹ See CDRH, *supra* note 16, at 4 (“We will implement the Innovation Initiative to the extent practical given current resources, and would consider expanding the Initiative should additional resources become available.); *id.* at 8 (“the number of devices that we would be able to accommodate under the Innovation Pathway would depend on available resources”).

such improvement occurs at all will depend in large part on how the programs are implemented.

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