FDA Releases Proposed Medical Device Reforms

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In response to protracted public and political criticism of the Food and Drug Administration's (FDA or Agency) regulation and review of medical devices under the premarket notification, or 510(k), process, the FDA's Center for Devices and Radiological Health (CDRH or Center) yesterday released a set of proposed reforms to better "foster medical device innovation and assure the safety and effectiveness of medical technology." [1]

In a cover letter accompanying the proposals, Center Director Jeffrey Shuren acknowledged that CDRH has received complaints from regulated industry about its "unpredictable, inconsistent and opaque" decision making, and has also faced accusations from consumer advocates that the 510(k) program is "[in]sufficiently robust to assure that some devices cleared under the program are safe and effective nor does it provide enough information on safety and effectiveness to make well-informed decisions." [2]

The new proposals mark the culmination of months of public deliberations and outreach by CDRH, including preliminary reports released in August 2010 by the Center's 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. [3] The proposals are, in turn, being shared by the FDA with the Institute of Medicine (IOM), which is in the midst of a separate, independent review of the 510(k) program.[4]

Overview of Proposed Reforms

CDRH proposed reforms that entail 25 specific deliverables or milestones in 2011, and classified them into four broad categories: (1) guidance development; (2) policy and regulatory reforms; (3) administrative reforms; and (4) issues referred - or deferred - for IOM's consideration.[5] Foremost among the eight guidance documents to be developed in 2011 will be draft guidances on:

- "streamlining" the *de novo* classification process;
- clarifying when device modifications do and do not require new 510(k) submissions;
- clarifying when clinical data should be submitted to increase predictability and transparency; and
- establishing a "510(k) paradigm" to address the need for clinical substantiation of claims, use of multiple predicates, the criteria for identifying "different questions of safety and effectiveness," and other programmatic issues.

CDRH also proposes a series of regulatory actions, ranging from “improving the IDE process” and its postmarket safety surveillance systems by mid-year, to issuing a proposed rule on unique device identification (UDI) by June 30. Similarly, the FDA promises internal reviews to otherwise “streamline” and “improve” its procedures for “notice to industry letters” signaling changes in regulatory expectations, for third party device reviews, as well as for unspecified improvements in the Center’s overall “guidance and regulation development.”

The most significant administrative proposals are for CDRH to establish a Center Science Council to help oversee continuous quality improvements to the 510(k) program, and develop “a network of external experts” to better enable the Center to “leverage external scientific expertise.”

Yet the Center deferred action on a number of key controversial issues until after the forthcoming IOM report is released, including the adequacy of its postmarket surveillance and 510(k) clearance rescission authorities; the desirability of establishing a “class IIb” of devices; the consolidation of “indications for use” and “intended use;” and issues related to off-label device use.

Conclusion

It is debatable whether the diverse proposals released by CDRH will adequately answer and correct the specific mistakes, procedural failures, and programmatic deficiencies raised in the FDA’s 2009 internal review of the Menaflex 510(k) clearance.[6] As the Agency concluded at the time, “[t]he predicate system, as implemented, appears to perpetuate questionable review decisions.”

Moreover, the proposals may address -- but are not specifically focused on -- the many issues raised during recent congressional oversight of novel diagnostics and the Center’s controversial draft guidance on *In Vitro* Diagnostic Multivariate Index Assays (IVDMIAs), suggesting that many questions unique to advanced molecular diagnostics, laboratory developed tests (LDTs), and CDRH’s Office of *In Vitro* Diagnostic Device Evaluation and Safety (OIVD) will receive further scrutiny.

Finally, in addition to innovative companies, regulated industry, and patient advocates, the Congress is a key audience of CDRH’s proposals, given the impending reauthorization of medical device user fees under the Medical Device User Fee and Modernization Act (MDUFMA) by September, 2012. Stakeholders should anticipate continued congressional scrutiny of the rigor and efficiency of FDA’s medical device regulation, particularly in light of President Obama’s recent focus on regulatory reforms to “make our economy stronger and more competitive” [7] as well as CDRH’s own claims that its reforms will suffice to “keep the United States the leader in medical device innovation.”

[1] Letter from the CDRH Director, January 19, 2011.

[2] Id.

[3] FDA Recommends Actions to Improve Oversight of Medical Devices, August 5, 2010.

[4] IOM,Public Health Effectiveness of the FDA 510(k) Clearance Process

[5] 510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps Plan of Action for Implementation of 510(k) and Science Recommendations.

[6] FDA, Review of the ReGen Menaflex: Departures from Processes, Procedures, and Practices Leave the Basis for a Review Decision in Question, September 2009; FDA Acknowledges Deviations in Menaflex Knee Device Clearance, September 25, 2009.

[7] President Barack Obama, "Toward a 21st-Century Regulatory System", Wall Street Journal, January 18, 2011.