510(k) Reform

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April 28, 2011

The “Why” of 510(k) Reform

- Negative attention from media, consumer groups, practitioners, Congress, raising concerns about “abbreviated” or “rubber stamp” process
- Obama Administration “Transparency”
- Industry Concerns
  - Need for greater consistency in FDA review process
  - Global harmonization
- FDA Concerns
  - Technological complexity and change since 1976
  - Reputation
  - ReGen

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510(k) Reform Activities

- GAO Report on 510(k)
  - No negative conclusion on overall effectiveness of process in assuring safety and effectiveness
  - Recommendation for FDA to complete reclassification of pre-amendments Class III devices
- FDA Report on 510(k) – August 2010
- IOM Review of 510(k) – Report due Summer 2011
  - Does the current 510(k) process optimally protect patients and promote innovation in support of public health?
  - If not, what legislative, regulatory, or administrative changes are recommended to achieve these goals?

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FDA Report on 510(k)

55 recommendations issued, prioritized

- Strong support for:
  - Posted 510(k) summaries
  - Streamlining of de novo
  - Improvement of guidance process
  - Guidance on technological characteristics, intended use/indications for use
  - Training of FDA reviewers and industry
  - Science Council
- Mixed reviews
  - Periodic reports
  - Class IIb
  - Rescission
  - Predicates (especially split predicates)
  - Providing “all information”

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FDA Report on 510(k) (cont'd)

Recommendations raising significant concerns

- Public database of labeling, pictures, schematics (public meeting April 2011)
- Combining intended use/indications
  - Concern that products must be identical
- Statutory authority for off-label use
- Manufacturing information/pre-clearance inspections

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FDA - 510(k) Work Plan – Chronological Implementation Timeline

MONTH	DATE(S)	ACTION	PURPOSE	MILESTONE
March	31, 2011	***Implement an "Assurance Case" Pilot Program***	To explore the use of an "assurance case" framework for 510(k) submissions	Start pilot program
	31, 2011	***Establish a Center Science Council***	To: 1) oversee the development of a business process and SOP for determining and implementing an appropriate response to new scientific information; 2) promote the development of improved metrics to continuously assess the quality, consistency and effectiveness of the 510(k) program; 3) periodically audit 510(k) review decisions to assess adequacy, accuracy and consistency; and 4) establish an internal team of clinical trial experts to provide support and advice on clinical trial design for Center staff and prospective IDE applicants	Post Council Charter to FDA Website
April	7-8, 2011	***Provide Additional Information About Regulated Products***	To make device photographs available in a public database without disclosing proprietary information	Public Meeting
	7-8, 2011	***Improve Medical Device Labeling***	To develop an on-line labeling repository	
Summer	2011	***Rescission Authority***	To consider defining the scope and grounds for the exercise of the Center's authority to fully or partially rescind a 510(k) clearance	IOM Report
		Postmarket Surveillance Authorities	To seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices	
		Establish a Class II(b)	To develop guidance defining "class IIb" devices for which clinical information, manufacturing information or, potentially, additional evaluation in the postmarket setting would typically be necessary to support a substantial equivalence determination	
		Predicate Clarification	To clarify when a device should no longer be available for use as a predicate	
		Clarify and Consolidate Regulatory Terms	To consolidate the concepts of "indication for use" and "intended use" into a single term, "intended use"	
		Device Review	To consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for CDRH to access upon request	
		Off-Label Use	To explore the possibility of pursuing a statutory amendment that would provide the agency with the express authority to consider an off-label use when determining the "intended use" of a device	

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June	15, 2011	***Establish a Center Science Council***	To: 1) oversee the development of a business process and SOP for determining and implementing an appropriate response to new scientific information; 2) promote the development of improved metrics to continuously assess the quality, consistency and effectiveness of the 510(k) program; 3) periodically audit 510(k) review decisions to assess adequacy, accuracy and consistency; and 4) establish an internal team of clinical trial experts to provide support and advice on clinical trial design for Center staff and prospective IDE applicants. (Note new milestone)	Post initial results of 510(k) audit to FDA Website
	15, 2011	***510(k) Modifications Guidance***	To clarify which changes do or do not warrant submission of a new 510(k) and which modifications are eligible for a Special 510(k)	Draft Guidance
	15, 2011	***Establish "Notice to Industry Letters" as a Standard Practice***	To clarify and more quickly inform stakeholders when CDRH has changed its regulatory expectations on the basis of new scientific information	Post SOP to FDA Website
	30, 2011	***Improve Collection and Analysis of Postmarket Information***	To develop better data sources, methods and tools for collecting and analyzing meaningful postmarket information, and to enhance the Center's capabilities to support evidence synthesis and quantitative decision making	Determine system requirements and select the platform for a new adverse event database
	30, 2011	***Improve the IDE process***	• To better characterize the root causes of existing challenges and trends in IDE decision making • Assess, characterize and mitigate challenges in reviewing IDE's	Complete program assessment
	30, 2011	***Implement a Unique Device Identification (UDI) System***	To permit the rapid and accurate identification of devices, to facilitate and improve adverse event reporting and identification of device-specific problems	Issue proposed regulation
July	15, 2011	***Assess Center Staffing Needs***	• To formalize the Center's internal process for identifying staffing needs, and to enhance recruitment, retention, training, and professional development of review staff. • To create a mechanism to assemble an experienced ad hoc team to temporarily assist with unexpected surges in workload.	Develop process for identifying, recruiting, retaining, and training needed staff
	31, 2011	***Clinical Trial Guidance***	To improve the quality and performance of clinical trials	Draft Guidance
	31, 2011	***Streamline Guidance and Regulation Development Process***	To provide greater clarity, predictability, and efficiency in the guidance and regulation development process	Post SOPs to FDA Website

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August	31, 2011	***Enhance Training***	• To train new Center staff on core competencies. • To train Center staff and industry on: 1) the determination of "intended use"; 2) the determination of whether a 510(k) raises “different questions of safety and effectiveness"; 3) the review of 510(k)s that use “multiple predicates”; 4) the development and assignment of product codes; 5) the interpretation of the “least burdensome” principles; and 6) the appropriate use of consensus standards	Develop and implement training on core competencies
September	15, 2011	***Leverage External Experts***	To develop a network of external experts to appropriately and efficiently leverage external scientific expertise. Also, to assess best-practices and develop SOPs for staff engagement with external experts	Post SOP to FDA Website
	30, 2011	***Evaluation of Automatic Class III Designation (De Novo) Guidance***	To streamline the de novo classification process	Draft Guidance
	30, 2011	***510(k) Paradigm Guidance***	To provide greater clarity regarding: 1) when clinical data should be submitted in support of a 510(k); 2) the submission of photographs or schematics for internal FDA use only; 3) the appropriate use of multiple predicates; 4) the criteria for identifying "different questions of safety and effectiveness" and technological changes that generally raise such questions; 5) resolving discrepancies between the 510(k) flowchart and the Food, Drug, and Cosmetic Act; 6) the characteristics that should be included in the concept of “intended use”; and 7) the development of 510(k) summaries to assure they are accurate and include all required information.	Draft Guidance
	30, 2011	***Continue Integration and Knowledge Management***	To improve knowledge management across the Center	Complete evaluation of methods used to integrate device information into a dynamic format so that it can be more readily used by staff to make regulatory decisions
	30, 2011	***Clarify and Improve Third-Party Review***	To develop a process for regularly evaluating the list of device types eligible for third-party review and to enhance third-party reviewer training	Post SOP to FDA Website

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October	31, 2011	***Standards Guidance***	To clarify the appropriate use of consensus standards	Draft Guidance
	31, 2011	***Appeals Guidance***	To clarify the process for appealing CDRH decisions, including decisions to rescind a 510(k)	Draft Guidance
	31, 2011	***Multiple Predicate Analysis***	To conduct additional analyses to determine the basis for the apparent association between citing more than five predicates and a greater mean rate of adverse event reports	Complete analysis and make results public
November	30, 2011	***Pre-Submission Interactions Guidance***	To supplement available guidance on pre-IDE meetings and enhance the quality of pre-submission interactions between industry and Center staff	Draft Guidance
December	31, 2011	***Product Code Guidance***	To more consistently develop and assign unique product codes	Draft Guidance
	31, 2011	***Draft 510(k) Transfer of Ownership Regulation***	To better document 510(k) transfers of ownership	Issue proposed regulation
	31, 2011	***Improve Medical Device Labeling***	To clarify the statutory listing requirements for the submission of labeling	Issue proposed regulation

510(k) and MDUFA

- Nearly half of 2010 510(k)s had decisions still pending at end of FY (ODE, OIVD)
- CDRH % AI requests on 1st cycle increased from 44% in 2005 to 77% in 2010. OIVD major reasons for AI letter (2010)
  - Concerns about labeling
  - Guidance not followed
  - Missing software data
- No information on meetings
- OIVD 510(k) review cycles average 1.72
- 510(k) NSE rates have doubled
- 510(k) review times are increasing, although MDUFA Tier I (90% in 90 days) and Tier II cycle goals (98% in 150 days) are still being met
- CDRH average time to 510(k) decision increased from 92 days in 2005 to 148 days in ’10 (no OIVD breakout)

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OIVD 2010 Industry Perception Survey

- 79% of participants (271) agreed OIVD reviewed premarket submission in timely fashion
- 95% - they were treated fairly, courteously and professionally
- 86% - scientific expertise level appropriate
- 71% - review procedures consistent
- 57% - guidelines, standards policies adequate to prepare submissions (small companies more favorable)
- 58% - premarket review meetings productive (small companies more favorable)
- 79% - interactive review used

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CDRH 2010 Review Staff Survey

- 68% - complexity of reviews increased since 2005
- 58% - number of consulting reviews increased (need for additional expertise)
- 43% - noted increase in time to review a submission, due to complexity (45%) and poor quality (30%)

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FDA/OIVD & Industry Concerns

- Performance NSEs- repeated requests for data, performance lower than predicate
- Ratio of managers to reviewers (1:14 ODE; 1:27 OIVD)
- Inadequate training of reviewers
- Time required for interactive review
- Late changes in FDA thinking; different data required than discussed during pre-IDE
- FDA deviation from guidance or standard
- Changes to labeling
- No rationale for additional data requests

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What's Next with MDUFA

- April 13 - FDA financial proposal: data already provided to suggest that total collections from MDUFA III must DOUBLE to maintain current performance
- FDA target for completion of agreement June 2011
- FDA Stakeholder meeting planned for October 2011
- Package to Hill by January 2012

Challenges for 510(k)/MDUFA

- ACLA participating in negotiations
  - FDA/OIVD plan for regulation
- Impact of FDA ongoing 510(k) changes on performance and fees
  - Preliminary 510(k) review “off the clock”
  - Lengthened review timelines/goals
- Impact of IOM report on 510(k) process
- Impact of politics on FDA decisions

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??QUESTIONS??