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Senior FDA Officials Share 510(k) and Enforcement Insights at King & Spalding's Device Summit

King & Spalding's October 13-14, 2010, East Coast Device Summit featured question and answer sessions regarding the Food and Drug Administration's (FDA or the Agency) 510(k) program and enforcement activities with two senior officials in the FDA's Center for Devices and Radiological Health (CDRH). Marjorie Shulman of CDRH's Premarket Notification (510(k)) Staff in the Office of Device Evaluation (ODE) discussed recent and planned changes to the 510(k) process, as well as answered questions regarding the current 510(k) program. Gregory O'Connell, the Acting Director of the Division of Enforcement A in CDRH's Office of Compliance (OC) responded to questions regarding device importation and recalls. Panels of King & Spalding experts in the 510(k) and enforcement areas and an industry representative asked Ms. Shulman and Mr. O'Connell questions submitted by the Device Summit participants.

Changes to the 510(k) Program

Ms. Shulman, who is a member of FDA's 510(k) Working Group and has been at FDA for 26 years, began by reassuring the audience that FDA is trying to improve the 510(k) process rather than eliminate or restrict it. She stated that FDA is reviewing the comments that the Agency received regarding the 510(k) Working Group's August 4, 2010 Preliminary Report and Recommendations (the 510(k) Report) as the comment period just closed on October 4, 2010. She explained that FDA is still deciding which recommendations in that report to adopt and thus, the Agency has not yet developed detailed plans for implementing any such changes. Ms. Shulman indicated that, for these reasons, there is little definitive information to share about many of the recommendations in the 510(k) Report. However, she discussed changes that FDA has recently made to the 510(k) program and changes that the Agency is working on implementing. She noted that many of these changes are intended to address issues identified in that Report. In addition, she answered some questions about the current 510(k) program, which she acknowledged is in a state of flux.

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Recent Changes

Ms. Shulman stated that FDA has recently implemented or begun implementing the following changes to the 510(k) program:

- This year, FDA began reviewing 510(k) summaries in detail prior to clearing the devices to ensure that they contain the information specified in 21 C.F.R. 807.92. She noted that FDA found that many of the 510(k) summaries for previously-cleared devices did not include the required information.
- FDA is in the process of reviewing the safety and effectiveness information the Agency requested regarding the 25 generic types of Class III devices that were on the market prior to the enactment of the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (“preamendments Class III Devices”) for which FDA has not yet called for premarket approval applications (PMAs). The purpose of this review is to determine whether to retain each of those types of preamendments devices in Class III but require PMAs or to downclassify the device type to Class II or Class I. Ms. Shulman noted that FDA has issued proposed rules regarding the classification or reclassification of several of these types of devices.¹ She said that FDA does not have a time frame for completing this review or amending the classification regulations.

Planned Changes

Ms. Shulman indicated that FDA is working on implementing the following changes to the 510(k) process:

- The streamlining of the *de novo* review of automatic Class III classification (“*de novo* review”) by: (1) posting the Agency’s *de novo* review decision memoranda on the Agency’s website; and (2) developing special controls other than guidance documents for devices classified as Class II *via de novo* review and identifying those special controls in their classification regulations. She pointed out the little-known fact that the device marketed *via de novo* review is often the only device of that type that FDA clears and thus, the guidance documents for those type of devices are rarely used. She explained that listing their special controls in the classification regulation would likely shorten review times because developing a guidance document is time consuming for both FDA and the submitter. (The average total review time for *de novo* requests reviewed by ODE in Fiscal Year 2009 was 752 days.²) It would also help conserve the Agency’s limited resources by eliminating guidance documents for one-of-a-kind devices. She noted that FDA could develop a guidance document later if the Agency receives 510(k) notices for other devices of that type. She stated that posting the decision memoranda would help companies seeking *de novo* review to understand the review process and the type and amount of data FDA expects in a request for *de novo* review.

¹ On August 25, 2010, FDA called for PMAs for the following four types of preamendments Class III devices: (1) ventricular bypass (assist) devices (21 CFR 870.3545); (2) pacemaker repair or replacement material (21 CFR 870.3710); (3) female condoms (21 CFR 884.5330); and (4) transilluminator for breast evaluation (21 CFR 892.1990). FDA has not yet proposed to reclassify any of the remaining preamendments Class III devices into Class I or II.

² CDRH Preliminary Internal Evaluations - Volume, *510(k) Working Group Preliminary Report and Recommendations*, at 65 (August 2010).



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- Ms. Shulman confirmed that FDA is revising the Agency's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (January 10, 1997) ("The Device Modifications Guidance"). She noted that the revised Device Modifications Guidance almost certainly will explicitly state that under 21 C.F.R. 807.81(a)(3), new 510(k) clearance is required if any modification to a legally marketed device could (regardless of whether it actually does) significantly affect (either positively or negatively) the safety or effectiveness of a device or the modifications collectively could do so. In addition, she mentioned that FDA is seriously considering removing the flow charts from the revised guidance. She explained that FDA has found that many device companies use the flowcharts in the current guidance to determine whether a modification to a device requires new 510(k) clearance or can be documented in a memorandum-to-file without reading or considering the explanatory text. In response to our question regarding when FDA expects to issue the revised Device Modifications Guidance, she pointed out that it is on the list of guidance documents that FDA expects to issue in 2011. She indicated that FDA had not yet decided whether to issue the revised guidance in draft or final form, but interested parties may submit comments in either case.
- FDA is developing a more comprehensive training program for CDRH staff. According to Ms. Shulman, FDA will continue to require all new ODE reviewers to attend a two-day training program regarding FDA's regulation of devices. In addition, they will have to review 510(k) training modules online and pass one or more tests demonstrating their understanding of 510(k) requirements, including the substantial equivalence (SE) criteria. Ms. Shulman stated that 510(k) submitters should contact the 510(k) Staff if they believe that a reviewer does not understand the SE criteria or is incorrectly applying them.
- Ms. Shulman indicated that FDA probably will disallow the use of split predicates, which occurs when one predicate has the same intended use but some technological differences while another predicate has the same or similar technological characteristics but a different intended use than the new device.
- FDA will continue to allow multiple predicate devices, but the submitter must demonstrate that the new device is substantially equivalent to each predicate individually.

Clarification Regarding FDA's Current 510(k) Program

Ms. Shulman provided the following answers to our questions regarding current 510(k) requirements:

- If the submitter of a 510(k) notice that includes a 510(k) statement refuses to provide a copy of the entire submission with only confidential commercial or trade secret information or patient identifiers redacted upon written request or does not respond to such a request, the requestor should notify the 510(k) Staff. The 510(k) Staff will forward the notification to OC, which will send a letter to the submitter requesting the redacted 510(k) notice. If the submitter still refuses to provide the redacted 510(k) notice or does not respond to OC's letter, FDA will provide the 510(k) notice to the requester via an expedited Freedom of Information (FOI) Act request.



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- If FDA clears a 510(k) notice for a device that does not qualify for its generic type of device's 510(k) exemption because it has a different intended use/indications for use or a different fundamental scientific technology, the 510(k) exemption then includes the cleared device's new intended use/indications and new technological characteristics(s).
- FDA issues a new product code for an existing classification regulation when the Agency clears a new type of device under that regulation or the Agency determines that it would be helpful to separate those devices into more specific categories, such as latex and non-latex patient examination gloves. FDA changes a cleared device's product code or adds a product code to its existing product code(s) when the cleared device fits within a newly-issued product code.
- The Medical Device User Fee and Modernization Act requires FDA to review 95% of all 510(k) notices within 90 days of their submission and 98% of them within 150 days of submission. Ms. Shulman explained that all devices initially have a 90-day review period. If FDA cannot complete the review of a 510(k) notice within 90 days, the Agency may extend the review period. FDA must complete the review for most of those 510(k) notices within 150 days.
- FDA has discontinued its practice of issuing SE or NSE decisions after three rounds of review, which consists of reviewing the original 510(k) notice plus the responses to two requests for additional information. However, FDA generally still makes a final decision by the three round of review unless there are only minor issues left to resolve, such as wording in the labeling.
- Approximately 12 - 15% of recent 510(k) notices include clinical data.
- FDA discourages submitters from contacting reviewers regarding the status of their 510(k) notices, especially during the first 90-day review period.
- Ms. Shulman is not aware of any plans to update FDA's "Guidance on the CDRH Premarket Notification Review Program" (June 30, 1986), which sets forth the SE criteria subsequently codified in Section 513(i) of the FDC Act and 21 C.F.R. 807.100(b), defines "intended use" and "indications for use," and explains how to determine a device's intended use and indication(s).

Enforcement Issues

Greg O'Connell, who was a consultant at King & Spalding before recently rejoining FDA, responded to questions about importation of devices and recalls. Mr. O'Connell discussed PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting), which is the Agency's new risk-based screening system for imports that will replace the admissibility screening function of OASIS (Operational and Administrative System for Import Support). The purpose of the PREDICT system will be to target the high-risk shipments for examination while expediting the clearance of lower-risk shipments. Each entry will be scored on the basis of a range of risk factors. For example, the system will consider information regarding a product's inherent risks, sample analyses from prior shipments, and facility inspections. Mr. O'Connell emphasized that it will be especially important for importers and filers to



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ensure that the data submitted to PREDICT, *e.g.*, product codes and firm identifiers, are accurate, consistent, and complete, in order to prevent delays in the processing. Otherwise, the products will fail PREDICT's automated lookup and require manual processing.

Mr. O'Connell recommended that companies notify FDA of corrections and removals that they have determined do not affect safety or effectiveness and thus, considered to be Class III recalls. He explained that FDA might disagree with the Company's conclusions. In addition, he recommended that companies send their communications regarding recalls to headquarters and the district office simultaneously to facilitate FDA's review. He acknowledged FDA's increased interest in "back-door recalls," whereby a company modifies a device to address a safety or effectiveness issue, but does not treat it as a recall.

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We did not record Ms. Shulman or Mr. O'Connell's Q&A sessions or transcribe them in order to encourage frank and open discussions. If you have any questions regarding their comments or the recommendations contained in the 510(k) Report, we would be happy to discuss them further.

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