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Client Alert

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FDA Working Group Issues 510(k) Medical Device Safety and Effectiveness Recommendations

Major Changes Likely in 2012 MDUFA Reauthorization

On August 4, the U.S. Food and Drug Administration's 510(k) Working Group (the Working Group) released its preliminary report which made multiple recommendations for changing the 510(k) pre-market notification process for medical devices. The Working Group was convened by the FDA in September 2009 as part of a two-pronged assessment of the 510(k) clearance process. The Working Group was charged with evaluating the 510(k) program and to recommend actions FDA's Center for Devices and Radiological Health (CDRH) could take to strengthen the program under its existing statutory authority.

The second prong of the FDA's assessment of the 510(k) process is an IOM report that is slated for completion in mid-2011, which we expect will recommend legislative changes to bolster the FDA's oversight powers for medical devices.

As a result of the Working Group's and the IOM's independent reviews of the 510(k) premarket notification process, major legislative reforms should be expected as part of the debate surrounding the reauthorization of the Medical Device User Fee Act (MDUFA) that is expected to occur in the next Congress. However, in the more immediate future, the FDA is soliciting public input on the recommendations contained in the just released Working Group report, including the feasibility of implementing the potential alternatives spelled out in the report. Once its assessment is completed, the FDA will then announce which improvements it will actually implement – through guidance or regulation – with projected timelines for the implementation.

Those companies that might be adversely impacted by any of the 510(k) reforms proposed by the Working Group's Recommendations may want to consider developing public comments about those specific recommendations.

The Heart of the Medical Device Controversy

Over the past several years, growing concerns about 510(k) device safety have been percolating in Congress. FDA's two pronged review was initiated after a 2009 Government Accountability Office (GAO) report found that the FDA has regularly used the 510(k) process to clear products that were much more complex and potentially life-threatening than were contemplated as part of the original 510(k) approval path. The 510(k) process has attracted enhanced scrutiny since 2007 when Menaflex -- a knee implant -- was cleared through the 510(k) process reportedly due to political pressure over the objections of FDA scientists who claimed that the manufacturer did not provide adequate data to prove the device's safety. Consumer advocates use the problems in the approval for Menaflex as evidence that the 510(k) process allows device manufacturers to bring potentially risky products to market.

Key FDA Working Group Recommendations

The multiple recommendations to modify the 510(k) process in the Working Group report focus substantially on moderate risk medical devices reviewed by CDRH. The 510(k) process for products reviewed by the Center for Biologics Evaluation and Research (CBER) -- e.g., blood products, HIV products, and cellular products -- are not affected by the recommendations in the report.

The most significant recommendations include:

> ***Class IIb Devices****:* The Working Group proposes dividing Class II devices based on complexity into two groups -- IIa (less complex) and IIb (more complex). Potential candidates for the Class IIb subset may include implantable devices, life-sustaining devices, and life-supporting devices which present greater risks to patients than other class II device types. The recommendations include requirements for Class IIb manufacturers to submit clinical information, manufacturing information, and possibly even information derived from additional evaluations in the post-market setting, in order to support a substantial equivalence determination. This is significant because dividing Class II in this manner could place Class IIb devices on nearly the same level as Class III – which can require a substantial investment to obtain sufficient clinical data to prove a device's safety and effectiveness. The Working Group also recommends that CDRH explore greater use of its post-market authorities, and potentially seek greater authority to require post-market surveillance studies as a condition of continued clearance for certain devices. Post-market surveillance is a controversial issue and will likely be thoroughly debated during any reauthorization of MDUFA.
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> ***Rescissions****:* The Working Group recommends that CDRH consider issuing a regulation to define the scope, grounds, and appropriate procedures -- including notice and an opportunity for a hearing -- for the exercise of its authority to fully or partially rescind a previously granted 510(k) clearance. As part of this process, the Working Group advises the Center to consider whether additional statutory authority would be required for it to act. Again, efforts to expanding FDA's post-market authority will likely be reserved for the legislative debate that will play out as part of the device safety and MDUFA reauthorization debates expected in Congress in 2011 and 2012.
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> ***Consistent Review Standards****:* It is also strongly recommended by the Working Group that the term "substantial equivalence" between new and predicate devices be clarified to produce a more consistent and clear standard for reviewing products. This recommendation attempts to address manufacturers' concerns about an unpredictable application of the equivalence criteria in the review process by the FDA. .
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> ***Enhancing the 510(k) Database****:* The Working Group also suggests the FDA enhance its database of previously approved products that are eligible for use as predicates for 510(k) submissions. The data base should be easily searchable and include updated summary data, which would then allow applicants to more easily identify appropriate predicate devices.

Expect Delays in Pending and Future 510(k) Device Reviews

While the FDA is determining how to reform its 510(k) review process, the agency is likely to take longer to review 510(k) submissions. Manufacturers should also expect the FDA to more closely scrutinize claims of substantial equivalence, particularly applications for devices that rely on multiple predicate devices.

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Womble Carlyle's FDA Regulatory Practice
With more than 15 years experience in food and drug law, Womble Carlyle's FDA Regulatory Practice is led by Peggy Binzer. Prior to joining Womble Carlyle, Peggy served as Senior FDA Health Counsel to the Senate Budget Committee on Budget and Health, Labor and Pensions, where she was a primary advisor to the Chairman and acted as lead counsel on many pieces of high profile legislation including. Today, she maintains strong relationships with FDA and works closely with Womble Carlyle's Federal and State Government Affairs Practice to deliver results for firm clients. With former senior members from both major political parties, our Federal and State Government Affairs Practice has a proven reputation for successful outcomes in addressing client concerns responsively and cost-effectively.