



August 6, 2008

**FDA Announces Significant Policy Changes Regarding Conflict of Interest Management and Conduct of Advisory Committees**

*Issues Five New Guidance Documents*

On August 4, 2008, the U.S. Food and Drug Administration (FDA) issued major new policies and procedures regarding its management of FDA advisory committees and conflicts of interest. Public comments are due by October 6, 2008.

FDA announced that its intent is to make the process for seeking advice from independent experts as open, public, and transparent as possible in order to ensure the highest public confidence. The centerpiece is a new approach to the review and management of potential financial conflict of interest and eligibility for participating in FDA advisory committees. In addition, FDA has redesigned its website so that advisory committee meeting announcements, briefing documents, and other information related to meetings are posted in a single location and more easily accessible to the public.

FDA provided details about these policy changes regarding advisory committees in four final guidance documents and one draft guidance document on these topics:

- Procedures for determining conflict of interest and eligibility for participation (final guidance)
- Public availability of financial interest information and waivers (final guidance)
- Voting procedures at advisory committee meetings (final guidance)
- Preparation and public availability of information (final guidance)
- Clarification of FDA decision-making on when an advisory committee is convened (draft guidance)

For more information, contact:

**Laura Loeb**  
(202) 661-7836  
lloeb@kslaw.com

**Beverly Lorell, M.D.**  
(202) 383-8937  
blorell@kslaw.com

**Christina M. Markus**  
(202) 626-2926  
cmarkus@kslaw.com

**King & Spalding**  
**Washington, DC**  
1700 Pennsylvania Avenue, NW  
Washington, DC 20006-4706  
Tel: (202) 737-0500  
Fax: (202) 626-3737

[www.kslaw.com](http://www.kslaw.com)



## FDA/Healthcare Practice Group

The major changes, outlined in the final guidance documents, include FDA's new approach for consideration of conflict of interest, the voting strategy that will be used at advisory committee meetings, and commitments for disclosure of information. FDA stated on its website that it believes that its final policies regarding conflict of interest are stricter than the requirements that were enacted in the FDA Amendments Act of 2007.

Further, FDA identified four major differences from its earlier 2000 Waiver Criteria:

- If an individual, spouse, or minor child has potential conflicting financial interests of more than \$50,000 regarding the matter that will be considered at the meeting, the individual will not be allowed to participate in the committee meeting.
- Four scenarios are identified where the FDA does not intend to issue a waiver, even if the potential conflicting financial interest is below \$50,000.
- Before issuing any waiver, FDA will require demonstration that the waiver is necessary to provide essential expertise needed for the committee meeting.
- As required by the FDA Amendments Act of 2007, FDA will progressively limit the number of waivers that are granted.

FDA has also announced several changes regarding the conduct of advisory committee meetings and public disclosure of information. A key change is that committee members will vote simultaneously on the formal questions that FDA asks the committee to answer. FDA identified this as a modification to ensure integrity of the voting process. It is a major change from previous sequential voting in which there was the potential for a voter to be influenced by the vocal voting decision, as well as comments about the vote, of those who preceded them. In addition, FDA committed to a timeline for notifying the sponsor that a meeting will be conducted and publicly posting all briefing materials no later than two full business days before the scheduled day of the meeting.

- The FDA press release and all new policies and procedures can be viewed at, <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01871.html>
- The new FDA Advisory Committee Home Page can be viewed at, <http://www.fda.gov/oc/advisory/>

Stakeholders with an interest in the topic of when FDA should refer a matter to an advisory committee should consider taking advantage of this opportunity to comment on FDA's proposed plan. Although FDA



**FDA/Healthcare Practice Group**

is required by statute to make referrals in some situations, FDA also has discretionary authority to decide whether to refer a matter to an advisory committee in most instances. The draft proposal can be accessed at, <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0417-gdl.pdf>.

Please contact us if you have questions or we can assist you in the preparation of public comments.

*King & Spalding is an international law firm with more than 800 lawyers in Abu Dhabi, Atlanta, Austin, Charlotte, Dubai, Frankfurt, Houston, London, New York, Riyadh (affiliated office), San Francisco, Silicon Valley and Washington, DC. The firm represents half of the Fortune 100 and in a Corporate Counsel survey in September 2007 was among the top firms representing Fortune 250 companies. For additional information, visit [www.kslaw.com](http://www.kslaw.com).*

*This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.*