



June 12, 2009

## FDA's New Transparency Task Force: Mission and Opportunity for Public Comment

On June 3, the U.S. Food and Drug Administration (FDA or Agency) announced the formation of the FDA Transparency Task Force (Task Force) to solicit public comments and to promulgate recommendations for enhancing the transparency of the FDA's internal activities and decision-making.<sup>i</sup> As part of its efforts to seek public input, the FDA has set up the FDA Transparency Blog to "inform the recommendations the Task Force will provide to the Commissioner about ways the agency can become more transparent."<sup>ii</sup>

The Task Force will be chaired by Principal Deputy Commissioner Dr. Joshua M. Sharfstein and include agency-wide representation by the Center directors, Associate Commissioner for Regulatory Affairs, Chief Counsel and Chief Scientist.

- The FDA noticed a public meeting of the Task Force on June 24, 2009, to solicit public input on ways in which FDA can make useful and understandable information about FDA processes and decision-making more readily available to the public in a timely manner.<sup>iii</sup> Advance registration is required.<sup>iv</sup>
- Interested parties are invited to submit electronic comments identified by the docket number [DOCID:fr03jn09-84] to <http://www.regulations.gov>.
- A second public meeting is planned in the fall of 2009.

### Response to Presidential Memoranda

Development of the Task Force, Transparency Blog, and the public meetings, as well as related new guidelines regarding the Freedom of Information Act (FOIA), is a response to two Presidential memoranda issued on January 21, 2009. In the Memorandum for the Heads of Executive Departments and Agencies on Transparency and Open Government,<sup>v</sup> President Obama charged executive departments and agencies to "harness new technologies to put

For more information, contact:

**Edward M. Basile**  
(202) 626-2903  
[ebasile@kslaw.com](mailto:ebasile@kslaw.com)

**Jennifer Bragg**  
(202) 626-5596  
[jbragg@kslaw.com](mailto:jbragg@kslaw.com)

**Daniel Donovan**  
(202) 661-7815  
[ddonovan@kslaw.com](mailto:ddonovan@kslaw.com)

**Beverly H. Lorell, MD**  
(202) 383-8937  
[blorell@kslaw.com](mailto:blorell@kslaw.com)

**King & Spalding**  
**Washington, D.C.**  
1700 Pennsylvania Avenue, NW  
Washington, D.C. 20006  
Phone: (202) 737-0500  
Fax: (202) 626-3737

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



information about their operations and decisions online and readily available to the public.” In addition, the President required the solicitation of public feedback “to identify information of greatest use to the public.” In a separate memorandum on the Freedom of Information Act,<sup>vi</sup> the President instructed executive agencies to adopt a presumption in favor of disclosure with respect to all decisions regarding the FOIA and required the Attorney General to issue guidelines for implementation. The President observed, “[t]he Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears.” On March 19, 2009, the Attorney General issued a memorandum<sup>vii</sup> to heads of executive departments and agencies with new guidelines for disclosures related to the FOIA. In this memorandum, the Attorney General rescinded the prior FOIA guidelines issued on October 12, 2001, and strongly encouraged agencies to make discretionary disclosures. However, the Attorney General also observed that the disclosure obligation under the FOIA is not absolute and stated, “[t]he Act provides exemptions to protect, for example, national security, personal privacy, privileged records, and law enforcement interests.”

### **Mission of the FDA Transparency Task Force**

In response to the Presidential memoranda, the FDA intends to take the following actions:

- Seek public input on issues related to transparency;
- Recommend ways that the agency can better explain its operations, activities, and decision-making, compatible with the agency’s goal of appropriately protecting confidential information;
- Identify information FDA should provide about specific agency operations, activities, processes, and decision-making, including enforcement actions, recalls, and product approvals (emphasis added);
- Identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision-making to the public, taking into consideration health literacy and the needs of special populations;
- Identify appropriate tools and new technologies for informing the public;
- Recommend changes to FDA’s current operations (e.g., internal policies and procedures, standards, information formats, and guidance) to improve the agency’s ability to provide such information to the public in a timely and effective manner;
- Recommend legislative or regulatory changes, if appropriate, to improve FDA’s ability to provide such information to the public; and
- Submit a written report to the Commissioner on the Task Force’s findings and recommendations.



## Implications for Medical Product Manufacturers and Healthcare Providers

The Task Force deliberations and the related public hearings are likely to have an impact on multiple stakeholders engaged with the FDA's processes and decision-making. Two specified focus areas of the Task Force are likely to be of particular interest: product approvals and postmarket safety.

- **Premarket review of marketing applications.** In response to the FDA Amendments Act of 2007 (FDAAA), FDA has already initiated multiple activities to increase transparency related to the review of marketing applications. For example, in compliance with Title VII, FDA has enhanced its review and disclosure of potential conflicts-of-interest of Advisory Committee members as well as the provision of waivers. FDA has also implemented more timely and complete public posting of briefing documents. Nonetheless, recent media, Congressional, and internal FDA staff criticisms of the premarket reviews of certain drugs and devices have focused attention on the processes used by FDA to select and exclude panel members, as well as on the ways that the agency interacts with both industry and its internal staff reviewers in the consideration of the approval of products. Because the premarket review process is highlighted as a specific focus of the Task Force, it is likely to provoke extensive public comment. This may stimulate new recommendations by the Task Force that in turn may result in more extensive and early public disclosure of agency decision-making in its oversight of clinical trial safety and data integrity, the management of internal disagreements regarding product approval, and agency interactions with outside stakeholders during the review process.
- **Postmarket safety surveillance.** FDA decision-making relating to postmarket product safety, including recalls, is also highlighted as a specific target of the Task Force. This focus area is noteworthy because extensive FDA activities are already underway to enhance the detection, disclosure, and mitigation of public health risk related to postmarket safety signals. As an example, in response to new requirements of Title IX of FDAAA regarding postmarket drug safety, FDA has launched the Sentinel initiative to develop multiple public-private partnerships with the aim of creating a massive and searchable system of electronic databases of real world patient data and records. The Sentinel initiative underscores the tension between the Task Force assignment of enhancing transparency versus federal protection of the exceptions to public disclosure, including certain personal privacy information. In June 2009, the General Accounting Office (GAO) issued a report<sup>viii</sup> to Congress that stated that the FDA will be faced with "significant privacy and security challenges as it continues to develop the Sentinel system" due to extensive access to sensitive electronic personal health data. The GAO noted that it is the intent of the Sentinel data acquisition and query process to potentially share some access with other parties as well as results with the public. However, the report observed that processes for oversight and enforcement that balance public disclosure and protection of personal health information are still under development by FDA.

King & Spalding will continue to monitor the activities of the Task Force and the upcoming public hearings. Please contact us with any questions or if we can assist with targeted analysis of the Task Force mission or related activities, including preparation of submissions to the docket.

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*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.*

<sup>i</sup> FDA Transparency Task Force, <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/default.htm> (last visited June 12, 2009).

<sup>ii</sup> The FDA Transparency Blog will run from June through November 2009, <http://fdatransparencyblog.fda.gov/> (last visited June 12, 2009).

<sup>iii</sup> Meeting Notice - Food and Drug Administration Transparency Task Force, 74 Fed. Reg. 26712 (June 3, 2009), *available at* <http://edocket.access.gpo.gov/2009/E9-12902.htm>.

<sup>iv</sup> Electronic registration may be submitted via email to [Transparency.Meeting@fda.hhs.gov](mailto:Transparency.Meeting@fda.hhs.gov) by close of business on June 17, 2009.

<sup>v</sup> Memorandum for the Heads of Executive Departments and Agencies: Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 26, 2009), *available at* [http://www.whitehouse.gov/the\\_press\\_office/Transparency\\_and\\_Open\\_Government/](http://www.whitehouse.gov/the_press_office/Transparency_and_Open_Government/).

<sup>vi</sup> Memorandum for the Heads of Executive Departments and Agencies: Freedom of Information Act, 74 Fed. Reg. 4683 (Jan. 21, 2009), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2009-01-26/pdf/E9-1773.pdf>.

<sup>vii</sup> Office of the Attorney General, Memorandum for the Heads of Executive Departments and Agencies on The Freedom of Information Act (March 19, 2009), <http://www.usdoj.gov/ag/foia-memo-march2009.pdf>.

<sup>viii</sup> U.S. Gov. Accountability Office, Privacy and Security: Food and Drug Administration Faces Challenges in Establishing Protections for Its Postmarket Risk Analysis System, GAO-09-355 (2009).