



November 5, 2009

**FDA Holds Second Transparency Task Force  
Public Meeting**  
*Including Issues Related to Disclosure of Clinical Trial Data*

On November 3, the U.S. Food and Drug Administration's (FDA or Agency) Transparency Task Force held its second public meeting.<sup>1</sup> Principal Deputy Commissioner and Task Force leader Joshua Sharfstein stated that the Task Force's goal is to draft recommendations for FDA Commissioner Margaret Hamburg related to transparency. This process will take place in three phases: 1) development of an interactive FDA website; 2) recommendations related to Agency disclosure of information and bases for decision-making; and 3) recommendations concerning transparency towards industry. Once the Task Force releases its recommendations, there will be a period for public comment.

The meeting was held to seek stakeholder comment on three disclosure-related issues:

- Early communication related to emerging safety signals concerning FDA-regulated products;
- Disclosure of information about product applications that have been abandoned or withdrawn before approval; and
- Communication of agency decisions regarding pending applications.<sup>2</sup>

FDA provided hypothetical scenarios to guide discussion by invited panels of diverse stakeholders and questioning by the Task Force members.<sup>3</sup> The Task Force members did not provide comments of their own nor did they take questions.

**Early Communication Regarding Emerging Safety Issues**

FDA was interested in principles that the Agency should use when deciding if, when and how an early communication should be issued about an emerging safety signal associated with an FDA-regulated product. Two hypothetical cases focused on outbreaks of foodborne

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pathogens. Panelists were asked to discuss whether and how FDA should communicate to the public and/or industry in the face of an uncertain and evolving determination of the source, causal pathogen, and magnitude of the outbreak.

Six panelists,<sup>4</sup> representing the interests of the food and healthcare industries and of consumers, agreed that premature notification can be harmful. Generally, when the food sources involved in the outbreak are still so indeterminate that individuals cannot take any specific protective actions, the Agency should delay communication until the information is actionable. On the other hand, the panel members considered early public communication advisable if an outbreak were large and widespread, even if the food source was indeterminate; however, they had trouble identifying the threshold for communication in this circumstance. The panel emphasized that the Agency should be prepared to deliver multiple public communications as information emerges and clearly identify areas of uncertainty.

Regarding FDA's relationship with the public and other government entities, Task Force members questioned the panel about what the Agency should do if a state health department releases a communication to its citizens, but the Agency does not believe the available information supports the notification. The Task Force also asked questions exploring the tension between the need to consult with industry to expedite investigations and the need to avoid the appearance of collusion.

The discussion was limited to outbreaks in FDA-regulated products; there was no discussion of cooperation with the U.S. Department of Agriculture (USDA) when there is the potential that a USDA-regulated product, such as ground beef, may be implicated in an outbreak. Additionally, although multiple panelists stressed the importance of coordination with the Centers for Disease Control (CDC), there was no CDC discussant present at the meeting.

### **Abandoned or Withdrawn Product Applications**

The second area of focus was disclosure related to product applications that have been withdrawn or abandoned before approval. The hypothetical case posed by FDA involved the withdrawal/abandonment of two New Drug Applications (NDAs). One NDA was withdrawn for business reasons and the other was abandoned due to potential safety concerns. FDA sought opinions on whether to disclose to the public or to subsequent applicants the fact of the withdrawal or abandonment, the reason, or the information related to or contained in the applications.

Three panelists represented the interests of medical device manufacturers, pharmaceutical manufacturers, and consumers. Although FDA was interested in whether and under what circumstances FDA should disclose the mere fact of an NDA's withdrawal or abandonment, the panelists were more concerned with the disclosure of information contained within an NDA. There were strong differences of opinion as to whether any information from clinical trials is generalizable knowledge that should be publicly disclosed, or whether certain data is proprietary. However, the panelists largely agreed that if the withdrawal or abandonment was related to a safety concern, FDA should have more latitude to reveal the withdrawal or abandonment to the public. There was debate whether disclosure related to



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safety concerns should be limited to the circumstances in which the product was on the market for different indications or potentially related products were already on the market. The discussion did not examine the issue of disclosure of potential safety signals related to a withdrawn or abandoned product in the circumstance of informing active clinical investigations of related products that were being conducted under an Investigational New Drug application (IND) or Investigational Device Exemption (IDE).

### **Communicating Agency Decisions About Pending Product Applications**

During the final panel discussion, the Agency sought input on whether it should inform the public when a marketing application is submitted or when FDA decides not to approve or clear an application. In the hypothetical case, results of a clinical trial of a biologic product conducted under an IND have been published, leading to inquiries to the FDA from the public about access to the drug. Under the hypothetical, FDA reviewers do not share the optimistic view of the publications' authors. The Task Force elicited feedback regarding whether FDA should respond to the public inquiries and what, if any, information should be disclosed.

Four panelists represented the interests of the branded and generic pharmaceutical industries and the research and academic communities. They agreed that truly proprietary information should remain confidential and not be disclosed; however, they disagreed on the extent of the definition of proprietary information. The panelists' opinions ranged from the viewpoint that all clinical trial data submitted with an application is confidential and proprietary, to the belief that data should be made public because doing so improves the quality and completeness of data for clinical investigators, ultimately improving the public health. The panelists' views also differed on the issue of FDA disclosure of a deficiency letter issued for a pending application, as well as the situations in which disclosure might be considered. The Task Force's questioning highlighted FDA's concerns about being responsive to public inquiries while trying to protect the confidentiality and property interests of sponsors, as well as the potential that greatly expanded disclosure processes could compete for Agency resources.

The extensive discussion about disclosure of clinical trial data in both the second and third panels must be considered against the background of the Food and Drug Administration Amendments Act of 2007 (FDAAA).<sup>5</sup> FDAAA requires the public disclosure of results, including adverse events, of certain clinical trials conducted for approved or cleared products.<sup>6</sup> Currently, disclosure of clinical trial results is not required by federal law for products that are not approved or cleared. However, the Act requires the Secretary of the Department of Health and Human Services (HHS) to promulgate regulations by September 2010 concerning whether to require disclosure of results of clinical trials for drugs and devices that are not approved or cleared, whether or not approval or clearance was sought by the sponsor.<sup>7</sup>

King & Spalding will continue to monitor the activities of the Task Force. Please contact us with any questions or if we can assist with targeted analysis of the Task Force mission or related activities.

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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.*

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<sup>1</sup> The transcript of the meeting will be available on <http://www.regulations.gov>. Future Task Force activities will be posted on the Task Force's blog, <http://fdatransparencyblog.fda.gov/>, and website, <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/default.htm>.

<sup>2</sup> Meeting Notice - Food and Drug Administration Transparency Task Force, 74 Fed. Reg. 51161 (Oct. 5, 2009), available at <http://edocket.access.gpo.gov/2009/E9-23916.htm>.

<sup>3</sup> November 3 Public Meeting on Transparency: Hypothetical Case Studies, <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/ucm187750.htm> (last visited Nov. 4, 2009).

<sup>4</sup> November 3 Public Meeting on Transparency: Agenda, <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/ucm188633.htm> (last visited Nov. 2, 2009).

<sup>5</sup> Pub. L. 110-85, 121 Stat. 823 (2007), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110).

<sup>6</sup> Pub. L. 111-85, § 801, 121 Stat. 904, 910 (codified at 42 U.S.C. § 282(j)(3)(C)).

<sup>7</sup> Pub. L. 111-85, § 801, 121 Stat. 904, 910 (codified at 42 U.S.C. § 282(j)(3)D))