FDA Transparency Initiative: Opening FDA’s “Black Box”

by Afia K. Asamoah

Over the years, some stakeholders have complained about the Food and Drug Administration’s (FDA’s) lack of transparency. The agency has been referred to as a “black box” that makes important decisions without explaining them.

On June 2, 2009, Commissioner Margaret Hamburg, as one of her first acts at FDA, announced the formation of an internal task force to consider how to make FDA and its processes more transparent to the public. Commissioner Hamburg launched the FDA Transparency Initiative in response to the Obama Administration’s Open Government Initiative. The task force is charged with developing recommendations about how the agency can make useful, understandable information about FDA activities and decisionmaking more readily available to the public in a timely manner, while appropriately protecting confidential information.

I. Open Government Initiative

On President Obama’s first full day in office, he announced the Open Government Initiative, pledging to strengthen our democracy by creating an “unprecedented level of openness in Government.” The Obama Administration issued a memorandum to the heads of executive departments and agencies on transparency and openness in government.1 In the memorandum, the administration pledged to take appropriate action, consistent with law and policy, to disclose information to the public rapidly, and in a form that is easily accessible and user-friendly. Executive departments and agencies were instructed to solicit public input to identify information of greatest use to the public. Further, executive departments and agencies were charged with harnessing new technologies to make information about agency operations and decisions available online and readily available to the public.

President Obama directed the Chief Technology Officer, in coordination with the Director of the Office of Management and Budget (OMB) and the Administrator of General Services, to develop recommendations for an Open Government Directive. Over the summer, the administration created a series of online forums to allow the public to share ideas about how to make government more open, to discuss ideas generated, and to collaborate on drafting specific policy recommendations. The Open Government Directive, was issued by Peter Orszag, the Director of the OMB on December 8, 2009, is to instruct executive departments and agencies to take specific actions to implement a transparent, collaborative, and participatory government.

In another memorandum on the Freedom of Information Act (FOIA) issued the same day, the administration noted that principles embodied in the FOIA express our nation’s commitment to an open government. Executive agencies were instructed to adopt a presumption in favor of disclosure with respect to all decisions involving FOIA.2 The Attorney General was directed to issue new guidelines governing FOIA to the heads of executive departments and agencies.

On March 19, 2009, the Attorney General issued guidelines for implementing FOIA in a memorandum for heads of executive departments and agencies.3 Regarding the presumption of openness, the Attorney General strongly encouraged agencies to make discretionary disclosures, but also noted that FOIA’s disclosure obligation is not absolute and provides exemptions to protect, for example, national security, personal privacy, privileged records, and law enforcement interests.

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In June, the Department of Justice (DOJ) issued its 2009 edition of the Guide to FOIA (Guide). The Guide provides an overview of FOIA’s procedural requirements, exemptions, and litigation considerations. The Guide also includes a section on proactive disclosures of information. This section notes that President Obama’s memorandum on FOIA, echoed by the Attorney General’s FOIA guidelines, “is both a reaffirmation of, and an expansion upon, the long-standing proactive disclosure provision of the FOIA.” The Guide provides that agencies should exercise their discretion to make a broader range of records available beyond the minimum required by the FOIA statute. The Guide acknowledges that there may be circumstances where it is appropriate not to disclose a record, or a part of a record, if it falls within a FOIA exemption. The Guide states, however, whenever appropriate, discretionary release of information should be considered by the agency, which is permitted by a number of the FOIA exemptions.

II. FDA Transparency Task Force

In response to the Presidential memorandum, FDA formed an internal task force of FDA senior employees (referred to as the “Transparency Task Force” or “Task Force”). Commissioner Hamburg asked Joshua Sharfstein, M.D., FDA Principal Deputy Commissioner, to chair the internal task force. The current members of the task force are as follows:

- Acting Director of the Center for Biologics Research and Evaluation (CBER), Karen Miduthun;
- Acting Director of the Centers for Devices and Radiological Health (CDRH), Jeffrey Shuren;
- Director of the Center for Drug Evaluation and Research (CDER), Janet Woodcock;
- Director of the Center for Food Safety and Applied Nutrition (CFSAN), Stephen Sundlof;
- Director of the Center for Veterinary Medicine (CVM), Bernadette Dunham;
- Acting Associate Commissioner of the Office for Regulatory Affairs, Michael Chappell;
- Acting Chief Counsel, Michael Landa; and
- Acting Chief Scientist, Jesse Goodman

The Transparency Task Force is charged with seeking public input on issues related to transparency and developing recommendations for making useful and understandable information about FDA activities and decision making more readily available to the public in a timely manner and in a user-friendly format. These recommendations should be compatible with the agency’s goal of appropriately protecting confidential information. The Transparency Task Force will submit written reports to Commissioner Hamburg, as appropriate, outlining its recommendations.

III. Activities to Date

The Transparency Task Force established a public docket, launched an online blog, and held two public meetings, in June and November respectively, to solicit public input on improving agency transparency.

At the first public meeting, the Task Force invited speakers to present remarks related to how the agency could improve transparency. In addition to general suggestions about ways the agency could inform the public, the Task Force posed six questions about ways in which the agency should provide information to the public about what FDA is doing, the bases for the agency’s decisions, and the processes used to make agency decisions. Over 30 speakers delivered up to five minutes of prepared remarks and fielded questions from the panel of Task Force members (or their designees).

At the second public meeting, the Task Force solicited in-depth and detailed comments on three specific issues related to transparency at the agency: 1) early communication about emerging safety issues concerning FDA-regulated products, 2) disclosure of information about product applications that are abandoned (no work is being done or will be undertaken to have the application approved) or withdrawn by the applicant before approval, and 3) communication of agency decisions about pending product applications. The meeting was conducted as a series of three moderated discussion groups covering these three topics. The specific topic for each discussion was presented in the form of a hypothetical case study. During each moderated discussion, task force members (or their designees) posed questions to participants during the discussion group.

IV. Future Plans

The Transparency Task Force has received hundreds of comments from various stakeholders—regulated industry, consumers, patients, healthcare providers and others. As a result, the Task Force has decided to proceed with its recommendations in three phases. The Task Force has received a number of comments requesting that the agency provide basic information about the agency and how it does its work. The first phase of the Transparency Initiative, which we are calling FDA 101, will be a web-based curriculum that will provide information about commonly misunderstood agency activities and frequently asked questions about FDA. The curriculum will be presented in an easily accessible and user-friendly format.
and is intended for a consumer audience. Phase I of the Transparency Initiative is expected to launch in January 2010.

The second phase of the Transparency Initiative relates to FDA’s disclosure of information as well as FDA’s explanations to the public about the bases for agency decisions. This phase will address the comments the Task Force received about how to make information about agency activities and decision-making more transparent, useful, and understandable to the public.

During Phase II of the Transparency Initiative, the Task Force will assess the information and documents the agency has in its possession, and make recommendations regarding what information the agency should make accessible to the public and how that information should be communicated to the public in a useful and user-friendly manner. The three topics discussed during the public meeting are illustrative of some of the topics that will be addressed during this phase. The Transparency Task Force will consider various factors and balance different interests in order to develop recommendations about how the agency can better explain its activities and the basis for its decisions, while appropriately protecting confidential information.

The third phase of the Transparency Initiative will address comments the Task Force received about FDA’s transparency to regulated industry. For example, commenters requested more information from the agency regarding the status of an application under review by the agency. The Task Force will seek further input about these concerns before issuing recommendations.

The Transparency Task Force is meeting regularly to work on all aspects of the Transparency Initiative. Following the launch of the FDA 101 curriculum, the Task Force will release the recommendations related to Phase II of the Initiative, followed by the recommendations for Phase III of the Initiative—transparency to regulated industry. The Transparency Task Force plans to issue the recommendations developed during the second and third phase of the initiative for public comment before finalizing the recommendations. Some of the recommendations may require regulatory or statutory changes for implementation.

V. Conclusion

Transparency promotes accountability, enhances the work of the agency, and increases its credibility with the public. Opening the proverbial “black box” will help FDA more effectively implement its mission to promote and protect the public health.

The Task Force recognizes that the agency cannot and should not disclose all types of information. But the agency can do a better job of providing useful information to the public in a timely manner. The agency can and should communicate with the public in a way that provides more clarity about agency activities and processes.

Additional information about Transparency Initiative, including meeting materials from the public meetings, can be found at the FDA website at www.fda.gov/transparency. ▲

5 Id. at 9-10.
6 Id. at 10.
7 Id. at 11.
10 See 74 Fed. Reg. at 26,713.
11 The meeting was webcast and is available on the Transparency Task Force webpage of the FDA website, www.fda.gov/transparency. Meeting materials can be found here also.
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