

Phase II of the FDA'S Transparency Initiative

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The Transparency Task Force Releases Draft Recommendations on FDA's Public Disclosure Policies

Transparency Initiative

In June 2009, Dr. Margaret Hamburg, the newly appointed Commissioner of Food and Drugs, announced the Food and Drug Administration ("FDA" or "Agency") Transparency Initiative and created the FDA Transparency Task Force to carry out the Initiative.¹ The goals of the initiative were in keeping with President Obama's January 2009 memorandum calling for "creating an unprecedented level of openness in Government" to "promote accountability and provide information for citizens about what their Government is doing."²

On Wednesday, the FDA took another step forward in the Transparency Initiative with the highly publicized release of twenty-one suggested recommendations on the public disclosure policies of the Agency. These draft proposals are open for public comment for 60 days, and are contained in a report titled "FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration" (referred to as the "Report" in this article).³ In addition to the release of the Report on the FDA's website, the New England Journal of Medicine carried an article announcing the Report by Principal Deputy Commissioner Joshua Sharfstein, M.D., Chair of the Transparency Task Force, and Afia Asamoah, J.D., Director of FDA's Transparency Initiative and senior advisor in the Commissioner's Office.⁴ Dr. Sharfstein and Ms. Asamoah also held a conference call with interested stakeholders and the media to explain the Report and answer questions.

According to the Report and comments from Ms. Asamoah during the conference call, the Report marks the near-conclusion of Phase II of the Transparency Initiative.

- Phase I occurred in January 2010 when FDA announced its new FDA Basics website intended to provide the public with basic information about FDA and how the Agency operates.⁵
- Phase II relates to FDA's policies on public disclosure. Phase II began with the Transparency Task Force soliciting public input through a variety of mechanisms, including the Transparency Blog, two public meetings, multiple listening sessions, and an open public docket. Based on the more than 1,500 comments received through these channels, the Task Force drafted the public disclosure recommendations contained in Wednesday's Report.⁶
- Phase III, the final phase of the Transparency Initiative, will focus on transparency to regulated industry. Dr. Sharfstein indicated that draft recommendations on industry transparency will be forthcoming from the FDA this summer.

Draft Public Disclosure Recommendations

The draft public disclosure recommendations fall into seven categories: (1) adverse event reports; (2) docket management practices; (3) enforcement priorities and actions; (4) import procedures; (5) inspections; (6) product applications; (7) recalls; and (8) warning and untitled letters.

Ten of the twenty-one draft recommendations are related to product applications. For example, in the Report, FDA recommends that:

"(10) FDA should disclose the fact that an NDA, NADA, ANDA, ANADA, BLA, PMA, or 510(k) application or supplement was submitted (or resubmitted) to the Agency at the time the application is received by FDA. The disclosure should include the name of the application sponsor, the date the application was received, the proposed indications or intended use of the product, and the proposed proper and/or

trade name of the product, if available.”

“(13) FDA should disclose the fact that the Agency has issued a refuse-to-file or complete response letter in response to an original NDA, BLA, or an efficacy supplement for an NDA or BLA at the time the refuse-to-file or complete response letter is issued, and should, at the same time, disclose the refuse-to-file or complete response letter, which contains the reasons for issuing the letter.”

These recommendations are likely to be the most controversial, and were discussed at length at the November 2009 public meeting on transparency. To assuage industry concerns, Dr. Sharfstein made clear on the stakeholder conference call that “trade secrets” should remain confidential. The Report reiterates the importance of trade secrets, stating that “[t]he Task Force believes that trade secrets have limited value for public disclosure, and that the value for public disclosure of other types of data, such as clinical trial results and adverse event reports, is significantly greater....As a result, the Task Force believes that trade secrets should remain confidential.” According to the Report and Dr. Sharfstein, the agency will redact trade secret information from documents before public disclosure.

However, the assurance that trade secrets will continue to be protected may not fully address industry’s concerns with respect to product-related disclosures. Currently, the Agency protects trade secrets, but also other confidential commercial and financial information as described in 21 C.F.R. § 20.61(b).⁷ The current draft recommendations could result in public disclosure of some confidential commercial and financial information, though the FDA does acknowledge that statutory and regulatory changes (with attendant notice-and-comment procedures) would likely be necessary to allow this.

In addition to the twenty-one recommendations on public disclosure open for public comment, the report includes a section on “Other Areas of Public Comment.” This section is devoted to interest areas that received significant public attention in the form of public comments to the docket or the Transparency blog, but which FDA chose not to address through formal recommendations. These include advisory committee meetings, the citizen petition process, communicating about safety concerns, the Freedom of Information Act, food facility inspection results, media policy, and stakeholder meetings. For each of these sections, the Report summarizes the comments received, and indicates why FDA did not draft a formal recommendation. For example, under the citizen petitions section, in response to comments requesting that FDA disclose the materials reviewed by FDA to respond to a particular petition to more fully “explain to the public why certain citizen petitions were denied or granted,” FDA concluded that its “current practice sufficiently explains to the public the reason for its decision on any particular citizen petition.”

Next Steps

The FDA is actively seeking public comments on the draft public disclosure policies for 60 days (July 20, 2010). Comments can be submitted to Docket No. FDA-2009-N-0247 [here](#), or through links on the FDA Transparency [website](#).

Dr. Sharfstein indicated on Wednesday that the agency is specifically looking for comments on the substantive nature of the proposals, as well as input on how the Agency should prioritize implementing the proposals. Based on public input, the Task Force will then recommend specific proposals to the Commissioner for consideration. Sharfstein noted that the “Task Force did not, at this stage of the review, consider the feasibility of implementing the proposals” and that “some of the draft proposals may require extensive resources to implement, and some may require changes to regulations and possibly even legislation.” Consequently, based on public input and further internal consideration, the Task Force may ultimately recommend some, but not all, of the draft proposals to the Commissioner for implementation.

FDA is also looking for public comments on FDA-TRACK, a new agency-wide program performance management system that monitors over 100 FDA program offices through key performance measures. FDA-TRACK went live several weeks ago as part of the Transparency Initiative.⁸

Finally, the agency continues to solicit public input regarding transparency to regulated industry to inform the draft industry transparency recommendations that will be released this summer.

¹FDA Transparency Initiative [website](#).

²Memorandum from President Barack Obama to the Heads of Executive Departments and Agencies Regarding Transparency and Open Government (January 2009).

³FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration (May 19, 2010).

4Transparency at the Food and Drug Administration, J Sharfstein, A Asamoah, NEJM Online (May 19, 2010).

5FDA Basics.

6Links to the Transparency blog, the transcripts of the public meetings, and the public docket can be found on the Transparency Initiative [website](#).

7See also, 21 C.F.R. § 20.85 and CDER MAPP 4112.2, available [here](#) (discussing inter- and intra-agency sharing of confidential information).

8FDA Track [website](#).

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