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FDA's Transparency Proposals Would Disclose Inspectional Results and Other Significant Postmarket Enforcement Information

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As part of President Obama's Open Government Initiative, the U.S. Food and Drug Administration (FDA or the Agency) launched its own Transparency Initiative in June 2009. FDA commissioner Dr. Margaret Hamburg created and charged an internal task force to develop recommendations that would help explain how the FDA operates and makes key decisions. On May 19, 2010, this Transparency Task Force released a report containing 21 draft proposals that would significantly expand the disclosure of information by the FDA. The report states that "[the] proposals reflect a careful balancing of the importance of transparency with the importance of protecting trade secrets and confidentiality." Dr. Joshua Sharfstein, principal deputy commissioner of FDA and chair of the Transparency Task Force, has requested input "on whether we have struck the right balance between disclosure and confidentiality in support of public health."

FDA's draft proposals cover a broad array of the Agency's actions, including both premarket decision-making and postmarket enforcement and related activities. This Law Flash focuses on proposals that would disclose information relating to FDA and DOJ enforcement priorities and actions, import evaluations, inspectional results, recalls, and Warning Letters and untitled letters. Morgan Lewis is concurrently issuing a companion LawFlash that discusses FDA's proposals addressing premarket transparency proposals and issues.

Proposals Relating to Enforcement and Other Postmarket Activities: Is There an Appropriate Balance Between Disclosure and Confidentiality?

A primary goal of the Transparency Initiative, as described by FDA officials, is to better explain the FDA's actions. The Transparency Task Force took a broad approach to achieving this objective; its report describes three phases: FDA Basics, which provides information for the public on FDA and how it works; FDA's Public Disclosure Policy; and Transparency to Regulated Industry. This FDA report containing 21 proposals addressed only the second phase of the transparency initiative. Thus, these proposals are not intended to make recommendations for greater transparency to regulated industry, but rather, to provide for greater disclosure of information to the public.

In developing its proposals, the FDA adopted its own definition of "trade secret" and used this definition in deciding which information could be disclosed. The Task Force believes that trade secrets should remain confidential, and should be redacted before documents are disclosed. The Task Force also

considered information that is currently withheld from disclosure on the basis that it is "confidential commercial information." Significantly, the Task Force made a determination that some information previously treated as "confidential commercial information" need not be protected from disclosure, notwithstanding protection of such information under the Freedom of Information Act (FOIA) and existing FDA regulations. The report states only that "[c]hanges to statutes or regulations may be needed to implement some of the proposals." As the legality of FDA's release of trade secrets and confidential information could potentially violate the FOIA statute and/or the U.S. criminal code relating to protection of trade secrets (18 U.S.C. § 1839), it is likely these recommendations will be closely vetted and potentially legally challenged if they move forward.

Specific Proposals Addressing Enforcement Actions and Postmarket Information

Provided below is a brief summary of the specific proposals addressing postmarket enforcement information and other activities:

1. **Adverse Event Reports:** The FDA is proposing to make adverse event reports more accessible to the public, and to make available the same level of information across all categories of FDA-regulated products. Currently, for example, Medical Device Reports, which contain adverse event information on devices, are available on FDA's website, but comparable information for drugs is not available.

2. **Enforcement Priorities and Actions:** The FDA is proposing to disclose in its weekly Enforcement Report when the U.S. Department of Justice files a case seeking enforcement action on FDA's behalf in a court of law and the final determination of that case, if known. Additionally, the FDA is proposing to post on its website Agency work plans that are older than five years. FDA acknowledges that disclosure of such work plans is unlikely to be of any assistance to regulated industry, given the age of the documentation, but observed that it may inform the public about how enforcement is conducted.

3. **Imports:** The FDA is proposing to disclose the outcome of its "filer evaluation" for importers or third parties working on behalf of importers. Importers of foods, drugs, cosmetics, tobacco products, devices, and radiation-emitting products are required to file information about the imported product with the U.S. Customs and Border Protection and the FDA. FDA conducts evaluations of the filers who submit information electronically to determine if they are submitting accurate information about the products to be imported. This proposal is intended to give the public additional information regarding the steps taken by the FDA to protect the supply of food and medical products. The information disclosed, however, would include information about all product detentions, regardless of whether the product is subsequently determined to be compliant and released.

4. **Inspections:** The FDA is proposing to disclose the name and address of every entity inspected by the Agency, the date(s) of inspection, type(s) of FDA-regulated product involved, and the final inspectional classification (i.e., Official Action Indicated, Voluntary Action Indicated, or No Action Indicated). This would include inspections of all facilities that manufacture an FDA-regulated product that is currently marketed, as well as inspections of clinical trial investigators and Institutional Review Boards. This proposal, if implemented, could result in such information being used by purchasers to compare alternative sources of FDA-regulated products. Because of the variability of approach among inspections and

inspectors, this information could trigger misleading comparisons, which may affect manufacturers' operations. This type of information also likely will be used in product liability lawsuits.

FDA is also proposing to generate and share with the public general information about the most common inspectional observations of objectionable conditions or practices identified during FDA inspections.

5. **Recalls:** FDA intends to seek authority to require companies to submit certain information to the Agency when they initiate a voluntary recall (or action to recover or correct a product in the chain of distribution), which the FDA could then disseminate to the public. FDA proposes to disclose this information as soon as practicable after receiving it from the recalling firm. The Agency currently does not have statutory authority to require manufacturers of FDA-regulated products to submit such information, so this would likely be the subject of future legislation and/or rulemaking.

   The proposal also would encourage FDA to support industry efforts to communicate information to the public about food or other products not subject to mandatory recall or correction/removal reporting, if FDA determines that disclosure of such information would be in the interest of the public health.

   Finally, the proposal would facilitate disclosure of the termination of a recall. FDA states that this information is important to communicate to the public so that they know when the risk identified for a particular product has passed.

6. **Warning Letters/Untitled Letters:** FDA is proposing to post all untitled letters on its website. Currently, all Warning Letters are posted, but only the Center for Biologics Evaluation and Research (CBER) and the Division of Drug Marketing, Advertising, and Communications (DDMAC) post untitled letters. Many untitled letters address promotional issues, and may not address problems that pose a direct risk to the public health.

The FDA is seeking comments on all of the above proposals, as well as on how to prioritize the proposals before July 20, 2010. For additional information, or assistance in preparation of comments, please contact any of the following attorneys in our FDA and Healthcare Practice:

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