CONSUMER GROUPS SUE FDA FOR (LACK OF) NANOTECHNOLOGY RULEMAKING

As further evidence that manufacturers of products containing nanomaterials are likely to face increasing regulation in the future, several consumer advocacy and environmental groups have filed a lawsuit in an attempt to force the FDA to make rules regulating the technology. On December 21, 2011 the lawsuit was filed in the United States District Court for the Northern District of California by the International Center for Technology Assessment; Friends of the Earth; The Action Group on Erosion, Technology and Concentration; The Center for Environmental Health; Food and Water Watch; and The Institute for Agriculture and Trade Policy (collectively, the "Groups"). All of these groups, with the exception of Food and Water Watch and The Institute for Agriculture and Trade Policy, had previously joined in a petition to the FDA for rulemaking, submitted in May 2006.

Basis for Suit. The Groups claim that the FDA has failed to respond within a reasonable time to their 2006 Petition requesting that the FDA regulate nanotechnology products that fall under its jurisdiction, specifically sunscreen drug products composed of manufactured nanomaterials. The Groups rely upon the Administrative Procedure Act (APA), which requires agencies to "give an interested person the right to petition for the issuance, amendment, or repeal of a rule" and to conclude matters presented to them, including petitions, "within a reasonable time." *See* 5 U.S.C. §§ 553 & 555(e). The Groups have asked the Court to declare that the FDA has violated the APA by failing to respond to the 2006 Petition and to order the FDA to respond to the 2006 Petition as soon as reasonably practicable.

FDA's Action in Response to Petition. While the FDA has not made a decision on the 2006 Petition, it has not been unresponsive. In August 2006, the FDA formed a Nanotechnology Task Force. The mission of this task force is to determine "regulatory approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials." Nanotechnology Task Force The FDA held a Nanotechnology Public Meeting on October 10, 2006 and again on September 8, 2008.

In the intervening time between the meetings, the FDA released a Nanotechnology Task Force Report in 2007 Nanotechnology Task Force Report. As the Groups note in their lawsuit, the 2007 Task Force Report states that it takes the 2006 Petition into account but that the FDA has not reached a decision on the petition because "it raises complex issues requiring extensive review and analysis by agency officials, and in relation to which the agency is seeking public input." Task Force Report, fn 20. The Report went on to state that it reflects only the views of the Task Force and "does not constitute an agency answer to the petition in whole or in part."

Significance. Should the Court agree with the Groups' contention that the FDA has unreasonably delayed making a decision on the 2006 Petition and grant the requested relief, the FDA may choose to make rules regulating nanotechnology, as the groups

requested in their 2006 Petition. The FDA could also comply with the Court's order by simply denying the Petition.

The FDA's denial of the Petition would not have an immediate impact on the regulation of nanotechnology. But the very filing of the Petition and the choice of the Groups to seek enforcement through the courts is a harbinger of things to come. As time goes on, the FDA will face more and more pressure to make rules regulating nanotechnology. Companies who develop and market products with this technology should remain vigilant and involved in the process.

If you have any questions about the significance of this lawsuit or other issues concerning nanotechnology, please contact:

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