UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, et al.,

Plaintiffs,

v.

MARGARET A. HAMBURG, M.D.,

Defendant.
_____/

No. C 12-4529 PJH

ORDER GRANTING INJUNCTIVE RELIEF

This is an action brought by plaintiffs Center for Food Safety and Center for Environmental Health against Margaret Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration ("FDA") pursuant to the Administrative Procedures Act, 5 U.S.C. § 551, et seq. Plaintiffs seek declaratory and injunctive relief regarding the failure of the FDA to promulgate final regulations by mandatory deadlines contained in the FDA Food Safety and Modernization Act of 2010 ("FSMA"), Pub. L. No. 111-353, 124 Stat. 3885 (2011), codified in scattered sections of 21 U.S.C. § 301, et seq., as amended.

On April 22, 2013, the court issued an order granting plaintiffs' motion for summary judgment and denying defendant's motion for summary judgment. The court granted plaintiffs' request for a judicial declaration that the FDA had violated the FMSA by failing to promulgate the required regulations in accordance with the deadlines mandated by Congress. The court also found that plaintiffs were entitled to injunctive relief, but left the scope of such relief to be determined following further submissions by the parties, which the court suggested would preferably be in the form of a joint statement setting forth agreed proposed deadlines. The parties, however, were unable to reach agreement, and thus have submitted competing proposals.

Plaintiffs have submitted a schedule of proposed "deadlines" for publication of the proposed rules in the Federal Register, for the close of the comment period, and for the final rules to be submitted to the Federal Register. Plaintiff's schedule sets the close of the comment period on December 31, 2013 (with the exception of a deadline of November 30, 2013 for one set of rules), and sets May 1, 2014 as the latest date for submission of the final rules (with the possible exception of any rule that might trigger the need for an Environmental Impact Statement to comply with the requirements of the National Environmental Protection Act). Defendant has submitted a proposal for "target timeframes," with "goals" for publication of the proposed rules to the Federal Register in Summer 2013, Fall 2013, and Second Quarter 2014, and for submission of final rules at periods ranging from 15 to 21 months after the close of the respective comment periods.

As the court found in the April 22, 2013 order, by setting deadlines for the promulgation of the implementing regulations, Congress indicated that the rule-making process should be closed-ended, rather than open-ended. Thus, the court finds defendant's "target timeframes" to be an inadequate response to the request that the parties submit a proposal regarding deadlines that can form the basis of an injunction.

On the other hand, notwithstanding the urgent need for the FDA to promulgate the subject food safety regulations, the court finds the schedule and dates proposed by plaintiffs to be overly restrictive in light of the FDA's showing of the complexity of the task, which involves making major modifications to procedures for food inspection and food handling, and its showing of diligence in attempting to discharge its statutory duty to promulgate regulations. In addition, the court is not inclined to order curtailment of the public comment period, given the varying interests of the public, the health and medical establishment, and farming, business, and industry groups in the content and scope of the FSMA regulations.

Nor is the court inclined to order the elimination of any required review by the Office of Management and Budget ("OMB"), as requested by plaintiffs. While neither the court nor the FDA can control the OMB review process, the OMB plainly conducts an essential

analysis, and absent some indication that the OMB is using its authority to unduly delay promulgation of the regulations in this case, the court will not enjoin the FDA from OMB review or other associated requirements of complying with Executive Order 12866.

Finally, the court does not agree with plaintiffs' proposal that defendant be required to submit quarterly progress reports updating the court on the progress of the FSMA rulemaking. The court is persuaded that the FDA has limited resources, and does not see the utility of imposing another task on the FDA in connection with the promulgation of these regulations.

Accordingly, in view of the ruling in the April 22, 2013 order, and having attempted to balance the factors listed above, the court issues the following order.

ORDER

In completing the FDA's required rulemaking under the FSMA, with regard to proposed regulations that have not yet been published in the Federal Register, defendant is ORDERED to publish all proposed regulations by November 30, 2013. In each instance, the close of the comment period shall be no later than March 31, 2014. All final regulations shall be published in the Federal Register no later than June 30, 2015. Apart from these deadlines, defendant shall have the discretion to prioritize other matters relating to the rulemaking process.

The court retains jurisdiction to enforce the terms of this order, and to make such further orders as may be necessary or appropriate.

IT IS SO ORDERED.

Dated: June 21, 2013

PHYLLIS J. HAMILTON
United States District Judge