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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, Plaintiffs, v. MARGARET HAMBURG, M.D., *et al.*, Defendants.	No. 12-cv-04529 PJH

THIRD DECLARATION OF MICHAEL R. TAYLOR

Michael R. Taylor declares, pursuant to 28 U.S.C. § 1746, under penalty of perjury, that the following is true and correct:

1. I am the Deputy Commissioner for Foods and Veterinary Medicine, United States Food and Drug Administration (FDA). In that role, I provide oversight and leadership to FDA in, among other things, the development of regulations, policies, procedures, and guidance that are related to foods and veterinary medicine, including food safety and nutrition. In these capacities, I am fully familiar with the instant matter and the facts stated herein.

2. My office, the Office of Foods and Veterinary Medicine, was established to lead a functionally unified Foods and Veterinary Medicine Program to enhance FDA's ability to meet today's challenges and opportunities in food and feed safety, nutrition, and other critical areas. The Office of Foods and Veterinary Medicine is responsible, on behalf of the Commissioner, for providing all elements of FDA's Foods and Veterinary Medicine Program leadership, guidance, and support to achieve the agency's public health goals. The Office is also the focal point for planning and coordinating the implementation of the new food safety authorities contained in the FDA Food Safety Modernization Act of 2011 (FSMA), which amended the Federal Food, Drug, and Cosmetic Act (FDCA).

3. On November 30, 2012, I signed a declaration for this lawsuit regarding certain steps that FDA had taken to implement FSMA. On February 12, 2013, I signed a second declaration, which described some additional significant steps that the agency had taken since the date of my first declaration. This declaration addresses the implications of certain deadlines imposed by the Court's Order Granting Injunctive Relief entered on June 21, 2013.

4. As a general matter, the deadlines imposed by the Court have the potential to interfere with FDA's ability to regulate efficiently and effectively. The agency's submissions to the Court have explained in detail the enormity and the complexity of the rulemaking process and the various factors that may extend the time required to complete a rulemaking. In addition, while the agency is working on developing the seven regulations that are the subject of this complaint, it also has other FSMA deliverables to move forward, as well as other work that the agency undertakes to respond to outbreaks of food-borne illness, develop non-FSMA-related rulemakings and guidance documents, and oversee the safety of imported foods as they enter the country. For example, nutrition labeling enables consumers to maintain healthy dietary practices,

and Congress recently directed FDA to promulgate rules to expand nutrition labeling requirements to food sold in restaurants and similar retail food establishments and from vending machines. Over the next two years, FDA intends to publish the following proposed and final nutrition labeling rules: proposed rules "Food Labeling; Revision of the Nutrition and Supplement Facts Labels," "Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed," and the final rules "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," and "Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines." These rulemakings will draw on many of the same specialized FDA resources as the FSMA rules, particularly over the next two years. Congress also directed the agency to implement, during this same time period, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L.112-144), which, among other things, was intended enhance the safety of the drug supply chain. Under Title VII of FDASIA, Congress directed FDA to issue several final regulations by various due dates over the next two years. Implementing FDASIA requires substantial agency resources including resources and FDA staff from offices already involved in implementing FSMA. Further, the agency cannot predict what developments may occur over the coming years that may demand a reallocation of resources. The deadlines imposed by the Court will interfere with the agency's flexibility to establish priorities and allocate resources as it determines is most appropriate in fulfillment of its many responsibilities and with the goal of best protecting the public health.

5. With respect to the November 30, 2013 deadline for publishing the remaining proposed rules that are the subject of the complaint, the agency is striving to meet those deadlines to the greatest extent possible. However, as described in my November 30, 2012

declaration, because these rulemakings draw upon the same specialized agency resources, the agency could not staff the simultaneous development of all seven rules. Consequently, FDA prioritized the development of the regulations that are the subject of this complaint into two "waves." FDA selected certain rulemakings for the "first wave" because they are foundational for other rules and offer the most public health benefits. The "second wave" rules are not as far along in their development. Meeting the November 30, 2013 proposed rule deadline for two of these "second wave" rulemakings is particularly problematic, as described below.

Intentional Contamination

6. In section 106(a) of FSMA, Congress added a new section to the FDCA entitled "Protection Against Intentional Adulteration," which directed FDA, in coordination with the Department of Homeland Security and in consultation with the U.S. Department of Agriculture, to issue new regulations to protect against intentional contamination of food. 21 U.S.C. § 350i(b). These regulations are required to establish science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. The regulations are to include those foods for which the Secretary has identified clear vulnerabilities (including short shelf life or susceptibility to intentional contamination at critical control points) and that are in bulk or batch form, prior to being packaged for the consumer. In addition, section 103 of FSMA specifies that hazards that are subject to preventive controls include hazards that may be intentionally introduced. Further, section 105 of FSMA requires that the regulations to establish science-based minimum standards for the safe production and harvesting of certain fruits and vegetables consider hazards that may be intentionally introduced. FDA has tentatively decided to implement those parts of sections 103 and 105 of FSMA regarding intentional contamination in the same rulemaking that implements section 106. Although FDA has preliminarily

determined that the public will be best served if the agency considers these different aspects of prevention together in a single rule, the multi-faceted nature of this rulemaking also adds to its already substantial complexity.

7. This rulemaking will involve the development of novel requirements without clear regulatory precedent or models because the prevention of intentional adulteration is an area in which FDA has not previously regulated. The agency will need to develop criteria for when preventive controls are appropriate (i.e., the level of vulnerability of the points in the food supply chain that warrants action) and identify acceptable mitigation measures, which could encompass a range of activities. In order to do this effectively, FDA will need additional information to enable it to ascertain, among other things, "the best available understanding of uncertainties, risks, costs, and benefits." 21 U.S.C. § 420(a)(1)(B). To date, preventive controls against intentional adulteration have been voluntary, so the existing risk/benefit analyses in this area have not previously been publicly evaluated or weighed, and the task will be challenging and time-consuming. In addition, there are two types of intentional adulteration: 1) those for which the intent is to cause public health harm and/or economic disruption for the purpose of damaging the economic well-being of a company or a country (e.g., terrorism, acts of a disgruntled employee); and 2) those for which the sole intent is to incur economic gain to the benefit of the seller of the food (e.g., economically motivated adulteration). The agency must consider both types of intentional adulteration in this rulemaking, which further complicates the analysis.

8. FDA has engaged in considerable internal deliberation regarding possible mechanisms for accomplishing the statute's goals and requirements, and it determined through that process that the agency would benefit from a greater variety of information and ideas before formulating a proposed rule. The agency working group has therefore developed an initial draft

Advanced Notice of Proposed Rulemaking (ANPRM), which is undergoing review within FDA at this time.

9. To aid the agency in developing an appropriate proposed rule, FDA will be asking for information in the ANPRM on how industry currently assesses vulnerability, measures industry currently employs against intentional adulteration, and whether those measures are preventive for both intentional and unintentional adulteration. In addition to developing an accurate cost/benefit analysis, FDA will be asking about the costs and feasibility of available measures. This information is not readily available in the public arena, in part because much of it is sensitive, proprietary and confidential. Although FDA cannot predict how forthcoming the industry may be with respect to this type of information, FDA believes it is necessary to engage the stakeholder community to gather as much information and as many ideas as possible before promulgating a regulation on this subject.

10. FDA intended to issue the ANPRM, collect comments, and thoroughly review and consider the comments before developing a proposed rule. That would mean that the proposed rule would likely issue in the second half of 2015. Following that schedule, the final rule would likely issue in the second half of 2017. The Court's injunction therefore moves up the deadlines for issuing the proposed and final rules on intentional contamination by approximately two years for each.

11. If the agency were required to comply with the November 30, 2013 deadline for issuing a proposed rule on intentional contamination, it would need to immediately develop a proposed rule without the input of information and ideas that the agency has determined it needs. Short-circuiting this process could lead to an inadequately considered proposal that would hinder rather than expedite the promulgation of an effective and well-considered final rule. Given the

agency's current lack of information in many of these areas and the short timeframe available for developing a proposal, there is a significant risk that FDA would issue a proposed rule that does not strike the appropriate balance between public health risk and proposed requirements, that fails to consider currently employed mitigation strategies, or that has a cost/benefit analysis based on insufficient information. Any of these outcomes could lead FDA to determine that a re-proposal of some or all of the rule would be the most appropriate next step, which would lengthen the process and be an inefficient use of FDA's limited rulemaking resources. Shortcomings of this type could also leave the final rule vulnerable to legal challenge.

Sanitary Transport

12. In the 2005 Sanitary Food Transportation Act (SFTA), Congress directed FDA to establish sanitary transportation practices for all persons engaged in the transport of food. 21 U.S.C. § 350e(b) and note. In section 111 of FSMA, Congress added a timeline for issuance of the regulations.

13. As described in my earlier declaration, to aid in the development of the rulemaking required by the SFTA before the enactment of FSMA, FDA commissioned in 2008 a study by the Eastern Research Group (ERG) to characterize current baseline practices in the food transportation industry and to identify areas where food is at risk for adulteration. The study report issued in 2009. It includes a comprehensive literature review pertaining to food handling practices in the food transportation industry. The report also presents the findings from an expert opinion elicitation study which ERG conducted to identify the main problems that pose microbiological, chemical, and/or physical safety hazards to food during transportation and storage, and to determine the preventive controls needed to address each of the problems identified.

14. In 2010, FDA published an ANPRM on the Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713 (April 30, 2010), to request data and information on the food transportation industry and its practices and on the contamination of transported foods and any associated outbreaks. In requesting public comment, the agency cited problem areas identified in the ERG report.

15. When FSMA was enacted, FDA was in the process of evaluating the data and information received in response to the ANPRM in order to move forward with rulemaking. The agency working group has completed a first draft of the proposed rule, but the agency anticipates that the government will be unable to meet a November 30, 2013 publication date for the proposal because of the important steps in the decision-making and review processes that still need to be completed.

16. First, to move the proposed rule forward to publication, FDA must reach final decisions at the senior leadership level on complex policy and legal issues with respect to the approach taken in and the scope of the proposal (e.g., what entities and activities should be covered).

17. Second, FDA must complete a draft "regulatory impact analysis" -- the economic analysis that is required by executive order to accompany significant regulatory actions. This detailed document must be revised and reviewed repeatedly throughout the process of rule development, but final consideration and revisions can be performed only after the content of the proposed rule is set. Moreover, because of certain limitations in the available data, we need to develop innovative approaches to complete the analysis.

18. Third, the proposed rule and draft economic impact analysis must undergo Department of Health and Human Services (HHS) and interagency review. After FDA

completes its draft, the proposal will be submitted first to HHS and then to the Office of Management and Budget (OMB). Pursuant to Executive Order (EO) 12866, OMB, through Office of Information and Regulatory Affairs (OIRA), reviews significant regulatory actions to ensure consistency with law, policy, and actions by other agencies. EO 12866 provides for a minimum of 90 days for OIRA's review.

19. After the enactment of FSMA, FDA had placed this proposed rule in the "second wave" category because the rules selected as part of the "first wave" will likely have a broader public health impact, and because of overlapping and conflicting resource demands. In response to the Court's order of June 21, 2013 directing FDA to publish this proposal by November 30, 2013, the agency has re-prioritized its work on this proposal. However, FDA is not confident that the proposal can be published by November 30, 2013 given the number of steps yet to be completed and the relative shortness of time. At this time, the agency projects that it will be able to publish this proposed rule by January 31, 2014. Compliance with the November 30, 2013 deadline would likely lead to a curtailment of the policy, legal, and economic work remaining to be done as well as of the external review process, all to the potential detriment to the substance of the proposal.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Dated: Silver Spring, Maryland
July 19, 2013

Michael R. Taylor
Deputy Commissioner for Foods and Veterinary Medicine
United States Food and Drug Administration