



August 24, 2016

Stephen Ostroff, M.D.  
Deputy Commissioner for Foods  
and Veterinary Medicine  
FDA Office of Foods and Veterinary Medicine  
10903 New Hampshire Ave  
White Oak Building 1  
Silver Spring, MD 20993

Dear Dr. Ostroff,

At the end of this month the Food and Drug Administration (FDA) will start phasing in the first of seven major rules it has issued under the Food Safety Modernization Act (FSMA). This marks an important milestone in transforming the food safety system so that it better protects consumers from foodborne illnesses. The Center for Science in the Public Interest (CSPI) applauds the agency's work and looks forward to successful implementation of all seven rules. Nevertheless, we are concerned by the agency's lack of progress on other FSMA provisions that directly affect the health and safety of consumers. An essential one of these is the system for requiring grocery stores to post recall notices in locations where consumers are likely to see them.

The attached CSPI report, "Building a Food Recall System," examines the current system for alerting consumers to a recall and finds that it is woefully inadequate. FDA requires a recalling company to contact other companies in its distribution chain individually, but does not require the same level of notification to consumers. As a result, consumers never learn about food recalls in many cases. We understand that this system reflects FDA's historic attempts to work around limitations in its authority, but the agency should not allow these weaknesses in the current system to persist given the remedy provided in Section 211 of FSMA.

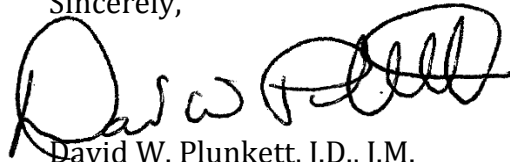
That section gives FDA a tool for alerting consumers about the need to dispose of or return contaminated food before they have eaten it. It not only authorizes but *requires* FDA to establish a recall notification program that would significantly improve the chances that a consumer actually sees a recall notice. It does so by requiring grocery stores to display an FDA prepared recall notice in a conspicuous location or manner. The advantage of grocery store notification is that it confronts consumers with a recall notice in the one place they are most likely to see it, their neighborhood grocery store. It thus overcomes the pitfalls of the current system's reliance on voluntary actions by the news media and retailers.

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We surveyed the leading chains for the report and found that most already post notices in the store. The practice, however, is not universal, demonstrating that voluntary actions, while laudable, cannot replace mandatory rules. The recall notification program is needed to ensure that *all* chains with 15 or more locations undertake the effort to alert their customers to recalls.

FDA to date has conducted one public hearing and issued an advanced notice of proposed rulemaking (ANPRM) to gather information on how to establish the program. Over two years have passed since the ANPRM. Surely that is sufficient time to consider comments and begin drafting a rule to implement the program. We urge the agency to complete work on the recall notification system under Sec. 211 and provide consumers with better notice about recalled foods they may have purchased.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Plunkett". The signature is fluid and cursive, with a large initial "D" and "W".

David W. Plunkett, J.D., J.M.

Senior Staff Attorney for Food Safety

cc: Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition.