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MEMORANDUM

From: Martin J. Hahn
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Date: June 5, 2017

Re: **Consumer Groups File Complaint Against FDA for GRAS Final Rule**

On May 22, 2017, the Center for Food Safety (CFS), Breast Cancer Prevention Partners (BCPP), Center for Science in the Public Interest (CSPI), and Environmental Defense Fund (EDF), filed a complaint for declaratory and injunctive relief against the U.S. Food and Drug Administration (FDA) for the agency's final rule regarding substances that are Generally Recognized as Safe (GRAS) for use in human and animal foods (the Final Rule). 1/ The Plaintiffs take issue with the voluntary nature of the GRAS notice program and allege the Final Rule is an "unlawful[ ] sub-delegation of authority," an arbitrary and capricious agency action, and an abdication of statutory duty that violates the Administrative Procedure Act (APA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). 2/

By way of brief background, on August 17, 2016, FDA published the Final Rule to comply with a consent decree with CFS from another lawsuit that claimed the agency violated the APA by "indefinitely operating under a proposed rule in lieu of promulgating a final rule." 3/ The Final Rule clarified the criteria for when the use of a substance is GRAS and exempt from premarket approval requirements of the FFDCA for food additives. It also finalized the administrative procedure for any person to voluntarily notify FDA the basis of a conclusion that a substance is GRAS.

We believe it will be challenging for the Plaintiffs to convince a court the voluntary nature of the GRAS notice program violates the FFDCA. As FDA itself noted in the Final Rule, the agency lacks the statutory authority to require companies to submit GRAS notices under the plain language of the FFDCA. 4/ The FFDCA imposes a mandatory premarket approval requirement on food additives and specifically exempts GRAS ingredients from the food additive definition. A mandatory GRAS

1/ *Center for Food Safety v. Price*, Case No. 1:17-cv-03833, Complaint, ECF No. 1 (May 22, 2017).
2/ Compl. ¶¶ 122-132.
3/ *Center for Food Safety v. Burwell*, Case No. 1:14-cv-267-RC, Consent Decree, ECF No. 14-1 (Oct. 20, 2014).
4/ 81 Fed. Reg. at 54971 (Aug. 17, 2016).

notification program would impose a significant administrative burden on the industry and FDA by requiring the agency review of all GRAS ingredients, including those ingredients that are GRAS on the basis of common use in foods. Indeed, since the program was initiated in 1998, the GRAS program has been considered by FDA and many stakeholders as highly successful, with 695 voluntary GRAS notices for substances used in human food filed as of today. 5/ It is important to note that while the case is pending, the Final Rule will remain in effect and FDA will continue to accept and review GRAS notices through its voluntary program.

Below we provide an overview of the key issues raised in the Complaint.

The Plaintiffs claim self-certification is a mechanism for industry to circumvent the premarket review process. The Plaintiffs allege that the voluntary GRAS program allows manufactures to include carcinogens and novel substances and uses, such as nanotechnologies, in foods without FDA approval, in direct contravention of FFDCA standards. 6/ The Plaintiffs maintain that the lack of mandatory recordkeeping requirements for manufacturers who submit GRAS notifications prevents manufacturers, FDA, watchdogs, and consumers from accurately estimating dietary exposure to chemical substances, which in turn limits the ability to accurately determine whether a substance is GRAS, making it impossible for FDA or manufacturers to comply with the FFDCA. 7/

The Plaintiffs assert the voluntary notification system is an unconstitutional delegation of statutory authority to private parties because it "removes the key and statutorily-required independent determination . . . from FDA's control and places it within the purview of the industry to regulate." 8/ The Plaintiffs also note the system gives manufacturers discretion to withdraw notifications at any time, emphasizing this feature as a possible escape hatch from negative FDA feedback. 9/

Finally, the Plaintiffs claim the Final Rule's criteria for GRAS determinations are insufficient and violate the FFDCA. 10/ In particular, the Plaintiffs assert the Final Rule "allows a manufacturer's determination . . . to be based on published information corroborated by unpublished information" violating FFDCA's requirement that safety is "generally recognized" based on "common knowledge" among qualified scientific experts. 11/ The Plaintiffs claim this allows manufacturers to rely on their own employees in lieu of a consensus among the scientific community, thus violating the FFDCA. 12/

The Plaintiffs contend that with this Final Rule, FDA abdicated its statutory duty to ensure food safety and enforce the 1958 Food Additives Amendment to the FFDCA. 13/ FDA addressed this concern in the Final Rule, clarifying that the voluntary GRAS notification program does not violate the Act because the FFDCA "is silent with respect to industry submissions to [FDA] on the use of

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5/ *See* FDA GRAS Notices Inventory, *available at*: http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices.
6/ Compl. ¶ 5, 10, 11.
7/ Compl. ¶ 6, 7, 100 - 104.
8/ Compl. ¶ 89.
9/ Compl. ¶ 59, 73 - 78.
10/ Compl. ¶ 9, 63 - 66, 105 - 110.
11/ Compl. ¶ 63 - 66.
12/ Compl. ¶ 105 - 110.
13/ Compl. ¶ 3, 91, 94.

GRAS substances" and the Final Rule merely "replaces one longstanding voluntary administrative procedure with a different voluntary administrative procedure." 14/

While the Plaintiffs are asking for injunctive relief, we believe it will be challenging for the courts to enjoin FDA from implementing the final rule while the lawsuit is pending. To qualify for the requested relief, the Plaintiffs must show irreparable harm. The Plaintiffs claim that their "organizational purposes are adversely affected" because they feel obligated to reallocate resources to "fight" the GRAS program do not rise to the level of irreparable harm. 15/ Plaintiffs also claim that members "are exposed to potentially dangerous chemical substances that the FDA has not evaluated for safety" establish irreparable harm. 16/ We believe the courts will find both of these arguments unpersuasive. FDA has been implementing the GRAS notification program since 1998, thus complicating an ability to demonstrate irreparable harm. With regard to the allegation that members are exposed to potentially dangerous chemical substances, FDA has the legal authority to remove from the market any food ingredient that is an unapproved food additive or that contains poisonous or deleterious substances. We would expect the courts to recognize the GRAS notification program in no way hinders the broad authority granted to FDA to protect the ingredients added to foods.

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We will continue to follow this lawsuit, as well as other developments concerning the GRAS notice program. Please contact us if you have any questions.

14/ *See supra* note 4.
15/ Compl. ¶¶ 20, 22, 24, 26, 28.
16/ Compl. ¶ 13.