UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, 1220 L Street NW, Suite 300, Washington, DC 20005, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, White Oak Building 1, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Defendant.	)	Civil Action No. 15-1651

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Center for Science in the Public Interest (CSPI) brings this action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 & 706, to compel defendant U.S. Food and Drug Administration (FDA), to act on CSPI's November 2005 citizen petition.

2. CSPI's petition asked FDA to initiate a rulemaking to help ensure the safe use of salt as a food or food additive. Specifically, pursuant to 5 U.S.C. § 553(e) and 21 C.F.R. §§ 10.25 and 10.30, CSPI petitioned FDA to, among other things, (1) revoke the "generally recognized as safe" (GRAS) status of salt, an action that would render salt a food additive subject to more stringent regulation for certain uses, (2) amend any "prior sanctions" (i.e., agency approvals) for other uses of salt, (3) require food manufacturers to reduce the amount of sodium in all processed foods, including foods sold to restaurants, and (4) require health

messages on retail packages of salt one-half ounce or larger. *See* CSPI Citizen Petition at 2-3, *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0196-0030.

3. Ample scientific and medical research demonstrates that Americans' excessive salt intake poses public health dangers. However, ten years after CSPI's petition and eight years after holding a hearing and soliciting public comment on the petition, FDA has neither granted nor denied the petition with respect to the relief described above. Therefore, to protect public safety and prevent needless death and injury, CSPI seeks a declaration that defendant has acted unlawfully by withholding action on CSPI's petition and an order requiring defendant to act thereon.

PARTIES

4. Plaintiff CSPI is a national nonprofit organization founded in 1971. With approximately 700,000 members and subscribers in the United States, CSPI is an advocate on issues of nutrition and health, food safety, and sound science. CSPI and its members have been, and continue to be, injured by defendant's failure to act on CSPI's petition. As long as FDA continues to regulate salt as a GRAS substance and fails to take the other regulatory actions that CSPI seeks, CSPI's members will continue to be exposed to high quantities of salt in processed food and will not have the benefit of public warnings regarding the dangers of salt.

5. Defendant U.S. Food and Drug Administration is a federal government agency within the Department of Health and Human Services and is responsible for implementing the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq., including the FDCA's provisions regarding food additives and food ingredients generally recognized as safe.

JURISDICTION

6. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. *See In re Natural Resources Def. Council*, 645 F.3d 400, 407 (D.C. Cir. 2011).

FACTS

7. Excessive sodium consumption is associated with high blood pressure, also called hypertension. *See* CSPI Citizen Petition at 10-11. As FDA recognizes, individuals with high blood pressure are at greater risk of serious health problems, including heart disease and stroke. *See* 21 C.F.R. § 101.74(a)(2), (b)(1); *see also, e.g.*, CSPI Citizen Petition at 12-14; U.S. Dep't of Agriculture and U.S. Dep't of Health and Human Services, Dietary Guidelines for Americans 2010 (2010 Dietary Guidelines), at 3, *available at* http://health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf; 2015 Dietary Guidelines Advisory Committee Report, Part D, Ch. 6 at 4-5, *available at* http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/11-Part-D-Chapter-6.pdf.

8. Despite its associated adverse health effects, hypertension is widespread. Roughly one-third of American adults have hypertension. FDA, Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11,880, 11,885 (proposed Mar. 3, 2014); *see also* CSPI Citizen Petition at 10. Another thirty-six percent have prehypertension, that is, higher-than-normal blood pressure that does not yet constitute hypertension. 2010 Dietary Guidelines at 3. And the estimated lifetime risk of developing hypertension is now 90 percent. 2015 Dietary Guidelines Advisory Committee Report, Part D, Ch. 6 at 4.

9. The federal government has long called for Americans to reduce their sodium consumption to combat these adverse health effects. *See, e.g.*, FDA, Food Labeling: Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content, 47

Fed. Reg. 26,580, 26,581 (proposed June 18, 1982) (citing recommendations based on federal dietary guidelines in 1980); *see also* CSPI Citizen Petition at 14-15 (tracing history of scientific consensus, including among government agencies). Salt "is the single greatest contributor of sodium in the American food supply." 47 Fed. Reg. at 26,580. Accordingly, "a reduction in sodium intake almost always means reducing one's salt intake." *Id.*

10. Nearly all Americans consume more sodium than is safe. FDA, Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. at 11,885. Federal dietary guidelines recommend no more than 2,300 milligrams of sodium per day, and no more than 1,500 milligrams for certain groups of people, including children, African Americans, and individuals with diabetes and hypertension. 2010 Dietary Guidelines at 21. Yet, according to FDA, the average American consumes roughly 3,650 milligrams of sodium per day. 79 Fed. Reg. at 11,914; *see also* CSPI Citizen Petition at 3. Fewer than 15 percent of Americans eat less than 2,300 milligrams of sodium per day. 2010 Dietary Guidelines at 24.

11. Consumers can exert relatively little control over their sodium intake by adjusting discretionary use of salt, such as salt added during the cooking process or at the table. According to the federal government, discretionary use accounts for only five to ten percent of the average American's sodium intake. FDA, Salt and Sodium; Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium, 72 Fed. Reg. 59,973, 59,973 (Oct. 23, 2007) (citing 2005 federal dietary guidelines); *see also* CSPI Citizen Petition at 3 n.16, 7.

12. The biggest driver of sodium consumption is processed food, including food sold directly to restaurants: More than three-quarters of the average American's salt intake comes from salt added to processed and restaurant foods. FDA, Approaches to Reducing Sodium

Consumption: Request for Comments, 76 Fed. Reg. 57,050, 57,050 (Sept. 15, 2011); *see also* FDA, Salt and Sodium; Petition to Revise the Regulatory Status of Salt, 72 Fed. Reg. at 59,973; CSPI Citizen Petition at 3 n.16.

13. A significant reduction in Americans' sodium consumption would save tens of thousands of lives. For example, a 2004 paper in a prominent health journal estimated that a 50 percent reduction in sodium in processed and restaurant foods would lead to at least a 20 percent reduction in the prevalence of hypertension and 150,000 fewer deaths per year. *See* Havas, Roccella, & Lenfant, *Reducing the Public Health Burden from Elevated Blood Pressure Levels in the United States by Lowering Intake of Dietary Sodium*, 94 Am. J. Pub. Health 19-22 (2004), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449816; *see also* CSPI Citizen Petition at 12-14 (describing research underlying this study and others). More recent evidence confirms that a reduction in sodium consumption would have extensive life-saving benefits. One study found that a 1,200-milligram-per-day reduction in sodium would lead to 44,000 to 92,000 fewer deaths and health-care-related savings of $10 to $24 billion per year in the United States. *See* Bibbins-Domingo, et al., Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease, 362(7) New Eng. J. Med. 590-99 (2010), *available at* http://www.nejm.org/doi/full/10.1056/NEJMoa0907355; *see also* CSPI, Reducing Sodium: A Look at State Savings in Health Care Costs (2015), *available at* http://cspinet.org/new/pdf/Sodium%20Report%20Final%205%2020%2015.pdf.

14. The federal government has recognized that "[a]n immediate, deliberate reduction in the sodium content of foods in the marketplace is necessary to allow consumers to reduce sodium intake to" recommended levels. 2010 Dietary Guidelines at 24. In 2010, in a report sponsored by FDA, the Institute of Medicine recommended "mandatory national standards for

the sodium content in foods." Institute of Medicine, Report Brief: Strategies to Reduce Sodium Intake in the United States 2 (2010), *available at* http://goo.gl/Mkhvt6. The committee that drafted the report explained that "[r]egulatory action is necessary because four decades of public education campaigns about the dangers of excess salt and voluntary sodium cutting efforts by the food industry have generally failed to make a dent in Americans' intakes." Press Release, FDA Should Set Standards for Salt Added to Processed Foods, Prepared Meals (Apr. 20, 2010), *available at* http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12818.

15. FDA has authority to regulate the amount of salt in processed foods and to require health messages on salt packaging that refer to salt's adverse health effects. To date, however, it has not done so.

16. Specifically, FDA is charged with implementing the FDCA. Under that law, it is unlawful to market food that is "adulterated." 21 U.S.C. § 331(a). A food that contains a "food additive" is deemed adulterated, *see id.* § 342(a)(2)(C)(i), unless FDA has adopted a regulation "prescribing the conditions under which [the] additive may be safely used," and the additive's use conforms with that regulation, *id.* § 348(a)(2).

17. The FDCA's definition of "food additive" does not include two categories of ingredients that are, in fact, added to food. First, ingredients are not considered food additives if they are GRAS, that is, "generally recognized as safe," by "experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food." 21 C.F.R § 170.30(a); 21 U.S.C. § 321(s). Second, ingredients are not considered "food additives" for specific uses—including the levels and conditions of the ingredients' use—if FDA (or predecessor agencies) granted companies permission to utilize the ingredients for those uses before 1958; in FDA terminology, these ingredients are known as foods with "prior sanction"

status. 21 C.F.R. §§ 181.1(a), 181.5(a), (b); *see also* 21 U.S.C. § 321(s)(4). Under the existing regulatory scheme, then, only a "food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation . . . before it may be directly or indirectly added to food." 21 C.F.R. § 170.30(g).

18. "New information may at any time require reconsideration of the GRAS status of a food ingredient." *Id.* § 170.30(l). In addition, FDA may "establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient" altogether where "scientific data or information . . . shows that use of a prior-sanctioned food ingredient may be injurious to health," and therefore within the definition of adulterated food. *Id.* § 181.1(b).

19. FDA presumptively classified salt as GRAS based on salt's common use in food before 1958, when Congress amended the FDCA to authorize the FDA to regulate food additives. *See id.* § 182.1(a). In addition, FDA has stated that "many uses of salt are prior sanctioned," FDA, Salt and Sodium; Petition to Revise the Regulatory Status of Salt, 72 Fed. Reg. at 59,977, although its regulations do not specifically identify those uses, *see generally* 21 C.F.R. Part 181.

20. In the 1970s, FDA established regulations in which it committed to revisit the GRAS status of various food ingredients, including salt; those ingredients would be "reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction." *Id.* § 170.30(f). In justifying the review, FDA stated that more data had "bec[o]me available on the properties of particular substances" and "the science of toxicology [had] developed" since Congress amended the FDCA to regulate food additives. FDA, GRAS Safety Review of Sodium Chloride, 47 Fed. Reg. 26,590, 26,591 (June 18, 1982). FDA concluded, as a result, that "to

ensure the safety of the food supply, the agency's earlier safety determinations should be reviewed and modified where appropriate." *Id.*

21. To facilitate its GRAS review, FDA contracted with a committee from the Federation of American Societies for Experimental Biology to evaluate available data and make recommendations to FDA. In 1979, that committee concluded that it could not give salt a clean bill of health—that the "evidence on sodium chloride [was] insufficient to determine that the adverse effects reported [were] not deleterious to the health of a significant proportion of the public" when salt was used at then-current levels. *Id.* at 26,592. The committee recommended that FDA take steps to lower salt consumption because of the potential for adverse health effects. *Id.*

22. Despite the committee's conclusions regarding salt's potential dangers, FDA announced in 1982 that it would "defer any action on the current GRAS status of salt until the agency c[ould] assess the impact" of "efforts by manufacturers to reduce voluntarily the salt and sodium content of their products" and the impact of sodium labeling regulations that FDA simultaneously proposed. *Id.* Those regulations aimed to require manufacturers to state sodium content on processed foods, but only when nutrition labeling was otherwise required or was provided voluntarily. FDA, Declaration of Sodium Content of Foods, 47 Fed. Reg. at 26,587. FDA "believe[d] that a voluntary program w[ould] produce the desired results with less regulatory burden." FDA, GRAS Safety Review of Sodium Chloride, 47 Fed. Reg. at 26,594. However, it stated that "if no significant progress" occurred toward the goals of reducing sodium in processed foods and informing consumers "in a reasonable time," the agency would "consider additional regulatory actions." *Id.*

23. The following year, CSPI sued FDA for failing to take action sought by two citizen petitions that CSPI had submitted to the agency. Those petitions asked FDA to reclassify salt from GRAS to food additive status, to set limits on the quantity of salt in processed foods, and to require sodium labeling of processed foods. The lawsuit sought, among other things, (1) a declaration that FDA's decision to defer indefinitely a regulatory decision on the safety of current levels of salt consumption violated the FDCA and 21 C.F.R. § 170.30(f) and constituted unreasonable delay under the APA, 5 U.S.C. § 706(1); and (2) an order compelling FDA to complete its review of salt within a reasonable time.

24. The district court dismissed CSPI's suit. In rejecting CSPI's claim that FDA's failure to issue a final decision on the GRAS status of salt violated 21 C.F.R. § 170.30(f), the court relied on the absence of a deadline in the regulation for FDA to revisit salt's GRAS status and on FDA's representation that it would "consider proposing a change in the GRAS status of salt if there [was] no substantial reduction in the sodium content of processed foods and if information[al] sodium labeling [was] not adopted after a reasonable period of time." *CSPI v. Novitch*, Mem. Op., No. 83-801 (D.D.C. June 11, 1984). Under these circumstances, the court concluded that FDA's decision to "defer revision in the GRAS status of salt [was] rational." *Id.*

25. For similar reasons, the district court rejected CSPI's unreasonable delay claim. The court noted that FDA had received the outside report on salt in 1979, issued a proposed rule for voluntary sodium labeling in 1982, and finalized that rule in 1984. Because "[t]he effectiveness of the new rule [would] have a part in determining what action the agency [would] take with regard to the GRAS status of salt," and because FDA was "moving forward with its voluntary programs" and "examining additional scientific and medical data on the effects of sodium consumption," the court held that the delay was not unreasonable at that time. *Id.*

26. Although the court dismissed the case, it also stated that "FDA must make a decision on the GRAS status of salt after it ha[d] completed its review, i.e., after the voluntary programs ha[d] been in effect for a reasonable period of time and FDA . . . had an opportunity to assess their impact and to review new scientific studies on sodium chloride consumption. Title 21, Code of Federal Regulations, section 170.30(f) clearly indicates that FDA must review those food additives classified as GRAS, including salt, and either affirm and [sic] GRAS or determine them to be a food additive or subject to a prior sanction." *Id.*

27. By 2005, more than two decades after the district court's decision, FDA still had not completed its review of salt's GRAS status. In the intervening years, sodium consumption had increased rather than decreased relative to levels in the early 1980s, when CSPI filed its first lawsuit. *See* CSPI Citizen Petition at 8-9. And the federal government continued to warn of the adverse health effects related to salt intake and acknowledged that "[n]early all Americans consume substantially more salt than they need." U.S. Dep't of Health and Human Services and U.S. Dep't of Agriculture, Dietary Guidelines for Americans 2005, at 39-40, *available at* http://health.gov/dietaryguidelines/dga2005/document/pdf/Chapter8.pdf.

28. Accordingly, CSPI petitioned the U.S. Court of Appeals for the D.C. Circuit for a writ of mandamus to end the agency's unreasonable delay in reconsidering salt's GRAS status. *See In re Center for Science in the Public Interest*, No. 05-1057 (D.C. Cir. filed Feb. 24, 2005). The FDA responded that its failure to close an earlier docket to reconsider salt's GRAS status was an administrative oversight and that no proceeding to reconsider the issue was pending. In light of that response, the court of appeals dismissed the petition for lack of jurisdiction because the court of appeals determined that CSPI "did not seek a remedy from the agency or initiate any

proceeding in the agency before resorting" to suit. Order, *id.* (filed July 14, 2005) (internal quotation marks and alteration omitted).

29. CSPI then filed a citizen petition in 2005 asking FDA to undertake a rulemaking to (1) revoke the GRAS status of salt, (2) to ensure salt's safe use by amending any prior sanctions for certain uses of salt, (3) to require food manufacturers to reduce the amount of sodium in all processed foods, and (4) to require health messages on retail packages of salt one-half ounce or larger. *See* CSPI Citizen Petition at 2-3.

30. FDA responded on November 8, 2005, that CSPI's petition had been received and assigned a docket number. In a letter to CSPI dated November 17, 2005, it stated that "[f]urther action awaits our scientific review and evaluation by our scientific divisions."

31. By letter dated June 5, 2006, FDA stated that it was providing a "tentative response" to CSPI. FDA explained that it had "not reached a decision on [CSPI's] petition because [the agency] need[ed] additional information" and that it was "considering what, if any, additional procedures it might use to obtain further information and input."

32. In 2007, FDA published in the Federal Register a notice of public hearing concerning the agency's policies regarding salt and sought public comments on CSPI's petition. *See* FDA, Salt and Sodium; Petition to Revise the Regulatory Status of Salt, 72 Fed. Reg. 59,973. In that notice, FDA acknowledged the role of excessive sodium consumption in the development of hypertension and heart disease, and the large share of salt intake attributable to processed foods. *Id.* at 59,973.

33. FDA held the public hearing in November 2007. The public comment period ended in 2008. Approximately 200 documents were submitted as part of the agency record. *See* http://www.regulations.gov/#!docketDetail;D=FDA-2007-0545.

34. Many of the comments supported the actions requested by CSPI or suggested other regulatory actions that FDA should take to reduce Americans' sodium consumption and to help address the corresponding serious public health consequences. *See*, *e.g.*, Comment by New York State Department of Health, http://www.regulations.gov/#!documentDetail;D=FDA-2007-0545-0076; Comment by American Medical Association, http://www.regulations.gov/#!documentDetail;D=FDA-2007-0545-0022; Comment by American Diabetes Association, http://www.regulations.gov/#!documentDetail;D=FDA-2007-0545-0037; Comment by American Heart Association, http://www.regulations.gov/#!documentDetail;D=FDA-2007-0545-0031; Comment by Wisconsin Department of Health Services, http://www.regulations.gov/#!documentDetail;D=FDA-2007-0545-0057.

35. In 2011, FDA opened a separate docket to request comments, data, and information related to approaches to reducing sodium consumption. *See* FDA, Approaches to Reducing Sodium Consumption: Request for Comments, 76 Fed. Reg. 57,050. That comment period closed in 2012. FDA, Approaches to Reducing Sodium Consumption: Extension of Comment Period, 76 Fed. Reg. 74,039, 74,039 (Nov. 30, 2011).

36. CSPI's petition and the administrative record developed by FDA provide sufficient grounds, including citation to scientific evidence, for FDA to determine whether to adopt a rule revoking salt's GRAS status and providing the other relief sought by CSPI.

37. To date, despite the significant public health consequences of excessive sodium consumption documented in CSPI's petition, FDA has not issued a decision on the petition.

38. The considerable danger to public health caused by excessive sodium consumption counsels in favor of expeditious action on CSPI's petition. The pace of defendant's decisional process has lagged unreasonably in light of the nature and extent of the public health

interests at stake and the defendant's longstanding regulatory commitment in 21 C.F.R. § 170.30(f) to review the GRAS status of salt and take one of several enumerated actions.

CLAIMS FOR RELIEF

39. Defendant's failure to act on CSPI's petition constitutes agency action unlawfully withheld or unreasonably delayed, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1).

40. Defendant's failure to act on CSPI's petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

WHEREFORE, plaintiff requests that this Court

A. Declare unlawful defendant's failure to act on CSPI's petition;

B. Order defendant to issue a decision on CSPI's petition within 30 days of the Court's order;

C. Award CSPI its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,

/s/ Julie A. Murray

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