IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST 1220 L Street, N.W. Suite 300 Washington, D.C. 20005, MERCURY POLICY PROJECT 1420 North Street Montpelier, VT 05602, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET A. HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendants.	)	Civ. No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs Center for Science in the Public Interest and Mercury Policy Project bring this action pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399(f) ("FFDCA"), and the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706 ("APA"), to require the United States Food and Drug Administration and Margaret A.

Hamburg, in her official capacity as Commissioner, United States Food and Drug Administration (collectively, "FDA") to render a final decision on Plaintiffs' citizen petition ("Petition"), which seeks FDA rulemaking on package labeling and point-of-sale advisories that would clarify and better communicate federal seafood consumption advice to women of child-bearing age, pregnant or nursing women, and parents of young children ("Target Group").

2. Every year, hundreds of thousands of children in the United States are born with elevated blood mercury levels caused by their mothers' consumption of fish and shellfish contaminated with methylmercury, a neurotoxin that can lead to learning disabilities, lowered IQ, and impaired cognitive and nervous system functioning. Exposure to methylmercury can be significantly reduced, however, by providing the Target Group with better information about the types of seafood that contain higher levels of mercury and types that contain lower levels of mercury, so that the Target Group can make healthier, more informed decisions when consuming fish.

3. On July 5, 2011, Plaintiffs submitted their Petition to FDA requesting, among other things, regulations that would require (1) informational labeling on packaged seafood that reflects the joint recommendations of FDA and the Environmental Protection Agency ("EPA") in their online advisory ("Online Advisory"); (2) consumption recommendations at the point of sale of unpackaged, fresh seafood, presented in a user-friendly format; and (3) informational mercury level and consumption limit labeling on packaging or at the point of sale for seafood species with moderate or high mercury content that are not otherwise listed in the Online Advisory.

4. FDA received, filed, and assigned the Petition a docket number on July 18, 2011.

5. FDA's regulations require it to respond to Plaintiffs Petition "within 180 days of receipt of the petition[,]" 21 C.F.R. § 10.30(e)(2) (2013), and its response therefore was due by January 14, 2012. That date came and went without any response from FDA.

6. Over 200 days after that date, on or about August 8, 2012, FDA sent Plaintiffs a cursory letter stating that it "ha[d] not yet reached a decision on [the] petition because [] the ongoing review and analysis of the science [was] not yet completed."

7. Plaintiffs have not received any communication from FDA since August 8, 2012. The agency has not granted or denied the Petition, nor has it provided any additional reasons for its failure to issue a decision, nor any information on when it intends to take final action on the Petition.

8. FDA has repeatedly acknowledged the link between seafood consumption and exposure to methylmercury in the United States, and yet it has not improved the availability or clarity of information about mercury in seafood for people in the Target Group so that they can make informed decisions regarding seafood consumption.

9. Plaintiffs seek declaratory and injunctive relief requiring FDA to issue a final decision on the Petition by a court-ordered deadline.

JURISDICTION AND VENUE

10. This lawsuit is brought pursuant to the FFDCA, 21 U.S.C. §§ 301-399(f), and the APA, 5 U.S.C. §§ 551-559, 701-706. Plaintiffs seek judicial review under the APA, 5 U.S.C. § 706(1).

11. This Court has subject matter jurisdiction over the claim for relief set forth herein pursuant to 28 U.S.C. § 1331 (2006) (actions arising under the laws of the United States), 28

U.S.C. § 1346 (2006) (action against the United States), and 28 U.S.C. §§ 2201-02 (2006) (power to issue declaratory judgments in cases of actual controversy).

12. Venue properly lies in this Court under 28 U.S.C. § 1391(e)(1)(C) (Supp. 2011), as this is a civil action in which the defendants are an agency of the United States and an officer of that agency acting in her official capacity, one of the plaintiffs resides in this judicial district, and the action does not involve real property.

13. This Court may award Plaintiffs all necessary injunctive relief pursuant to the APA, 5 U.S.C. § 706(1), and may award declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

PARTIES

Plaintiffs

14. Plaintiff Center for Science in the Public Interest ("CSPI") is a non-profit corporation with over 900,000 members committed to advocating for nutrition, health, and food safety, and to educating consumers about current, useful information about their health and well being. Since the organization was founded in 1971, CSPI has done extensive work to promote the passage of laws that require nutrition information on packaged food and to improve food safety laws to reduce the incidence of foodborne illness. CSPI's members and staff include scientists engaged in work on nutrition and health issues, as well as hundreds of thousands of people, many of whom are in the Target Group, who consume fresh and packaged seafood and feed it to their families.

15. In 2000, CSPI petitioned FDA to set a regulatory limit for mercury in seafood to accurately reflect the risk to women and children of consuming seafood with elevated levels of mercury. It has also written numerous letters to the agency urging it to develop point-of-sale

information that communicates the mercury content of seafood to consumers, as well as co-sponsored an extensive report about the level of mercury in tuna served in U.S. school lunch programs.

16. CSPI's health, educational, and scientific interests are harmed by FDA's failure to promulgate regulations that would provide much-needed information to consumers about the levels of mercury in fish and shellfish. CSPI's members and staff value the ability to make informed choices about their seafood consumption and to advocate for better and more accessible consumer information about the levels of mercury in seafood. CSPI brings this action on behalf of itself and its adversely affected members and staff.

17. Plaintiff Mercury Policy Project ("MPP") is a non-profit corporation dedicated to promoting policies to eliminate mercury uses, reduce the export and trafficking of mercury, and significantly reduce mercury exposures at the local, national, and international levels. MPP provides the general public with educational materials and resource information on mercury issues, including reprints of news articles, scientific and policy reports, and press releases. MPP's reports include, "Hold the Mercury: How to Avoid Mercury When Buying Fish," and "Is Our Tuna 'Family-Safe'? Mercury in America's Favorite Fish." MPP also authored a comprehensive report that was co-sponsored by CSPI about the level of mercury in tuna served in U.S. school lunch programs.

18. MPP helped found the Zero Mercury Working Group in 2005, an international coalition of 98 public interest environmental and health organizations dedicated to reducing mercury in the global environment.

19. MPP brings this action on behalf of itself and its extensive network of people and groups committed to reducing mercury in the environment and providing better information to

the public about ingestion of harmful levels of mercury from eating fish. MPP has advocated for better and more accessible information regarding the levels of mercury in seafood, particularly directed at members of the Target Group, and its scientific, educational, and health interests are harmed by FDA's failure to promulgate regulations to require that this information be provided to the general public and the Target Group at the point of sale and on seafood packaging.

20. Plaintiffs' and their members' health, educational, and scientific interests in minimizing harm to the Target Group from ingestion of mercury have been, are being, and unless the relief prayed for is granted, will continue to be directly and adversely affected by the defendants' failure to comply with the law.

21. FDA's failure to substantively respond to the Petition within a reasonable time also harms Plaintiffs' procedural interests, as Plaintiffs are unable to take further action on the Petition until FDA issues a final response. FDA's failure to make a decision on the Petition deprives Plaintiffs of the benefits and information a final decision might afford, thereby frustrating their ability to protect their members, their children, and the public, including the Target Group, from excessive risks associated with mercury exposure through seafood consumption.

22. Plaintiffs' injuries would be redressed by a declaratory judgment that FDA's failure to timely respond to the Petition is unlawful, and by an order compelling FDA to issue a final response to the Petition by a specific deadline.

Defendants

23. Defendant FDA is an agency within the United States Department of Health and Human Services and is responsible for assuring that foods are safe, wholesome, sanitary, and

properly labeled. It has broad authority and an agency mandate to protect public health. Specifically, FDA has statutory obligations under the FFDCA to require certain information on labels that enable consumers to make informed choices about food, as well as to prevent the adulteration and misbranding of foods, and to respond to citizen petitions requesting rulemaking.

24. Defendant Margaret A. Hamburg, in her official capacity as Commissioner of FDA, is responsible for FDA's administration and implementation of its legal duties, and for executing the FFDCA.

STATUTORY FRAMEWORK

The Federal Food, Drug, and Cosmetic Act

25. Congress passed the FFDCA in 1938 "[t]o prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics[.]" Pub. L. No. 75-717, 52 Stat. 1040 (current version at 21 U.S.C. §§ 301-399(f)). Among other things, the Act mandates legally-enforceable food and food packaging standards to ensure food integrity for the protection of American consumers.

26. FDA is the federal agency charged with enforcing the FFDCA. 21 U.S.C. § 393. Part of its mission, as set forth in the Act, is to "protect the public health by ensuring that [] . . . foods are safe, wholesome, sanitary, and properly labeled[.]" Id. § 393(b)(2) (2006).

27. The FFDCA prohibits "[t]he receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise." 21 U.S.C. § 331(c) (Supp. 2011).

28. Under the Act, "[a] food shall be deemed to be adulterated . . . [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health[.]" 21

U.S.C. § 342(a)(1) (2006). This provision applies specifically to "added substances," id., which federal courts have held includes mercury in seafood.

29. "A food shall be deemed to be misbranded . . . [i]f . . . its labeling is false or misleading in any particular[.]" 21 U.S.C. § 343(a)(1) (2006). An item is misbranded not only when the label reveals false or misleading information, but where "the labeling or advertising fails to reveal facts . . . material with respect to consequences which may result from the use of the article . . . under such conditions of use as are customary or usual." Id. § 321(n) (2006) (emphasis added).

30. Under broad powers granted to it under the FFDCA, FDA has "[t]he authority to promulgate regulations for the efficient enforcement of [the Act]." 21 U.S.C. § 371(a) (2006).

31. In addition to the prohibition against the receipt in interstate commerce of adulterated or misbranded food, in 1990 Congress amended the FFDCA with the Nutrition Labeling and Education Act ("NLEA") to require uniform food product labeling that provides nutritional information. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of Title 21 of the U.S. Code) Congress amended the FFDCA via the NLEA because of the "need to have consistent, enforceable rules pertaining to the claims that may be made with respect to the benefits of nutrients in foods." H.R. Rep. No. 101-538, at 8 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3338.

32. The NLEA provides that FDA may, by regulation, require labeling of additional nutrients not otherwise specifically listed in the statute "for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices[.]" 21 U.S.C. § 343(q)(2)(A) (2006).

33. Pursuant to the NLEA, the agency can also issue voluntary guidelines that provide information to grocery stores and fish markets about posting nutritional information for raw seafood. Id. § 343(q)(4)(A) (2006).

34. Regulations promulgated pursuant to the FFDCA provide that citizens can petition FDA to "issue . . . a regulation or order" through a citizen petition. 21 C.F.R. § 10.25(a)(2) (2013). The requirements for filing a citizen petition with the agency are set forth in 21 C.F.R. § 10.30(b) and (c) (2013).

35. The regulations require that "[t]he Commissioner shall . . . rule upon each petition filed under [21 C.F.R. 10.30(c)], taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute." Id. § 10.30(e)(1) (2013).

36. In any case, within 180 days of receiving a petition, "the Commissioner shall furnish a response to each petitioner." Id. § 10.30(e)(2) (emphasis added). The Commissioner's response must "[a]pprove the petition," "[d]eny the petition[,]" or "[p]rovide a tentative response, indicating why the agency has been unable to reach a decision on the petition[.]" Id. This response must be furnished to each petitioner within the aforementioned 180 days.

FACTUAL BACKGROUND

Health Risks Associated with Methylmercury in Seafood

37. Consumption of seafood contaminated with mercury is the primary source of human methylmercury exposure in the United States. Coal-fired power plants are a major source of mercury, which is deposited into the oceans and converted into methylmercury

through a process called methylation that allows mercury, when ingested, to be incorporated into the body tissue of animals.

38. Consumption of seafood contaminated with mercury presents serious health risks to hundreds of thousands of children in the United States. Mercury accumulates in human tissues, and a woman's long-term exposure to mercury can become a risk to fetal health through pregnancy and nursing. Fetuses and young children are more susceptible than adults to mercury's adverse neurodevelopmental effects, like lower IQ, developmental delays, or impaired memory, attention span, language skills, and visual perception, because the human blood-brain barrier takes time to fully develop, during which time methylmercury can easily pass through it.

39. In March 2004, recognizing the harm that mercury causes to human health, the FDA and EPA issued the Online Advisory, entitled "What You Need to Know About Mercury in Fish and Shellfish," at: http://www.fda.gov/Food/FoodborneIllnessContaminants/BuyStoreServeSafeFood/ucm110591.htm. The Online Advisory recommends that the Target Group avoid certain high-mercury species of fish (e.g., shark, swordfish, tilefish, and king mackerel), limit albacore and fresh/frozen tuna intake to 6 ounces per week, and eat up to 12 ounces per week of lower-mercury seafood, including shrimp, salmon, pollock, catfish, and (again, according to FDA and EPA) canned light tuna.[1]

[1] Canned light tuna is the most popular fish in the American diet, accounting for a substantial portion of total mercury exposure. Most light tuna contains an above-average level of mercury.

The Need for Package Labeling and Point-of-Sale Advisories

40. Despite FDA's issuance of the Online Advisory, studies have shown that a large segment of the public, including many people in the Target Group, do not know of the risks inherent in exposing themselves or their families to mercury by eating seafood. Jay P. Shimshack et al., Mercury Advisories: Information, Education, and Fish Consumption, 53 J. of Envtl. Econ. & Mgmt. 158, 177 (2007); Joanna Burger & Michael Gochfeld, Knowledge About Fish Consumption Advisories: A Risk Communication Failure Within a University Population, 390 Sci. Total Env't 346, 351-52 (2008).

41. The Shimshack study specifically found that many Target Group consumers did not have adequate knowledge about the risks and benefits of seafood consumption and were in need of outreach methods regarding the levels of mercury in seafood in addition to the Online Advisory, including in-store advisory signs and mandatory product labeling. Shimshack et al., supra, at 177.

42. The Burger study similarly concluded that of the people surveyed, "[n]early 85% knew some of the reasons why fish were healthy, while only 38% knew any specific information about the risks" of fish consumption, which "provides fertile ground for both risk communication and risk management." Burger& Gochfeld, supra, at 351. The study determined that "knowledge about the risks and benefits of [fish from commercial sources] is essential for appropriate risk balancing decisions[,]" but despite existing "risk communication vehicles" like the Online Advisory, "the data indicate that the specific information [on the risks and benefits of fish consumption] is not reaching a general audience, or that they are not retaining this information." Id. at 352.

43. Notably, between July 2011, when Plaintiffs submitted the Petition to FDA, and the filing of this Complaint, the internet Uniform Resource Locator (or web address) for FDA's Online Advisory changed. An attempt to navigate to the website where the guidance was previously located resulted in a "webpage cannot be found" message. This is not an adequate or responsible way to convey important health information to the consumer. It requires not only that the consumer know that the Online Advisory exists and have computer access, but that the consumer either stay current on the advisory's location on FDA's extensive website or know how to successfully redirect to the current webpage when encountering the "webpage cannot be found" alert.

44. The relief that Plaintiffs seek in the Petition would make information accessible at grocery stores and fish markets so that the Target Group and the general public are not forced to grope through the internet for basic information that allows them to make healthy seafood choices.

45. Because of this documented failure to adequately disseminate information to the Target Group about the risks of seafood consumption and the ongoing public health risk caused by exposure to mercury, Plaintiffs filed the Petition with FDA to request that the agency initiate rulemaking to better communicate and clarify its current recommendations for seafood consumption directed at the Target Group through labeling disclosures on seafood packaging and point-of-sale advisories in grocery stores and fish markets. Specifically, the Petition asks FDA to enact regulations that would:

a. Provide for informational labeling on packaged seafood to generally reflect the Online Advisory recommendations;

b. Require grocery stores to post the Online Advisory's seafood consumption recommendations at the point of sale of unpackaged, fresh seafood, simplified into a user-friendly chart aimed at the Target Group; and

c. Provide for informational mercury level and consumption limit labeling on packaged seafood or at the point of sale for seafood species with higher mercury content that are not otherwise listed in the Online Advisory.

46. Detailed, accessible information about the level of mercury in seafood would allow Target Group consumers to maximize the health benefits of eating seafood while reducing the risk of mercury exposure to themselves and their families.

FDA's Failure to Respond to Plaintiffs' Petition

47. On July 18, 2011, FDA sent Plaintiffs a letter acknowledging receipt of the Petition, and informing Plaintiffs that the agency had filed it and assigned it docket number FDA-2011-P-0537-0001/CP.

48. After receiving the July 18 letter, Plaintiffs did not receive any further communication from FDA during the 180-day response period established under 21 C.F.R. § 10.30(e)(2).

49. After the lapse of the 180-day period, Plaintiffs sent FDA a certified letter on January 26, 2012, alerting the agency to the fact that it had failed to timely respond to the Petition. FDA did not immediately respond to the letter.

50. Plaintiffs did not receive any communication from FDA until over six months later on August 8, 2012, over one year after Plaintiffs filed the Petition, when FDA finally sent Plaintiffs a "tentative response" letter. The letter stated that the agency "had not yet reached a decision on [the P]etition because of the ongoing review and analysis of the science [was] not yet completed." FDA further indicated that it "intend[ed] to issue a final response as soon as possible after this review is completed."

51. Plaintiffs have not received any further communication from FDA since August 8, 2012, over 18 months ago. It has now been more than two and one-half years since Plaintiffs

filed the Petition, and FDA has neither issued a final response, nor undergone the minimal effort of informing Plaintiffs of when it intends to do so.

52. FDA's failure to respond to Plaintiffs' Petition is intolerable, as human health and welfare are at stake: the failure to properly communicate to women of childbearing age and to parents of young children the presence of elevated mercury levels in certain seafood and the recommended fish consumption limits exposes these people to harmful levels of the methylmercury neurotoxin, which can lead to impaired fetal and child development.

53. The agency's delay is particularly unreasonable in light of the fact that on March 1, 2013, it issued a substantive denial of another citizen petition that requested the agency take action related to mercury content in seafood. That petition, filed by the Center for Biological Diversity and Turtle Island Restoration Network ("CBD Petition") on June 20, 2011, just a few weeks before Plaintiffs' Petition, asked the agency to take a variety of actions related to reducing human exposure to mercury through seafood and limiting the allowable levels of mercury in seafood commercially sold in the United States. The CBD Petition included a request similar to Plaintiffs' request -- that updated fish consumption advice be posted at point-of-sale locations or on packaging of high-mercury fish. While the CBD Petition primarily dealt with legal issues that differ from the legal issues raised in Plaintiffs' Petition, the two petitions are based upon similar facts and science. Therefore, much of the agency's review and scientific analysis of the CBD Petition would be applicable to Plaintiffs' Petition, i.e., FDA could easily reference its analysis and the scientific studies it cited in the CBD Petition to help craft its response to Plaintiffs' Petition.

54. FDA's delay places Plaintiffs, their members, and the general public, including the Target Group, at risk by depriving them of vital information disclosing the mercury content

of seafood in grocery stores and fish markets, which would help them make more informed, healthier purchasing decisions for themselves and their families. It also deprives them of a decision on the Petition's merits, and the opportunity to seek judicial review of a final decision, if necessary.

55. Because of FDA's ongoing delay, a court-ordered deadline is necessary to ensure that FDA responds to the Petition within a specified time frame.

CLAIM FOR RELIEF
(Failure to Issue a Final Decision)

56. Plaintiffs re-allege and incorporate by reference each and every allegation contained in paragraphs 1-55 of this Complaint.

57. The APA directs federal agencies to "within a reasonable time . . . conclude a matter presented to it[,]" 5 U.S.C. § 555(b) (2012), and mandates that the Court "shall . . . compel agency action unlawfully withheld or unreasonably delayed[,]" id. § 706(1) (2012).

58. The FFDCA's implementing regulations require that "[t]he Commissioner shall . . . rule upon each petition filed under [21 C.F.R. § 10.30(c)]." 21 C.F.R. § 10.30(e)(1). FDA has unreasonably delayed agency action by failing to issue a final response to Plaintiffs' July 2011 Petition in violation of the APA, 5 U.S.C. § 555(b), and the FFDCA and its implementing regulations, 21 U.S.C. §§ 301-399(f); 21 C.F.R. § 10.30(e).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

1. Enter a declaratory judgment that FDA's delay in issuing a final response to Plaintiffs' Petition is unreasonable and a violation of the APA and the FFDCA;

2. Enter an order compelling FDA to issue a final response to Plaintiffs' Petition by a deadline imposed by the Court;

3. Retain jurisdiction of this matter until FDA fulfills its legal and Court-ordered obligations as set forth in this Complaint;

4. Award Plaintiffs the costs of this litigation, including reasonable attorney and expert witness fees;

5. Issue such other and further relief as the Court deems just and appropriate.

DATED: March 10, 2014.

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