

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

_____)	
PHYSICIANS COMMITTEE FOR)	
RESPONSIBLE MEDICINE,)	
5100 Wisconsin Avenue, NW, Suite 400)	
Washington, DC 20016,)	Case No.: 20-2686
)	
Plaintiff)	
)	
v.)	
)	
STEPHEN HAHN, MD,)	
Commissioner,)	
Food and Drug Administration)	
10903 New Hampshire Avenue)	
Silver Spring, MD 20993,)	
)	
and)	
)	
U.S. DEPARTMENT OF HEALTH AND)	
HUMAN SERVICES,)	
200 Independence Avenue, SW)	
Washington, DC 20201,)	
)	
Defendants.)	
_____)	

COMPLAINT FOR INJUNCTIVE RELIEF

1. This is an action under the Administrative Procedure Act, 5 U.S.C. § 706, seeking injunctive relief ordering the Commissioner of the Food and Drug Administration (“FDA”) and the U.S. Department of Health and Human Services (“HHS”), of which FDA is a constituent agency, to respond to a citizen petition submitted by the Physicians Committee for Responsible Medicine (“Physicians Committee”). The petition requested, on the product packaging and labeling of all dairy cheese products, a notice disclosing that dairy cheese contains reproductive hormones that may increase breast cancer mortality risk. Defendants have failed to respond to the petition within the

time period prescribed by federal regulations, in violation of the Administrative Procedure Act. In addition, HHS has failed to timely respond to two Physicians Committee's Freedom of Information Act appeals.

JURISDICTION AND VENUE

2. Pursuant to the Administrative Procedure Act, 5 U.S.C. § 706, Defendants' citizen petition regulation, 21 C.F.R. § 10.30, and the Freedom of Information Act, 5 U.S.C. § 552(a)(6)(C)(i), the Physicians Committee has exhausted all administrative remedies and now seeks judicial review. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. §§ 552, 706. This court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1361. Venue lies in this district under 5 U.S.C. § 703.

PARTIES

3. Plaintiff Physicians Committee is a nonprofit public health organization that advocates for preventive medicine through proper nutrition, encourages higher standards for ethics and effectiveness in medical research, and conducts clinical research on the relationships between food and disease. The Physicians Committee is a national organization representing more than 175,000 members, including 12,000 physicians, as well as other medical professionals, scientists, and lay persons. The Physicians Committee brings this action on behalf of its members and on behalf of itself.

4. The Physicians Committee has a long history of educating the public about cancer prevention and assisting individuals with cancer in leading healthier lives:

a. In 1991, the Physicians Committee conducted a cancer prevention survey that showed that most members of the public were not aware of basic steps in cancer prevention.

b. In 1993, the Physicians Committee created the Cancer Prevention and Survival Fund, which operated a hotline to assist those with cancer, distributed printed educational material to health care providers, and produced and distributed public service announcements regarding cancer prevention. The Physicians Committee also started its Cancer Prevention and Survival Series publication line.

c. In 1999, the Physicians Committee created The Cancer Project to perform educational outreach on nutrition and cancer, support human clinical research, study the effects of diet changes in humans, and review the literature on factors affecting cancer risk.

d. In 2001, the Physicians Committee launched Food for Life, a community-based nutrition education program that teaches laypersons how certain foods and nutrients work to promote health and fight disease. Each Food for Life class features a nutrition lecture and live cooking demonstration in a group setting. The program offers a cancer prevention curriculum and operates in 44 states.

e. In 2019, the Physicians Committee launched Let's Beat Breast Cancer, a nationwide initiative that helps women reduce their risk for breast cancer via four strategies: eating plant-based foods, getting regular exercise, limiting alcohol, and maintaining a healthy weight.

5. Defendant Stephen Hahn, MD, is the Commissioner of Food and Drugs for FDA, which regulates the labeling of certain food products and is an agency within the meaning of 5 U.S.C. § 552(f)(1).

6. Defendant U.S. Department of Health and Human Services is an agency, within the meaning of 5 U.S.C. § 552(f)(1), of which FDA is a constituent agency.

STATEMENT OF FACTS

7. On October 3, 2019, the Physicians Committee submitted a petition pursuant to the citizen petition regulation, 21 C.F.R. § 10.30, requesting that the product packaging and labeling of all dairy cheese products disclose that dairy cheese contains reproductive hormones that may increase breast cancer mortality risk.

8. According to the Centers for Disease Control, breast cancer is among the most common causes of death in women. In 2016, the latest year for which incidence data are available, 245,299 new cases of female breast cancer were reported, and 41,487 women died of breast cancer in the United States. The average cost of breast cancer treatment services in the first year after diagnosis is \$47,452.

9. Consumption of high-fat dairy products, such as cheese, is associated with an increased risk for breast cancer, according to a 2017 study funded by the National Cancer Institute. Researchers examined the dietary intakes of 1,941 women diagnosed with breast cancer and compared them with the diets of women without breast cancer. The results showed that those who consumed the most American, cheddar, and cream cheeses had a 53 percent increased risk for breast cancer. Components in dairy such as insulin-like growth factor and other growth hormones may be among the reasons for the increased risk for cancer.

10. Australian researchers who measured hormone levels in 766 postmenopausal women found that those who consumed the most dairy products had 15 percent more estradiol in their bloodstreams, compared with women consuming little or no dairy products. Postmenopausal women with higher levels of estradiol in their bloodstreams have more than double the cancer risk, compared with women with lower levels.

11. Among women previously diagnosed with breast cancer, consumption of high-fat dairy products is associated with increased mortality risk. The Life After Cancer Epidemiology study included 1,893 women previously diagnosed with early-stage invasive breast cancer. After a median follow-up of 11.8 years, those consuming one or more servings of high-fat dairy products (e.g., cheese, ice cream, or whole milk) daily had a 49 percent higher breast cancer mortality, compared with those consuming less than one-half serving daily. This is in keeping with an earlier case-control study including 111 women diagnosed with breast cancer.

12. Data from the Women's Health Initiative show that a lower-fat, higher-carbohydrate diet emphasizing fruits, vegetables, and grains resulted in long-term health benefits. Compared with women who made no diet changes, the dietary intervention group had 15 percent lower long-term risk of breast cancer mortality, a 30 percent reduction in heart disease, and 13 percent lower risk of developing insulin-requiring diabetes. Possible mechanisms for these results include increased fiber intake, reductions in hormones associated with breast cancer, and improvements in LDL cholesterol, blood pressure, insulin, and glucose levels.

13. To ensure that Americans understand the potential significant risks, and resulting long-term costs, of consuming dairy cheese products, the petition requested the following mandatory disclosure on the product packaging and labeling of all dairy cheese products: “Dairy cheese contains reproductive hormones that may increase breast cancer mortality risk.”

14. By letter dated October 4, 2019, Defendants acknowledged the petition and assigned it docket number FDA-2019-P-4643.

15. To date, however, Defendants have not provided a substantive response to the Physicians Committee’s petition despite a regulatory mandate to furnish a response within 180 days of receipt of a citizen petition.

16. The Physicians Committee is harmed by Defendants’ failure to timely respond to its petition. Despite the passage of nearly a year, Defendants have not made a determination regarding the product packaging and labeling disclosure requested by the Physicians Committee in the petition. This has made it more difficult and costly for the Physicians Committee to achieve its organizational objective of protecting its members and the public from the negative health effects of consuming harmful products. Defendants also have deprived the Physicians Committee of valuable information concerning their reasons and justifications for failing to carry out the action requested in the petition, thereby requiring the Physicians Committee to expend additional resources monitoring emerging science and sharing its findings with the public.

17. For example, a study funded by the National Cancer Institute, National Institutes of Health, and the World Cancer Research Fund and published in the *International Journal of Epidemiology* earlier this year showed that higher intakes of

cow's milk are associated with an increased risk for breast cancer. Researchers followed 52,795 women and found that those who consumed 1/4 to 1/3 cup of cow's milk per day had a 30 percent increased chance for breast cancer. One cup per day increased the risk by 50 percent, and 2 to 3 cups were associated with an 80 percent increased chance of breast cancer. Replacing dairy milk with soy milk was associated with a 32 percent reduced risk of breast cancer. The Physicians Committee widely publicized these findings.

18. Members of the Physicians Committee are also harmed by Defendants' failure to respond to the petition. The Physicians Committee's membership includes more than 12,000 physicians, as well as other medical professionals. Because Defendants, in failing to address the Physicians Committee's petition, continue to withhold from the public valuable information linking consumption of cheese and other high-fat dairy products to increased risk of breast cancer, these medical professionals must expend additional resources to treat their patients.

19. In January 2016, HHS published the *2015–2020 Dietary Guidelines for Americans* (“*2015 Dietary Guidelines*”).

20. The *2015 Dietary Guidelines* remain in effect and are implemented in all federal food and nutrition programs.

21. The *2015 Dietary Guidelines* state that “[b]reast cancer is the third leading cause of cancer death in the United States” and acknowledge evidence “that healthy eating patterns also are associated with a reduced risk of . . . postmenopausal breast cancers[.]”

22. Yet the document's "Healthy U.S.-Style Eating Pattern" recommends consuming three cups of dairy per day, which can increase breast cancer risk. Additionally, the document does not identify which food products may increase breast cancer mortality risk.

The Physicians Committee's First Freedom of Information Act Appeal

23. On September 11, 2015, the Physicians Committee requested from HHS's Program Support Center pursuant to the Freedom of Information Act, 5 U.S.C. § 552, all records relating to conflicts of interest and financial disclosures collected pursuant to the Federal Advisory Committee Act and/or 18 U.S.C. § 208, for all members of the 2015 Dietary Guidelines Advisory Committee.

24. On April 14, 2016, HHS denied the request, withholding 68 responsive pages in their entirety because, among other things, HHS collected relevant material from the federal advisory committee on "Executive Branch Confidential Financial Disclosure Forms (OGE 450)" statutorily exempt from disclosure.

25. On April 20, 2016, the Physicians Committee appealed, arguing that HHS's search had been inadequate. The Physicians Committee stated, "Sections 101 and 102 of the Ethics in Government Act expressly provide for public disclosure of certain reports by covered employees, including 'special government employees,' under certain circumstances. The purpose of these provisions is to ensure that relatively high level government officials provide public disclosures of interests that may bear on their work. Given the Dietary Guidelines Advisory Committee's high profile and immense influence, it seems without question that its members submitted such non-confidential reports to HHS."

26. The Physicians Committee further stated, “Even if HHS took special steps to eliminate public oversight of the Committee by using confidential reports to collect **all** information from the Committee, any discussions that ensued among agency personnel concerning those reports (e.g., a discussion whether a particular matter raised a serious conflict) still should be disclosed” (emphasis in original).

27. On April 26, 2016, HHS acknowledged the appeal and assigned it case number 16-0082-AA.

28. On August 3, 2017, HHS informed the Physicians Committee by telephone that its response to the appeal was still pending.

29. On August 28, 2018, the Physicians Committee contacted HHS by telephone regarding the status of the appeal. HHS stated that its response to the appeal was still pending.

30. On February 11, 2019, the Physicians Committee contacted HHS by telephone and left a voicemail message requesting an update regarding the status of the appeal.

31. HHS did not respond.

32. On August 17, 2020, HHS inquired whether the Physicians Committee intended to continue pursuing the appeal. The Physicians Committee confirmed that it intended to pursue the appeal.

33. The Physicians Committee has not received a response to appeal number 16-0082-AA.

The Physicians Committee’s Second Freedom of Information Act Appeal

34. On September 11, 2015, the Physicians Committee requested from HHS’s

Office of the Secretary pursuant to the Freedom of Information Act, 5 U.S.C. § 552, all records relating to conflicts of interest and financial disclosures collected pursuant to the Federal Advisory Committee Act and/or 18 U.S.C. § 208, for all members of the 2015 Dietary Guidelines Advisory Committee.

35. On September 21, 2015, HHS denied the request, withholding all responsive pages in their entirety because, among other things, HHS collected relevant material from the federal advisory committee on forms that were statutorily exempt from disclosure.

36. On October 15, 2015, the Physicians Committee appealed, arguing that HHS's search had been inadequate. The Physicians Committee stated, "Sections 101 and 102 of the Ethics in Government Act expressly provide for public disclosure of certain reports by covered employees, including 'special government employees,' under certain circumstances. The purpose of these provisions is to ensure that relatively high level government officials provide public disclosures of interests that may bear on their work. Given the Dietary Guidelines Advisory Committee's high profile and immense influence, it seems without question that its members submitted such non-confidential reports to HHS."

37. The Physicians Committee further stated, "Even if, as HHS asserts, HHS inappropriately took special steps to eliminate public oversight of the Committee by using confidential reports to collect **all** information from the Committee, any discussions that ensued among agency personnel concerning those reports (e.g., a discussion whether a particular matter raised a serious conflict) still should be disclosed" (emphasis in original).

38. On November 10, 2015, HHS acknowledged the appeal and assigned it case number 2016-00008-A-OS.

39. On March 15, 2017, the Physicians Committee contacted HHS by email regarding the status of the appeal.

40. On March 28, 2017, HHS responded, stating, “We have requested that a second search be performed for records within the scope of your request.”

41. On August 28, 2018, the Physicians Committee contacted HHS by email regarding the status of the appeal.

42. HHS did not respond.

43. On February 11, 2019, the Physicians Committee contacted HHS by telephone regarding the status of the appeal. HHS stated that its review was pending and that this had been the status since July 2018.

44. The Physicians Committee has not received a response to appeal case number 2016-00008-A-OS.

CLAIMS FOR RELIEF

CLAM ONE **(Administrative Procedure Act)**

45. The Physicians Committee realleges and incorporates by reference paragraphs 1–44.

46. According to the Administrative Procedure Act, 5 U.S.C. § 555(b), each agency shall proceed to conclude a matter presented to it within a reasonable time.

47. According to 21 C.F.R. § 10.30(e)(2), Defendants shall furnish a response within 180 days of receipt of a citizen petition.

48. More than 180 days have passed since the Physicians Committee submitted its petition.

49. Defendants' failure to provide a substantive response to the Physicians Committee's petition in accordance with Defendants' regulations constitutes an unreasonable delay under the Administrative Procedure Act, 5 U.S.C. § 706(1).

50. Defendants' failure to provide a substantive response to the Physicians Committee's petition in accordance with Defendants' regulations constitutes agency action unlawfully withheld under the Administrative Procedure Act, 5 U.S.C. § 706(1).

51. Defendants' actions harm the Physicians Committee as described in paragraphs 16–18.

CLAIM TWO
(Freedom of Information Act)

52. The Physicians Committee realleges and incorporates by reference paragraphs 1–44.

53. According to the Freedom of Information Act, 5 U.S.C. § 552(a)(6)(A)(ii), an agency shall make a determination with respect to any appeal within 20 business days.

54. HHS's failure to provide a determination with respect to the Physicians Committee's appeal, case number 16-0082-AA, within 20 business days constitutes a violation of the Freedom of Information Act.

CLAIM THREE
(Freedom of Information Act)

55. The Physicians Committee realleges and incorporates by reference paragraphs 1–44.

56. According to the Freedom of Information Act, 5 U.S.C. § 552(a)(6)(A)(ii), an agency shall make a determination with respect to any appeal within 20 business days.

57. HHS's failure to provide a determination with respect to the Physicians Committee's appeal, case number 2016-00008-A-OS, within 20 business days constitutes a violation of the Freedom of Information Act.

RELIEF REQUESTED

WHEREFORE, the Physicians Committee respectfully requests that this Court:

- A. Order Defendants to respond to the Physicians Committee's citizen petition by a date certain;
- B. Order HHS to promptly respond to the Physicians Committee's Freedom of Information Act appeals;
- C. Award the Physicians Committee its reasonable attorney fees and litigation costs incurred in this action; and
- D. Grant such other relief as the Court may deem just and proper.

Respectfully submitted,

/s/ Mark Kennedy

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Dated: September 22, 2020