

October 3, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted via <http://www.regulations.gov>

CITIZEN PETITION

The Physicians Committee for Responsible Medicine submits this petition pursuant to 21 C.F.R. § 10.30 to request that the Commissioner of the Food and Drug Administration (“FDA”) require all product packaging and labeling for dairy cheese products to disclose that such products contain reproductive hormones that can increase the risk of breast cancer mortality.

A. ACTION REQUESTED

The Physicians Committee requests that the Commissioner require manufacturers to include the following notice on the product packaging and labeling of all dairy cheese products:

Dairy cheese contains reproductive hormones that may increase breast cancer mortality risk.

B. STATEMENT OF GROUNDS

According to the Centers for Disease Control (“CDC”), breast cancer is among the most common causes of death in women.¹ 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.² The average cost of breast cancer treatment services in the first year after diagnosis is \$47,452.³

High-fat dairy products, such as cheese, are 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 (IGF-1) and other growth hormones may be among the reasons for the increased risk for cancer.⁴

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.⁵ Postmenopausal women with higher levels of estradiol in their bloodstreams have more than double the cancer risk, compared with women with lower levels.⁶

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, whole milk) daily had a 49 percent higher breast cancer mortality, compared with those consuming less than one-half serving daily.⁷ This is in keeping with an earlier case-control study including 111 women diagnosed with breast cancer.⁸

New 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.⁹

It should be noted that limited evidence suggests that dairy intake in general (that is, not specifically high-fat dairy products) is associated with a lower risk of breast cancer.¹⁰ This likely is because health-conscious individuals tend to consume high amounts of dairy products due to their successful promotion as "health foods." High-fat dairy products are much higher than low-fat dairy products in their concentrations of fat, saturated fat, and estrogenic hormones associated with cancer risk. Although some of the apparent effects of high-fat dairy products may be attributable to other factors, such as persistent organic pollutants and saturated fat present in those products, there is compelling evidence that the presence of reproductive hormones, and not those other substances, causes cancer progression.

To ensure that Americans understand the potential significant risks, and resulting long-term costs, of consuming dairy cheese products, the FDA should ensure that the notice above is prominently placed on product packaging and labeling for all dairy cheese products.

C. ENVIRONMENTAL IMPACT

The requested action is excluded under the provisions of 21 C.F.R. § 525.30 because the action will not result in the introduction of any substance into the environment.

D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30(b)(3), this information will be submitted if requested by the Commissioner following review of the petition.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

A handwritten signature in blue ink, appearing to read "Neal Barnard", is written over a horizontal line.

Neal D. Barnard, MD
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REFERENCES ATTACHED

- 1 CDC, *Breast Cancer Statistics*, <https://www.cdc.gov/cancer/breast/statistics/index.htm> (last reviewed May 28, 2019).
- 2 U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on November 2018 submission data (1999-2016): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; www.cdc.gov/cancer/dataviz, June 2019.
- 3 Blumen H, Fitch K, Polkus V. Comparison of treatment costs for breast cancer, by tumor stage and type of service. *Am Health Drug Benefits*. 2016;9:23-32.
- 4 McCann SE, Hays J, Baumgart CW, et al. Usual consumption of specific dairy foods is associated with breast cancer in the Roswell Park Cancer Institute Databank and BioRepository. *Curr Dev Nutr*. 2017;1:e000422.
- 5 Brinkman MT, Baglietto L, Krishnan K, et al. Consumption of animal products, their nutrient components and postmenopausal circulating steroid hormone concentrations. *Eur J Clin Nutr*. 2010;64:176-183.
- 6 Endogenous Hormones and Breast Cancer Collaborative Group. Endogenous sex hormones and breast cancer in postmenopausal women: reanalysis of nine prospective studies. *J Natl Cancer Inst*. 2002;94:606-616.
- 7 Kroenke CH, Kwan ML, Sweeney C, Castillo A, Caan BJ. High- and low-fat dairy intake, recurrence, and mortality after breast cancer diagnosis. *J Natl Cancer Inst*. 2013;105:616-623.
- 8 Ronco AL, De Stéfani E, Dáttoli R. Dairy foods and risk of breast cancer: a case-control study in Montevideo, Uruguay. *Eur J Cancer Prev*. 2002;11:457-463.
- 9 Prentice RL, Aragaki AK, Howard BV, et al. Low-fat dietary pattern among postmenopausal women influences long-term cancer, cardiovascular disease, and diabetes outcomes. *J Nutr*. 2019;149:1565-1574.
- 10 World Cancer Research Fund/American Institute for Cancer Research. *Diet, Nutrition, Physical Activity and Cancer: a Global Perspective*. Continuous Update Project Expert Report 2018. Available at <https://www.wcrf.org/dietandcancer>.