

**Petition**  
**Before the United States Food and Drug Administration**

April 25, 2024

**Requesting Rulemaking to Require a Warning Label for Milk and Other Dairy Products:**  
**“Warning: Linked to Increased Risk of Prostate, Breast, and Ovarian Cancer.”**

Submitted by People for the Ethical Treatment of Animals

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People for the Ethical Treatment of Animals (PETA)<sup>1</sup> submits this petition under the Administrative Procedure Act and Federal Food and Drug Administration (FDA) regulations,<sup>2</sup> requesting that the FDA commence rulemaking proceedings to require a label on milk and other dairy products warning consumers that the consumption of these products is associated with an increased risk of prostate, breast, and ovarian cancer.

## **A. ACTION REQUESTED**

PETA urges the FDA to issue a regulation requiring the following warning on milk and other dairy products:

### **“Warning: Linked to Increased Risk of Prostate, Breast, and Ovarian Cancer.”**

The “overwhelming majority of studies” indicate that the consumption of milk is associated with an increased risk of developing prostate cancer.<sup>3</sup> For instance, a prospective study published in 2013 found that a higher intake of skim/low-fat milk was primarily associated with low-grade and early-stage cancer and that a higher intake of whole-fat milk was associated with fatal prostate cancer.<sup>4</sup> The study also found that men who consumed only 1 serving of total dairy per day had a 12% higher risk of developing prostate cancer than men who rarely consumed dairy.<sup>5</sup> Many other studies have made similar findings, as discussed in Part B below.

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<sup>1</sup> PETA entities have more than 9 million members and supporters globally, and PETA U.S. is the largest animal rights organization in the world. PETA advances its mission, in part, by educating the public about the adverse health, environmental, and welfare effects of factory farming and consuming animals.

<sup>2</sup> 5 U.S.C. § 553(e); 21 C.F.R. § 10.30.

<sup>3</sup> Alex Sargsyan & Hima Bindu Dubasi, *Milk Consumption and Prostate Cancer: A Systematic Review*, 39 WORLD J. MEN’S HEALTH 419-28, 426 (2021), <https://doi.org/10.5534/wjmh.200051> (emphasizing that the studies included in the review suggest a link between consuming milk and developing prostate cancer). Pursuant to regulatory requirements, all studies cited for support herein are included in the appendix to this submission. See 21 C.F.R. §§ 10.30(b), 10.20(c)(1).

<sup>4</sup> Yan Song et al., *Whole Milk Intake is Associated with Prostate Cancer-Specific Mortality Among U.S. Male Physicians*, 143 J. NUTRITIONAL EPIDEMIOLOGY 189-196, 191 (2013), <https://doi.org/10.3945/jn.112.168484>.

<sup>5</sup> *Id.*

Studies also indicate that dairy consumption is associated with an increased risk of breast and ovarian cancer. A prospective study published in 2020 found that a higher milk intake more than doubled breast cancer risk, noting an “especially strong rise in risk up to 2/3 of an 8 ounce cup of milk” per day.<sup>6</sup> Another prospective study found that women who consumed 1 or more glasses of milk per day had a 55% increased risk of serous ovarian cancer,<sup>7</sup> which is the most common subtype of ovarian cancer.<sup>8</sup> As summarized in Part B below, many other studies have addressed the relationship between dairy consumption and risk for both cancer types.

Milk’s influence on insulin-like growth factor-1 (IGF-1)—which is important for the growth and survival of cancer cells—and estrogens in milk are likely contributors to the positive association between dairy consumption and the risk of prostate and breast cancer.<sup>9</sup> For ovarian cancer, the breakdown of lactose into galactose, which apparently has toxic effects on ovarian tissues, may explain its positive association with dairy consumption.<sup>10</sup> Although the exact mechanisms underlying these associations remain under investigation,<sup>11</sup> scientific studies

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<sup>6</sup> Gary E. Fraser et al., *Dairy, Soy, and Risk of Breast Cancer: Those Confounded Milks*, 49 INT’L J. EPIDEMIOLOGY 1526-37, 1534 (Feb. 25, 2020), <https://doi.org/10.1093/ije/dyaa007>.

<sup>7</sup> Kathleen M. Fairfield et al., *A Prospective Study of Dietary Lactose and Ovarian Cancer*, 110 INT’L J. CANCER 271-77, 273 (2004), <https://onlinelibrary.wiley.com/doi/10.1002/ijc.20086>.

<sup>8</sup> *What is Ovarian Cancer?*, AM. CANCER SOC’Y, <https://www.cancer.org/cancer/types/ovarian-cancer/about/what-is-ovarian-cancer.html> (last visited Apr. 22, 2024).

<sup>9</sup> See generally Li-Qiang Qin et al., *Milk Consumption and Circulating Insulin-Like Growth Factor-I Level: A Systematic Literature Review*, 60 INT’L J. FOOD SCIS. NUTRITION 330-40, 334 (2009) [hereinafter Qin et al., *Milk Consumption*], <https://doi.org/10.1080/09637480903150114>; see also Eleanor L. Watts et al., *Circulating Insulin-Like Growth Factor-I, Total and Free Testosterone Concentrations and Prostate Cancer Risk in 200,000 Men in UK Biobank*, 148 INT’L J. CANCER 2274-88, 2279, 2285-86 (2021), <https://doi.org/10.1002/ijc.33416>; Neil Murphy et al., *Insulin-Like Growth Factor-1, Insulin-Like Growth Factor-Binding Protein-3, and Breast Cancer Risk: Observational and Mendelian Randomization Analyses with ~ 430,000 Women*, 31 ANNALS ONCOLOGY 641-49, 641 (2020), <https://doi.org/10.1016/j.annonc.2020.01.066>.

<sup>10</sup> See Susanna C. Larsson et al., *Milk and Lactose Intakes and Ovarian Cancer Risk in the Swedish Mammography Cohort*, 80 AM. J. CLINICAL NUTRITION 1353-57, 1353, 1356-57 (2004), <https://doi.org/10.1093/ajcn/80.5.1353>.

<sup>11</sup> The FDA has required a warning label even when the exact mechanism causing adverse consequences was not fully understood. See 49 Fed. Reg. 13681 (requiring a warning label for certain protein products because the prolonged use resulted in sudden deaths, although “[t]he exact mechanism of such deaths remain[ed] in question”). In addition, the FDA has permitted certain health claims even without “significant scientific agreement.” See, e.g., Letter from Claudine J. Kavanaugh, Ph.D., M.P.H., R.D. Director, Off. of Nutrition and Food Labeling, to Guy H. Johnson, Ph.D., Johnson Nutrition Sols. LLC (Mar. 1, 2024), <https://www.fda.gov/media/176608/download?attachment>.

nonetheless strongly support the conclusion that the consumption of milk and other dairy products is associated with an increased risk of prostate, breast, and ovarian cancer.

Overall, studies reflect that consuming just 1 glass of milk per day—which is 1/3 of U.S. dietary guidelines’ recommended 3 servings of dairy per day—increases cancer risk. People should be warned of the association between dairy consumption and cancer risk because it is material information for consumers purchasing these products.<sup>12</sup> PETA urges the FDA to issue a regulation requiring a warning label on the packaging of milk and other dairy products.<sup>13</sup>

## **B. STATEMENT OF GROUNDS**

### **1. Legal Framework**

The FDA is responsible for assuring that food packaging is properly labeled.<sup>14</sup> Under the Food, Drug, and Cosmetic Act (FD&C Act), the FDA has the authority to require specific warnings and notices on food packaging labels.<sup>15</sup> The FDA derives this authority, in part, from section 403(a)(1) of the FD&C Act, which provides that a food product is misbranded if its labeling is false or misleading.<sup>16</sup> In determining whether a product’s labeling is misleading, the FDA considers, among other things,

not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the

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<sup>12</sup> The FDA should, at a minimum, require a warning label for milk in light of the numerous studies that have found an association between consuming milk and an increased cancer risk. Although study results are inconsistent as to the association between dairy products *other than milk* and cancer risk, the association between milk and total dairy consumption and cancer risk warrants a protective approach because any potential cancer risk is an important public health implication and is material for consumers to make an informed decision. *See* 63 Fed. Reg. 37030 (explaining that a warning statement was necessary on unprocessed juice products to warn consumers “of the potential hazard [of foodborne illness] so that they may make informed decisions on whether to purchase and consume such juice products”).

<sup>13</sup> 21 U.S.C. § 371(a); *see* 21 C.F.R. § 101.17 (detailing current warnings and notices).

<sup>14</sup> 21 U.S.C. § 371(a); *see* 21 U.S.C. § 343(a)(1).

<sup>15</sup> 21 U.S.C. §§ 321(n), 343(a)(1), 371(a).

<sup>16</sup> *Id.* § 343(a)(1); *see also* 21 U.S.C. § 321(k) (defining “label” to mean any “display of written, printed, or graphic matter upon the immediate container of any article”); 21 U.S.C. § 321(m) (defining “labeling” to mean “all labels and other written, printed, or graphic matter” either on any article or its containers or wrappers or that accompany the article).

use of the article to which the labeling or advertising relates under the conditions of use prescribed.<sup>17</sup>

The FDA has previously exercised this authority in eight circumstances to inform consumers of the potential health and safety consequences associated with certain food products, including a notice on foods containing psyllium husk due to the risk of choking<sup>18</sup> and a warning for unprocessed juices due to the risk of foodborne illnesses.<sup>19</sup> The FDA relies on scientific evidence demonstrating a link between the consumption of the product at issue and the risk of death or serious harm.<sup>20</sup> Accordingly, the FDA has the authority to require a warning that informs consumers of the link between dairy consumption and the risk of breast, ovarian, and prostate cancer.

## 2. Scientific Framework

Cancer is the second most common cause of death in the United States.<sup>21</sup> Studies have reported an association between the consumption of milk and other dairy products and an increased risk of prostate, breast, and ovarian cancer.<sup>22</sup>

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<sup>17</sup> 21 U.S.C. § 321(n).

<sup>18</sup> 21 C.F.R. § 101.17(f) (“NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty swallowing.”).

<sup>19</sup> *Id.* § 101.17(g) (“WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.”).

<sup>20</sup> *See, e.g.*, 49 Fed. Reg. 13679 (Apr. 6, 1984) (“FDA is establishing these requirements because of evidence that very low calorie diets consisting primarily of protein may cause serious medical problems or death. . . . [E]vidence has accumulated supporting the hypothesis that prolonged use of these protein products for rapid weight loss is related to the sudden onset of cardiac arrhythmias and death in otherwise healthy individuals.”).

<sup>21</sup> *Cancer*, CDC, <https://www.cdc.gov/chronicdisease/resources/publications/factsheets/cancer.htm> (last visited Apr. 22, 2024).

<sup>22</sup> *See, e.g.*, Song et al., *supra* note 4, at 191-95 (concluding milk, especially whole milk, was associated with a higher risk of developing prostate cancer); Fraser et al., *supra* note 6, at 1531-37 (indicating that dairy consumption, particularly milk, was positively associated with an increased risk of breast cancer); Fairfield et al., *supra* note 7, at 271, 274 (determining that lactose and dairy consumption was associated with ovarian cancer risk); *see also* Shaoyue Jin & Youjin Je, *Dairy Consumption and Total Cancer and Cancer-Specific Mortality: A Meta-Analysis of Prospective Cohort Studies*, 13 *ADVANCES NUTRITION* 1063-82, 1080 (2022), <https://doi.org/10.1093/advances/nmab135> (explaining that high milk consumption, particularly whole-fat milk, was associated with increased cancer mortality compared to low milk consumption, especially for females).

**a. The consumption of milk and other dairy products is associated with an increased risk of prostate cancer.**

Prostate cancer is a leading cause of cancer death in men.<sup>23</sup> Despite advancements in treatments, prostate cancer mortality rates remain high in the United States.<sup>24</sup> A 2021 systematic review found that “the overwhelming majority of studies . . . were suggestive of a link between milk consumption and increased risk of developing prostate cancer.”<sup>25</sup> Consequently, for “patients who are at higher risk of prostate development,” the study suggested that clinicians should recommend they “eliminate or reduce the consumption of milk or milk products.”<sup>26</sup> A 2021 meta-analysis determined that high milk consumption was associated with increased mortality of prostate cancer.<sup>27</sup> Notably, this meta-analysis included recent studies and accounted for several dairy products, which were individually stratified by, among other factors, cancer site.<sup>28</sup>

Among the prospective studies in the meta-analysis, one published in 2013 examined the relationship between the intake of different types of dairy and prostate cancer risk, noting cases that were high-grade, advanced, and fatal.<sup>29</sup> The study used data on 21,660 men from the Physicians Health Study.<sup>30</sup> All participants completed an initial questionnaire that asked about medical history and lifestyle, and they completed follow-up questionnaires about their health status after 18 weeks, 6 and 12 months, and annually thereafter.<sup>31</sup> Only the 18-week and 12-month questionnaires included food-frequency questions.<sup>32</sup> The 18-week questionnaire asked about the

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<sup>23</sup> *Key Statistics for Prostate Cancer*, AM. CANCER SOC’Y, <https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html> (last visited Apr. 22, 2024).

<sup>24</sup> *Id.*

<sup>25</sup> Sargsyan & Dubasi, *supra* note 3, at 426.

<sup>26</sup> *Id.*

<sup>27</sup> Jin & Je, *supra* note 22, at 1079-80 (noting that fermented milk consumption, however, was associated with decreased cancer mortality).

<sup>28</sup> *Id.*

<sup>29</sup> Song et al., *supra* note 4, at 189.

<sup>30</sup> *Id.* at 190 (explaining that the Physicians Health Study was “a randomized, blinded, and placebo-controlled trial of aspirin and  $\beta$ -carotene in the prevention of heart disease and cancer”).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

consumption of whole milk, skim/low-fat milk, and cold breakfast cereal.<sup>33</sup> The 12-month questionnaire asked about hard cheese and ice cream.<sup>34</sup> During 28 years of follow-up, the study identified 2,806 cases of prostate cancer.<sup>35</sup>

The study indicated that a higher intake of skim/low-fat milk was primarily associated with low-grade and early-stage cancer.<sup>36</sup> Furthermore, the study showed that “higher intakes of whole-fat milk predispose[d] men to a higher risk of developing fatal [prostate cancer] and, once they had the cancer, a higher risk of progression to fatal disease.”<sup>37</sup> Men with the highest total dairy consumption (1 serving per day) had a 12% higher risk of developing prostate cancer than men who rarely consumed dairy.<sup>38</sup> The study’s results support the conclusion that total dairy intake is associated with overall prostate cancer risk.<sup>39</sup>

A cohort study published in 2018 determined that dairy consumption was also associated with prostate cancer recurrence.<sup>40</sup> The study “prospectively examine[d] post-diagnostic intake of dairy foods in relation to risk of prostate cancer recurrence among 1334 men with non-metastatic prostate cancer who were enrolled in the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE™).”<sup>41</sup> “CaPSURE is a population-based registry of men with prostate cancer in the United States.”<sup>42</sup> From 2004 to 2006, CaPSURE participants completed a food-frequency questionnaire as part of a diet and lifestyle sub-study.<sup>43</sup> Importantly, the questionnaire asked

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<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 189-90.

<sup>36</sup> *Id.* at 191-92.

<sup>37</sup> *Id.* at 192.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 195.

<sup>40</sup> David Tat et al., *Milk and Other Dairy Foods in Relation to Prostate Cancer Recurrence: Data from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE)*, 78 THE PROSTATE 32-39, 33 (2018), <https://doi.org/10.1002/pros.23441>.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*



whether participants consumed more, less, or the same amount of each dairy product after diagnosis.<sup>44</sup> During 8 years of follow-up, the study identified 137 events of prostate cancer recurrence.<sup>45</sup>

The study determined that men “who consumed whole milk more than 4 times per week after prostate cancer diagnosis had a twofold increased risk of prostate cancer-specific mortality and a 51% increased risk of prostate cancer recurrence compared to men consuming whole milk [less than] 3 times per month.”<sup>46</sup> These results were particularly significant for “men at the upper range of overweight.”<sup>47</sup> The study’s findings align with the 2013 prospective study and indicate that whole milk consumption is most associated with fatal or prostate cancer-specific mortality.<sup>48</sup>

The positive association between dairy and prostate cancer is likely due, in large part, to milk’s influence on insulin-like growth factor-1 (IGF-1).<sup>49</sup> IGF-1 is associated with cancer risk because “[i]nsulin-like growth factors (IGF) and their associated binding proteins (IGFBP) are involved in the regulation of cell proliferation, differentiation and apoptosis.”<sup>50</sup> Approximately

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<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 35.

<sup>46</sup> *Id.* at 32, 36 (indicating there was no association between the other dairy items).

<sup>47</sup> *Id.* at 37.

<sup>48</sup> *Id.* at 37-38; Song et al., *supra* note 4, at 191.

<sup>49</sup> See generally Qin et al., *Milk Consumption, supra* note 9, at 334, 338 (explaining that most studies have found that milk is associated with increasing circulating IGF-1); see also Sargsyan & Dubasi, *supra* note 3, at 426 (emphasizing that the data suggests milk may contribute to prostate cancer development); D. Gunnell et al., *Are Diet-Prostate Cancer Associations Mediated by the IGF Axis? A Cross-Sectional Analysis of Diet, IGF-1, IGFBP-3 in Healthy Middle-Aged Men*, 88 BRITISH J. CANCER 1682-86, 1684-85 (2003), <https://doi.org/10.1038/sj.bjc.6600946> (“Men consuming higher levels of milk had raised levels of IGF-1.”); but see June M. Chan et al., *Dairy Products, Calcium, and Prostate Cancer Risk in the Physicians’ Health Study*, 74 AM. J. CLINICAL NUTRITION 549-54, 552-53 (2001), <https://doi.org/10.1093/ajcn/74.4.549> (indicating calcium intake may be the reason behind dairy’s association with prostate cancer); Li-Qiang Qin et al., *Estrogen: One of the Risk Factors in Milk for Prostate Cancer*, 62 MED. HYPOTHESES 133-42 (2004) [hereinafter Qin et al., *Estrogen*], [https://doi.org/10.1016/S0306-9877\(03\)00295-0](https://doi.org/10.1016/S0306-9877(03)00295-0) (studying estrogen as a causal factor for milk’s association with prostate cancer); Maria G. Kakkoura et al., *Dairy Consumption and Risks of Total and Site-Specific Cancers in Chinese Adults: An 11-Year Prospective Study of 0.5 Million People*, 20 BMC MED. 1-13, 10 (2022), <https://doi.org/10.1186/s12916-022-02330-3> (describing several mechanisms that may explain dairy’s association with cancer, like saturated fats, lactose, and various sex hormones).

<sup>50</sup> Ruth C. Travis et al., *A Meta-Analysis of Individual Participant Data Reveals an Association Between Circulating Levels of IGF-1 and Prostate Cancer Risk*, 76 CANCER RSCH. 2288-2300, 2289 (2016), <https://doi.org/10.1158/0008-5472.CAN-15-1551>; see generally Amir Abbas Samani et al., *The Role of the IGF System in Cancer Growth and Metastasis: Overview and Recent Insights*, 28 ENDOCRINE REVS. 20-47, 21 (2007), <https://doi.org/10.1210/er.2006->

99% of IGF-1 is bound to IGFBPs, with most bound to IGFBP-3.<sup>51</sup> This means “approximately 1% of total serum IGF-I is unbound.”<sup>52</sup> Studies suggest that raised levels of unbound, bioavailable IGF-1 increase cancer risk because IGF-1 is important for the growth and survival of cancer cells.<sup>53</sup> Studies further suggest that high milk intake increases the bioavailability of IGF-1.<sup>54</sup> Accordingly, milk’s influence on bioavailable IGF-1 likely explains the association between the consumption of milk and other dairy products and an increased risk of prostate cancer.<sup>55</sup>

An observational and Mendelian randomization study published in 2020 supports a causal connection between high concentrations of IGF-1 and prostate cancer risk.<sup>56</sup> This study

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0001 (“The IGF system consists of two ligands, IGF-I and IGF-II; three cell-membrane receptors, IGF-I receptor (IGF-IR), insulin receptor (IR), and IGF-II receptor (IGF-IIR); and six high-affinity IGF binding proteins, IGFBP-1 through -6.”); Thurkaa Shanmugalingam et al., *Is There a Role for IGF-1 in the Development of Second Primary Cancers?*, 5 CANCER MED. 3353-67, 3354 (2016), <https://doi.org/10.1002/cam4.871>.

<sup>51</sup> Murphy et al., *supra* note 9, at 641; The Endogenous Hormones and Breast Cancer Collaborative Group, *Insulin-Like Growth Factor 1 (IGF1), IGF Binding Protein 3 (IGFBP3), and Breast Cancer Risk: Pooled Individual Data Analysis of 17 Prospective Studies*, 11 LANCET ONCOLOGY 530-42, 540 (2010), [https://doi.org/10.1016/S1470-2045\(10\)70095-4](https://doi.org/10.1016/S1470-2045(10)70095-4) (noting that nutritional factors influence IGF concentrations).

<sup>52</sup> See Jeanette M. Beasley et al., *Associations of Serum Insulin-Like Growth Factor-I and Insulin-Like Growth Factor-Binding Protein 3 Levels with Biomarker-Calibrated Protein, Dairy Product and Milk Intake in the Women’s Health Initiative*, 111 BRITISH J. NUTRITION 847-53, 850 (2014), <https://doi.org/10.1017/S000711451300319X> (indicating that “a three-serving increase in milk intake per d[ay] was associated with an estimated average 18·6 % increase in free IGF-I levels”); The Endogenous Hormones and Breast Cancer Collaborative Group, *supra* note 51, at 540.

<sup>53</sup> Gunnell et al., *supra* note 49, at 1684-85; Shanmugalingam et al., *supra* note 50, at 3354.

<sup>54</sup> Kakkoura et al., *supra* note 49; Gunnell et al., *supra* note 49, at 1684-85 (indicating that “[m]en consuming higher levels of milk had raised levels of IGF-1”); Sean Harrison et al., *Does Milk Intake Promote Prostate Cancer Initiation or Progression via Effects on Insulin-Like Growth Factors (IGFs)? A Systematic Review and Meta-Analysis*, 28 CANCER CAUSES CONTROL 497-528, 519-20, 522 (2017), <https://doi.org/10.1007/s10552-017-0883-1> (suggesting that IGF-1 is a likely cause for the observed positive associations between milk and prostate cancer risk); *see also* Fraser et al., *supra* note 6, at 1534 (indicating that milk contains relatively high levels of IGF-1, which is unlikely to be destroyed by pasteurization).

<sup>55</sup> See Watts et al., *supra* note 9, at 2285-86; Travis et al., *supra* note 50; Pär Stattin et al., *Plasma Insulin-Like Growth Factor-I, Insulin-Like Growth Factor-Binding Proteins, and Prostate Cancer Risk: A Prospective Study*, 92 J. NAT’L CANCER INST. 1910-17 (2000), <https://doi.org/10.1093/jnci/92.23.1910>; *see also* Mitchell S. Harman et al., *Serum Levels of Insulin-Like Growth Factor I (IGF-I), IGF-II, IGF-Binding Protein-3, and Prostate-Specific Antigen as Predictors of Clinical Prostate Cancer*, 85 J. CLINICAL ENDOCRINOLOGY METABOLISM 4258-65, 4264 (Nov. 2000), <https://doi.org/10.1210/jcem.85.11.6990> (suggesting that “circulating IGF-I is a statistical risk factor for clinical prostate carcinoma”); Shanmugalingam et al., *supra* note 50, at 3354, 3358 (explaining recent studies have found that IGF-1 is associated with the risk of developing prostate cancer); *but see* Zhen-yu Song et al., *Circulating Vitamin D Level and Mortality in Prostate Cancer Patients: A Dose-Response Meta-Analysis*, 7 ENDOCRINE CONNECTIONS 294-303 (2018), <https://doi.org/10.1530/EC-18-0283> (studying vitamin D as a protective factor of prostate cancer); Edward Giovannucci et al., *A Prospective Study of Calcium Intake and Incident and Fatal Prostate Cancer*, CANCER EPIDEMIOL, BIOMARKERS & PREVENTION 203-10 (2006), <https://doi.org/10.1158/1055-9965.EPI-05-0586> (studying calcium); Qin et al., *Estrogen*, *supra* note 49 (studying estrogen).

<sup>56</sup> Watts et al., *supra* note 9, at 2279, 2285-86.

“examine[d] the associations of serum concentrations of IGF-1 . . . with prostate cancer incidence and mortality” and “investigated potential causal associations of IGF-1 with prostate cancer” using Mendelian randomization analyses.<sup>57</sup>

The observational study used data on 199,689 men from the UK Biobank, which is a large and prospective cohort of over 500,000 adults.<sup>58</sup> Between 2006 and 2010, the UK Biobank used a questionnaire to collect a range of information from participants, including diet and lifestyle.<sup>59</sup> The participants also provided blood samples.<sup>60</sup> Serum concentrations of circulating IGF-1, among other things, were measured from these samples.<sup>61</sup> A subset of cohort participants were part of a repeat assessment between 2012 and 2013.<sup>62</sup> During 6.9 years of follow-up, 5,402 men were diagnosed with prostate cancer and 295 men died from it.<sup>63</sup> The two-step Mendelian randomization study estimated IGF-1 associations with overall prostate cancer risk using data from a genome-wide association study of UK Biobank participants as the genetic instruments for IGF-1 and data from consortia (79,148 prostate cancer cases and 61,106 controls) for the genetic outcome analyses.<sup>64</sup>

The study concluded that its “observational and [Mendelian randomization] analyses provide[d] strong evidence that men with higher circulating IGF-1 have an elevated risk of prostate cancer.”<sup>65</sup> The observational study further suggested an increased risk of prostate cancer mortality, indicating “that IGF-1 is associated with risk for more severe forms of prostate cancer and/or may

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<sup>57</sup> *Id.* at 2275.

<sup>58</sup> *Id.* at 2276.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 2278.

<sup>64</sup> *Id.* at 2275, 2277-78.

<sup>65</sup> *Id.* at 2279.

increase the risk of prostate cancer progression.”<sup>66</sup> The study concluded that the association between IGF-1 and prostate cancer was likely causal, which was further supported by previous epidemiological evidence.<sup>67</sup>

Because the “overwhelming majority of studies” suggest a link between milk consumption and prostate cancer,<sup>68</sup> which is likely due to milk’s influence on IGF-1, men should be warned that the consumption of milk and other dairy products may increase their risk of prostate cancer. Moreover, men should be especially warned of the association between whole milk and the risk of fatal prostate cancer and mortality. Such consequences are material information for men to know before purchasing and consuming milk.

**b. The consumption of milk and other dairy products is associated with an increased risk of breast cancer.**

Globally, breast cancer is the most frequently discovered cancer in women.<sup>69</sup> In the U.S., breast cancer is the second leading cause of cancer death in women.<sup>70</sup> Additionally, “[i]n recent years, incidence rates have increased by 0.6% per year.”<sup>71</sup> About 240,000 cases of breast cancer are diagnosed each year in the U.S.<sup>72</sup>

Cohort studies show that the consumption of milk and other dairy products is associated with an increased risk of breast cancer.<sup>73</sup> For example, a prospective study published in 2020

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<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> Sargsyan & Dubasi, *supra* note 3, at 426.

<sup>69</sup> *Breast Cancer Statistics*, WORLD CANCER RSCH. FUND INT’L, <https://www.wcrf.org/cancer-trends/breast-cancer-statistics/> (last visited Apr. 22, 2024).

<sup>70</sup> *Key Statistics for Breast Cancer*, AM. CANCER SOC’Y, <https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html> (last visited Apr. 22, 2024).

<sup>71</sup> *Id.*

<sup>72</sup> *Basic Information*, CDC, [https://www.cdc.gov/cancer/breast/basic\\_info](https://www.cdc.gov/cancer/breast/basic_info) (last visited Apr. 22, 2024).

<sup>73</sup> See Fraser et al., *supra* note 6, at 1531 (indicating that dairy consumption, particularly milk, was positively associated with an increased risk of breast cancer,); Kakkoura et al., *supra* note 49, at 6 (suggesting dairy consumption was associated with a 17% increased risk of breast cancer); Joanna Kaluza et al., *Long-Term Consumption of Non-Fermented and Fermented Dairy Products and Risk of Breast Cancer by Estrogen Receptor Status – Population-Based Prospective Cohort Study*, 40 CLINICAL NUTRITION 1966-73, 1968 (2021), <https://doi.org/10.1016/j.clnu.2020.09.013> (determining that high, long-term consumption of milk was associated with an increased risk of hormone

“evaluate[d] associations between intakes of soy milk, other soy products, dairy milk and other dairy foods with risk of breast cancer.”<sup>74</sup> The study also evaluated the “independent associations between soy, dairy consumption and breast cancer incidence.”<sup>75</sup> In examining these associations, the study noted that the recommended consumption of milk per day in the U.S. is about 3 eight-ounce cups.<sup>76</sup>

The study used data from the Adventist Health Study-2—a large cohort of North American Adventists.<sup>77</sup> The study’s analytical sample consisted of 52,795 North American women who were initially free of cancer.<sup>78</sup> The women’s diets were assessed using a food-frequency questionnaire at the time of enrollment in the Adventist Health Study-2.<sup>79</sup> The questionnaire included 51 items related to soy and 17 items related to dairy.<sup>80</sup> During 7.9 years of follow-up, the study identified 1,057 incidents of breast cancer, 906 of which were in postmenopausal women and 121 were in premenopausal women.<sup>81</sup>

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receptor-positive breast cancer); *but see* Susan E. McCann et al., *Usual Consumption of Specific Dairy Foods is Associated with Breast Cancer in the Roswell Park Cancer Institute Data Bank and BioRepository*, 1 CURRENT DEVS. NUTRITION 1-6, 4-6 (2017), <https://doi.org/10.3945/cdn.117.000422> (indicating cancer risk may differ based on the type of dairy consumed); Lena M. Nilsson et al., *Dairy Products and Cancer Risk in a Northern Sweden Population*, 72 NUTRITION & CANCER. 409–20, 417 (2020), <https://doi.org/10.1080/01635581.2019.1637441> (finding no adverse or beneficial effects of milk and other dairy products from a cancer risk perspective). Case-control studies also support the conclusion that milk is associated with an increased risk of breast cancer, although these studies are mixed on other dairy products. *See, e.g.*, Hector R. Galván-Salazar et al., *Association of Milk and Meat Consumption with the Development of Breast Cancer in a Western Mexican Population*, 10 BREAST CARE 393-96, 395 (2015), <https://doi.org/10.1159/000442230> (finding that high milk consumption increased breast cancer risk); A. L. Ronco et al., *Dairy Foods and Risk of Breast Cancer: A Case-Control Study in Montevideo, Uruguay*, 11 EUROPEAN J. CANCER PREVENTION 457-63, 459-61 (2002), <https://doi.org/10.1097/00008469-200210000-00008> (concluding that a high intake of high-fat milk and other dairy products was associated with a significant, increased risk of breast cancer while intake of ricotta cheese and skim yogurt was associated with a decreased risk).

<sup>74</sup> Fraser et al., *supra* note 6, at 1527.

<sup>75</sup> *Id.* at 1527.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 1527, 1529.

<sup>79</sup> *Id.* at 1527-28.

<sup>80</sup> *Id.* at 1528 (explaining that a calibration study group of 542 women further provided an overnight urine sample and participated in six 24-hour dietary recalls).

<sup>81</sup> *Id.* at 1529.

The study found that dairy foods, especially milk, were associated with an increased risk of breast cancer.<sup>82</sup> The risk did not significantly differ among hormone-receptor cancer subtypes or between full-fat and reduced-fat milks.<sup>83</sup> The study determined that those who consumed a higher amount of milk had more than doubled their risk of breast cancer, noting an especially strong rise in risk up to 2/3 of an 8-ounce cup of milk per day.<sup>84</sup> When substituting soy milk for an equivalent quantity of dairy milk, the study found a “marked reduction in risk.”<sup>85</sup>

A prospective study published in 2021 revealed that the long-term consumption of two daily servings of non-fermented milk, compared to no milk, significantly increased the risk of estrogen receptor-positive (ER+) and progesterone receptor-positive (PR+) breast cancer by 30%.<sup>86</sup> This study “examined the association between long-term consumption of non-fermented and fermented dairy products in relation to the risk of breast cancer defined by hormone receptor status.”<sup>87</sup> The study also assessed whether any associations varied by body weight.<sup>88</sup>

The study used data on 33,780 women from the Swedish Mammography Cohort.<sup>89</sup> Cohort participants underwent a mammography screening and took two food-intake questionnaires.<sup>90</sup> Because the second questionnaire was more comprehensive, the study used its results to establish a baseline.<sup>91</sup> The second questionnaire included 96 food items and asked 3 questions about non-fermented milk—“milk 0.5% fat, milk 1.5% fat, and milk 3% fat”—and 5 questions about fermented dairy products—“sour milk/yogurt 0.5% fat, sour milk/ yogurt 3% fat, cottage cheese,

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<sup>82</sup> *Id.* at 1533-34.

<sup>83</sup> *Id.* at 1529, 1533.

<sup>84</sup> *Id.* at 1533-34 (“The non-linear positive association that we find for dairy milk, if causal, could indicate that a pathway becomes relatively saturated at around 2/3 of an 8 ounce cup of milk each day.”).

<sup>85</sup> *Id.* at 1531.

<sup>86</sup> Kaluza et al., *supra* note 73, at 1966-73.

<sup>87</sup> *Id.* at 1967.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

hard cheese low fat, and hard cheese full fat.”<sup>92</sup> During 16.6 years of follow-up, the study identified 1,870 women with breast cancer, and among these women, 66.7% were ER+/PR+ and 11.2% were ER-/PR-.<sup>93</sup>

The study concluded that the consumption of milk was associated with an increased risk of ER+/PR+ breast cancer, particularly in “normal weight women.”<sup>94</sup> The study separately examined low-fat and full-fat milk but found no difference in results based on fat content.<sup>95</sup> Although the study observed no association between fermented dairy products and ER+/PR+ breast cancer, the study found that high, long-term consumption of fermented dairy products was associated with a decreased risk of ER-/PR- breast cancer.<sup>96</sup> The study recognized, however, that the number of ER-/PR- cases was limited.<sup>97</sup> Importantly, the study found a significant association between the consumption of non-fermented milk and ER+/PR+ breast cancer.<sup>98</sup>

The results from a prospective study published in 2022 similarly showed that the consumption of dairy (mainly milk) was associated with an increased risk of breast cancer.<sup>99</sup> This study focused on Chinese adults because dairy consumption in China is lower than that of Western populations.<sup>100</sup> The study examined “the associations of habitual dairy consumption with total site-specific cancer incidence in the China Kadoorie Biobank,” which is “a large nationwide prospective cohort study of Chinese adults.”<sup>101</sup>

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 1968.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 1972.

<sup>99</sup> Kakkoura et al., *supra* note 49, at 2.

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

The study's analytical sample included 510,146 participants from the China Kadoorie Biobank study, which recruited adults from ten geographically diverse regions in China.<sup>102</sup> Diets were assessed at baseline using a questionnaire that collected information on the consumption of 12 major food groups, including dairy.<sup>103</sup> A blood sample was also collected.<sup>104</sup> Randomly selected participants took part in two resurveys.<sup>105</sup> The second resurvey collected detailed dietary data, including daily portions of 3 subtypes of dairy products: cow milk, yogurt, and other dairy products, like cheese and milk powder.<sup>106</sup> The study adjusted for soybean intake and fruit.<sup>107</sup> During 10.8 years of follow-up, the study identified 29,277 cancer cases.<sup>108</sup>

In comparison to non-consumers, the study concluded that regular dairy consumers, who consumed dairy at least once per week, had a 22% higher risk of female breast cancer.<sup>109</sup> The study indicated that this association was independent of other lifestyle factors.<sup>110</sup> Although the study could not assess the associations between different types of dairy products, the participants reported consuming mainly milk.<sup>111</sup> All in all, the consumption of milk and other dairy products was associated with an increased risk of breast cancer in Chinese adults with relatively low dairy consumption.<sup>112</sup>

As with prostate cancer, the positive association between dairy and breast cancer may be due, at least in part, to milk's influence on IGF-1. Several studies have found an association

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<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 2-3.

<sup>104</sup> *Id.* at 3.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 2, 7, 10 (noting that Chinese adults rarely consumed cheese and primarily consumed milk of any dairy product).

<sup>107</sup> *Id.* at 3.

<sup>108</sup> *Id.* at 5.

<sup>109</sup> *Id.* at 6.

<sup>110</sup> *Id.* at 10.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*



between high concentrations of IGF-1 and breast cancer, particularly hormone receptor-positive breast cancer.<sup>113</sup> A pooled analysis of seventeen prospective studies showed that circulating IGF-1 is positively associated with breast cancer risk and that this association does not differ markedly by menopausal status, but may be confined to estrogen-receptor-positive tumors.<sup>114</sup> Epidemiological evidence also suggests a positive association between IGF-1 and breast cancer risk, including breast cancer as a secondary primary cancer.<sup>115</sup>

For example, a recent observational and Mendelian randomization study published in 2020 found an association between IGF-1 and breast cancer that was likely causal.<sup>116</sup> The researchers conducted complementary studies to examine IGF-1's role in breast cancer development.<sup>117</sup> The observational study examined data on 206,263 women from the UK Biobank, a large prospective cohort.<sup>118</sup> Participants completed a questionnaire that gathered information related to, among other things, diet and lifestyle.<sup>119</sup> In addition, physical measurements and blood samples were collected

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<sup>113</sup> The Endogenous Hormones and Breast Cancer Collaborative Group, *supra* note 51, at 539-40; see Murphy et al., *supra* note 9; see Susan E. Hankinson et al., *Circulating Concentrations of Insulin-Like Growth Factor 1 and Risk of Breast Cancer*, 351 LANCET ONCOLOGY 1393-96, 1393 (1998), [https://doi.org/10.1016/S0140-6736\(97\)10384-1](https://doi.org/10.1016/S0140-6736(97)10384-1) (“A positive relation between circulating IGF-I concentration and risk of breast cancer was found among premenopausal but not postmenopausal women.”); Paolo Toniolo et al., *Serum Insulin-Like Growth Factor-I and Breast Cancer*, 88 INT’L J. CANCER 828-832, 830 (2000), [https://doi.org/10.1002/1097-0215\(20001201\)88:5<828::AID-IJC22>3.0.CO;2-8](https://doi.org/10.1002/1097-0215(20001201)88:5<828::AID-IJC22>3.0.CO;2-8) (“In this prospective cohort study, we observed that the risk of pre-menopausal breast cancer increases with increasing circulating levels of IGF-I. This association appeared to be limited to cancers arising before menopause and before age 50.”).

<sup>114</sup> The Endogenous Hormones and Breast Cancer Collaborative Group, *supra* note 51, at 540 (noting that nutritional factors influence IGF concentrations); see also S. Rinaldi et al., *IGF-I, IGFBP-3 and Breast Cancer Risk in Women: The European Prospective Investigation into Cancer and Nutrition (EPIC)*, 13 ENDOCRINE-RELATED CANCER 593-605, 601-02 (2006), <https://doi.org/10.1677/erc.1.01150> (observing an overall increased breast cancer risk in women over 50 whose serum IGF-1 levels were in the upper part of the normal range); Laura Baglietto et al., *Circulating Insulin-Like Growth Factor-1 and Binding Protein-3 and the Risk of Breast Cancer*, 16 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 763-68, 766-78 (2007), <https://doi.org/10.1158/1055-9965.EPI-06-0960> (finding age-dependent associations between circulating concentrations of IGF-1 and breast cancer risk).

<sup>115</sup> Shanmugalingam et al., *supra* note 50; see Rudolf Kaaks et al., *Insulin-Like Growth Factor 1 and Risk of Breast Cancer by Age and Hormone Receptor Status – A Prospective Study within the EPIC Cohort*, 134 INT’L J. CANCER 2683-90, 2686-89 (2013), <https://doi.org/10.1002/ijc.28589> (indicating a direct association between IGF-1 concentrations and the risk of developing receptor-positive breast cancer at or after 50 years old, although no association was found with receptor-negative cancer).

<sup>116</sup> Murphy et al., *supra* note 9, at 645.

<sup>117</sup> *Id.* at 642.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

from all participants.<sup>120</sup> During 7.1 years of follow-up, the study identified 4,360 cases of breast cancer.<sup>121</sup> The Mendelian randomization study “examine[d] potential causal associations by combining genetic variants associated with circulating IGF-1 and IGFBP-3 concentrations in genome-wide association studies (GWAS), and then assessing the association of these variants with breast cancer (overall, ER+, and ER-) risk in a large consortium of 122,977 breast cancer cases and 105,974 controls.”<sup>122</sup>

The results of the observational study showed “that higher circulating concentrations of IGF-1 were associated with a greater breast cancer risk” regardless of menopausal status.<sup>123</sup> The Mendelian randomization study similarly revealed a positive association between IGF-1 concentrations and breast cancer risk, specifically ER+ breast cancer.<sup>124</sup> The researchers concluded that the “observational and [Mendelian randomization] results support a probable causal relationship between circulating IGF-1 concentrations and breast cancer.”<sup>125</sup> Importantly, the results indicated that “pharmacological or *lifestyle interventions targeting the IGF pathway* may be beneficial in preventing breast [cancer].”<sup>126</sup>

In light of the studies demonstrating an association between dairy consumption and breast cancer risk, one lifestyle intervention is the elimination of dairy. Accordingly, women should be warned of the association between the consumption of milk and other dairy products and breast

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<sup>120</sup> *Id.*

<sup>121</sup> *Id.* at 644.

<sup>122</sup> *Id.* at 642.

<sup>123</sup> *Id.* at 645.

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* at 648.

<sup>126</sup> *Id.* (emphasis added). The estrogen content of milk provides an additional, plausible mechanism for dairy products’ influence on breast cancer risk. Estrogens are strongly associated with breast cancer risk, and dairy products contain measurable quantities of estrogens produced by cows. Fraser et al., *supra* note 6, at 1533-34; Kakkoura et. al, *supra* note 49, at 10.

cancer risk. This association is material information considering the potential consequences of consuming dairy, particularly milk, in high amounts and for a prolonged period of time.

**c. The consumption of milk and other dairy products is associated with an increased risk of ovarian cancer.**

In the U.S., ovarian cancer causes more deaths in women than any other cancer of the female reproductive system.<sup>127</sup> Because ovarian cancer incidence differs between countries, researchers suggest that diet could be the reason for such geographical variation.<sup>128</sup> Cohort and case-control studies have found an association between frequent intake of milk and other dairy products and ovarian cancer risk, particularly for the serous subtype.<sup>129</sup>

A prospective study published in 2004 examined the relationship between lactose consumption and ovarian cancer risk, noting that “current dietary recommendations for women include increasing calcium intake” and that “milk is widely promoted as a source of calcium.”<sup>130</sup> The study used data on 80,326 women from the Nurses’ Health Study, which invited registered nurses from eleven states to complete questionnaires biennially beginning in 1976.<sup>131</sup> The study added a 61-item questionnaire on food frequency in 1980.<sup>132</sup> The questionnaire assessed intake of

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<sup>127</sup> *Ovarian Cancer Statistics*, CDC, <https://www.cdc.gov/cancer/ovarian/statistics/index.htm> (last visited Apr. 22, 2024); *Key Statistics for Ovarian Cancer*, AM. CANCER SOC’Y, <https://www.cancer.org/cancer/types/ovarian-cancer/about/key-statistics.html> (last visited Apr. 22, 2024).

<sup>128</sup> See Fairfield et al., *supra* note 7, at 271 (“Differences in ovarian cancer incidence between countries as well as migrant studies suggest lifestyle and dietary patterns as possible etiologic factors.”); Mette T. Faber et al., *Use of Dairy Products, Lactose, and Calcium and Risk of Ovarian Cancer – Results from a Danish Case-Control Study*, 51 ACTA ONCOLOGICA 454-464, 454 (2012), <https://doi.org/10.3109/0284186X.2011.636754> (“Due to the geographical variation in ovarian cancer incidence it has been suggested that lifestyle parameters, such as type of diet may influence the risk of developing ovarian cancer.”).

<sup>129</sup> Fairfield et al., *supra* note 7, at 271, 274; Larsson et al., *supra* note 10, at 1356; Faber et al., *supra* note 128, at 460-63; Lawrence H. Kushi et al., *Prospective Study of Diet and Ovarian Cancer*, 149 AM. J. EPIDEMIOLOGY 21-32, 27-28 (1999), <https://doi.org/10.1093/oxfordjournals.aje.a009723>; but see Jeanine M. Genkinger et al., *Dairy Products and Ovarian Cancer: A Pooled Analysis of 12 Cohort Studies*, 15 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 364-72, 369-70 (2006), <https://doi.org/10.1158/1055-9965.EPI-05-0484> (finding no statistically significant association between milk and ovarian cancer risk and a marginally significant association between lactose and ovarian cancer risk).

<sup>130</sup> Fairfield et al., *supra* note 7, at 271.

<sup>131</sup> *Id.* at 271-72.

<sup>132</sup> *Id.*

skim or low-fat milk, whole milk, yogurt, ice cream, cottage cheese, hard cheeses, and butter.<sup>133</sup>

The study expanded the food-frequency questionnaire to 126 items in 1984, 1986, and 1990 by adding sour cream, cream cheese, and other cheeses.<sup>134</sup> During 16 years of follow-up, the study confirmed 337 cases of ovarian cancer, 301 of which were invasive.<sup>135</sup>

The study “observed an elevated risk of ovarian cancer associated with high cumulative lactose consumption that was statistically significant for the serous subtype,”<sup>136</sup> which is the most common subtype of ovarian cancer.<sup>137</sup> Specifically, the study found that women who consumed 1 or more servings of skim or low-fat milk per day had a 69% increased risk of serous ovarian cancer.<sup>138</sup> In combining all types of milk,<sup>139</sup> women had a 55% increased risk of serous ovarian cancer.<sup>140</sup> Notably, to reach the U.S. recommended intake of calcium from dairy alone, the study determined that women would need to drink 3 glasses of milk per day.<sup>141</sup> Yet, women “with dietary lactose at a level recommended for optimal calcium” had “a 2-fold increase in risk” for serous ovarian cancer.<sup>142</sup> Overall, the results showed that women who consumed a high intake of dairy,<sup>143</sup> particularly milk,<sup>144</sup> were at an increased risk of serous ovarian cancer.<sup>145</sup>

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<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 272.

<sup>136</sup> *Id.* at 274.

<sup>137</sup> *What is Ovarian Cancer?*, AM. CANCER SOC’Y, <https://www.cancer.org/cancer/types/ovarian-cancer/about/what-is-ovarian-cancer.html> (last visited Apr. 22, 2024).

<sup>138</sup> Fairfield et al., *supra* note 7, at 273.

<sup>139</sup> Although the study found no association between whole milk and ovarian cancer risk, the study noted that by 1990 whole milk contributed to less than 5% of dietary lactose. *Id.* at 274. Yet, in 1980, when whole milk accounted for 23% of dietary lactose, the study observed a positive association with whole milk consumption. *Id.*

<sup>140</sup> *Id.* at 273.

<sup>141</sup> *Id.* at 276.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* at 273 (indicating that women who consumed 5 or more servings of yogurt per week had an increased risk for serous ovarian cancer as well).

<sup>144</sup> *Id.* at 276 (explaining that skim and low-fat milk were the largest contributors to dietary lactose in the study).

<sup>145</sup> *Id.*

A prospective study published in 2004 similarly concluded that a high intake of milk and other dairy products is associated with an increased risk of serous ovarian cancer.<sup>146</sup> This study “examined the possibility of an association of the consumption of milk and other dairy products with the incidence of ovarian cancer.”<sup>147</sup> The study used data from the Swedish Mammography Cohort, noting that Sweden “has one of the highest rates of ovarian cancer in the world, and its citizens consume a wide range of dairy products.”<sup>148</sup> From 1987 to 1990, cohort participants took a self-administered food-frequency questionnaire, which included 3 types of milk, 2 types of yogurt, cheese, ice cream, and butter.<sup>149</sup> The study’s analytical sample included 61,084 women from the cohort.<sup>150</sup> During 13.5 years of follow-up, the study identified 266 women with invasive epithelial ovarian cancer, “including 125 serous, 48 endometrioid, 21 mucinous, 5 clear cell, and 67 other or unknown histologic subtypes.”<sup>151</sup>

The study’s results are largely consistent with the findings from the Nurses’ Health Study.<sup>152</sup> The study found that women who consumed more than 1 glass of milk per day had double the risk of serous ovarian cancer than women who seldomly drank milk.<sup>153</sup> The study indicated that each 11-gram per day increase in lactose (or 1 glass of milk) was associated with a 20% increased risk of serous ovarian cancer.<sup>154</sup> Of the dairy products studied, “milk showed the strongest positive association with serous ovarian cancer.”<sup>155</sup> This study indicates that a high intake of milk and other dairy products is associated with an increased risk of serous ovarian cancer.<sup>156</sup>

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<sup>146</sup> Larsson et al., *supra* note 10, at 1353.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.* at 1353-54.

<sup>150</sup> *Id.* at 1354.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.* at 1356.

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.* at 1355.

<sup>156</sup> *Id.* at 1357.

The results of a 2012 study further support the conclusion that dairy intake, particularly milk, is associated with an increased risk of ovarian cancer.<sup>157</sup> This study “examined the association between intake of specific dairy products and related nutrients (lactose and calcium) and ovarian cancer risk.”<sup>158</sup> The study used data on 554 women with invasive, epithelial ovarian cancer from the Danish MALOVA study—a large, case-control study of Danish women.<sup>159</sup> From 1995 to 1999, women, “who were scheduled for an explorative laparotomy or laparoscopy because of suspicion of an ovarian tumour,” provided blood and tissue samples for the study.<sup>160</sup> The women also participated in an interview where they answered open-ended questions about their intake of milk, soured milk products, yogurt, cheese, and sour cream.<sup>161</sup>

The results of the study showed that women who consumed more than 2 glasses of milk per day had a 41% increased risk of ovarian cancer than those who did not consume milk.<sup>162</sup> Each additional glass of milk was associated with a 14% increased risk of ovarian cancer.<sup>163</sup> Women who consumed soured milk products and yogurt also had an increased risk of ovarian cancer.<sup>164</sup> Similarly, lactose was associated with an increased ovarian cancer risk, and every additional 10 grams of lactose per day was associated with a 24% increase in ovarian cancer risk.<sup>165</sup> In sum, this study found that the frequent consumption of dairy, particularly milk, was associated with an increased risk of ovarian cancer.<sup>166</sup>

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<sup>157</sup> Faber et al., *supra* note 128, at 455.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* at 457.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Id.* at 460-63 (noting, however, that cheese intake was associated with a decreased risk).

Although IGF-1 could also be a contributor to dairy's association with ovarian cancer,<sup>167</sup> the breakdown of lactose into galactose may be the more likely explanation.<sup>168</sup> "Dairy products are the major source of galactose, a component sugar of lactose that may increase ovarian cancer risk by direct toxicity to oocytes or by elevating gonadotropin concentrations, thereby stimulating proliferation of ovarian epithelium" cancer.<sup>169</sup> Ovaries may be more susceptible to galactose toxicity because they "have an unusually high local concentration and a high tissue-specific activity of galactose-1-phosphate uridyltransferase," which is an enzyme involved in the galactose metabolic pathway.<sup>170</sup> This mechanism is supported by the studies discussed above indicating that lactose and dairy consumption is associated with an increased risk of ovarian cancer.

Any "adverse health effects of milk consumption would have important public health implications" for women.<sup>171</sup> Women should be warned of the association between the frequent consumption of milk and other dairy products and an increased risk of ovarian cancer, particularly the serous subtype. This increased risk is material information for women to know before purchasing or consuming dairy.

### **C. Environmental Impact**

Under 21 C.F.R. § 25.30(k), the requested action is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

### **D. Economic Impact**

Pursuant to 21 C.F.R. § 10.30(b)(3), PETA will submit this information upon request by the Commissioner following review of the petition.

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<sup>167</sup> Fairfield et. al, *supra* note 7, at 275-76.

<sup>168</sup> Larsson et al., *supra* note 10, at 1353, 56; *see also* Kushi et al., *supra* note 129, at 27; Fairfield et. al, *supra* note 7, at 275-76.

<sup>169</sup> Larsson et al., *supra* note 10, at 1353, 56; Fairfield et al., *supra* note 7, at 275-76; Faber et al., *supra* note 128, at 462.

<sup>170</sup> Larsson et al., *supra* note 10, at 1353, 56; Faber et al., *supra* note 128, at 462.

<sup>171</sup> Fairfield et al., *supra* note 7, at 271.

## **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.

A handwritten signature in black ink, appearing to read "Ashely Monti". The signature is fluid and cursive, with the first name "Ashely" written in a larger, more prominent script than the last name "Monti".

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