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*Attorneys for Plaintiff*

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

TRAVETTE COPELAND and LILA CHU,  
individually and on behalf of all others similarly  
situated,

Plaintiffs,

v.

BAYER HEALTHCARE  
PHARMACEUTICALS INC.,

Defendant.

Case No.:

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

1 Plaintiffs Travette Copeland and Lila Chu (“Plaintiffs”) bring this action on behalf of  
2 themselves and all others similarly situated against Defendant Bayer Healthcare Pharmaceuticals  
3 Inc. (“Defendant” or “Bayer”). Plaintiffs make the following allegations pursuant to the  
4 investigation of their counsel and based upon information and belief, except as to the allegations  
5 specifically pertaining to themselves, which are based upon personal knowledge.

6 **NATURE OF THE ACTION**

7 **I. DEFENDANT FAILED TO WARN PLAINTIFFS, CLASS MEMBERS, AND**  
8 **THEIR DOCTORS THAT USING THE MIRENA IUD WOULD RESULT**  
9 **IN A STATISTICALLY SIGNIFICANT INCREASED RISK OF BREAST**  
10 **CANCER**

11 1. This is a putative class action lawsuit on behalf of women who paid an out-of-pocket  
12 cost as a result of being prescribed Bayer’s Mirena intrauterine device (the “Mirena IUD,” “Mirena,”  
13 or the “Product”). Defendant markets and sells the Products as suitable for use as birth control, but  
14 Mirena IUDs are not suitable for that use because they increase the risk of breast cancer in users by  
15 a statistically significant amount of approximately 20-30%.

16 2. The Mirena IUD is a “hormonal intrauterine device,” specifically a “levonorgestrel-  
17 releasing intrauterine system” (“LNG-IUS”). The Mirena IUD is inserted into a woman’s uterus,  
18 whereupon it releases the hormone progestin. Progestin thickens mucus in the cervix to stop sperm  
19 from reaching or fertilizing an egg and thins the lining of the uterus and partially suppresses  
20 ovulation, which reduces the chances of pregnancy and decreases menstrual bleeding.

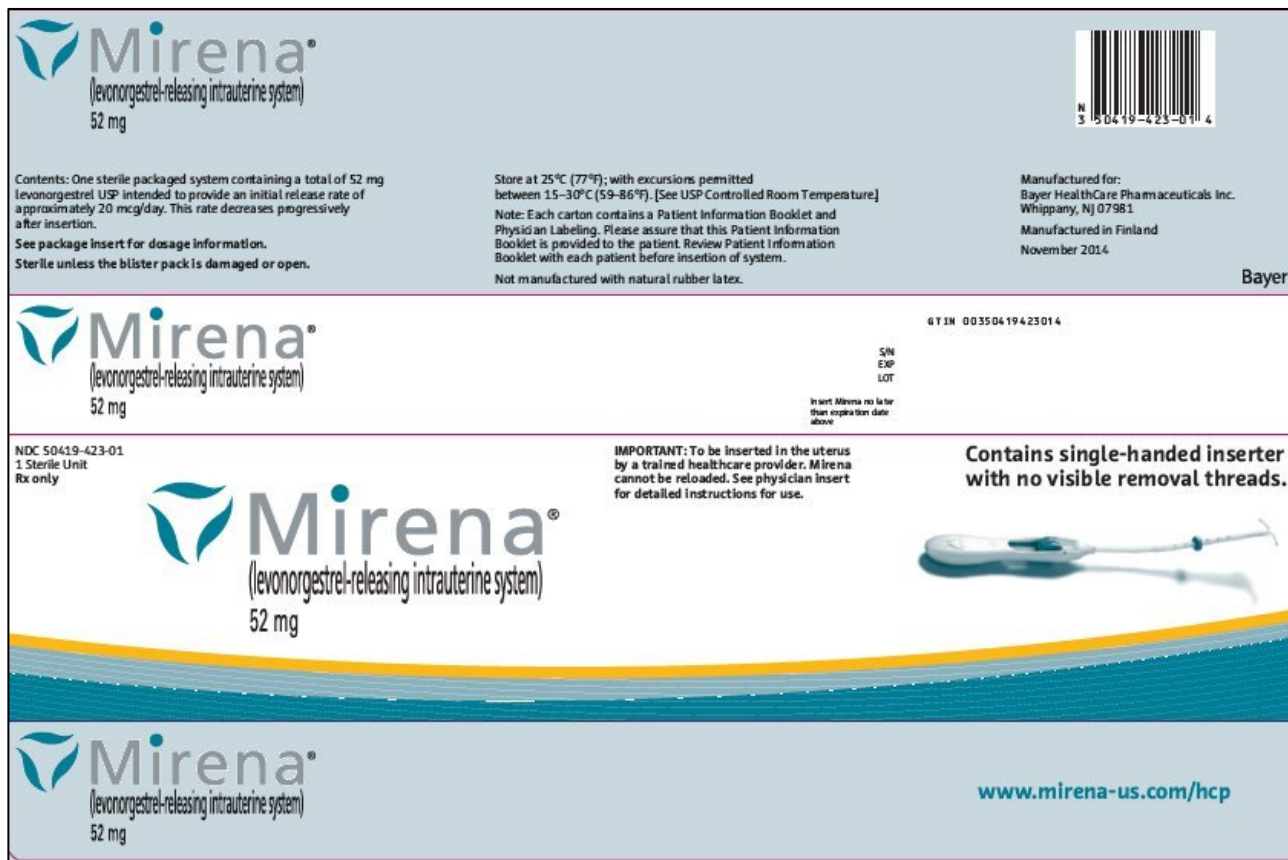
21 3. Defendant does note on its website that “Mirena isn’t right for everyone” and that  
22 “[a]n important part of your decision [to use the Product] is making sure you’re aware of possible  
23 side effects.”<sup>1</sup> But conspicuously absent from the list of “safety considerations” is any mention of  
24 the statistically significantly increased risk of breast cancer caused by the Product.

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<sup>1</sup> SAFETY CONSIDERATIONS FOR MIRENA, <https://www.mirena-us.com/mirena-side-effects-and-safety>.

1 4. Bayer's packaging for the Product does not disclose that it significantly increases the  
2 risk of breast cancer:



17 5. Nor do any of the other materials that Defendant distributes to consumers or doctors  
18 mention that the Product significantly increases the risk of breast cancer.

19 6. On the contrary, Defendant represents the opposite to doctors and patients.  
20 Specifically, Defendant's prescribing information for Mirena states that "[w]omen who *currently*  
21 *have* or *have had* breast cancer, or *have a suspicion of* breast cancer, should not use hormonal  
22 contraception because some breast cancers are hormone-sensitive." MIRENA PRESCRIBING  
23 INFORMATION, at § 5.9 (emphasis attached).<sup>2</sup> But for women like Plaintiffs who do not currently  
24 have or previously have breast cancer, or who had no suspicion of breast cancer, Defendant tells  
25 doctors and patients that "[o]bservational studies of the risk of breast cancer with use of an LNG-  
26 releasing IUS *do not provide conclusive evidence of increased risk.*" *Id.* (emphasis added).

27  
28 <sup>2</sup> Available at [https://labeling.bayerhealthcare.com/html/products/pi/Mirena\\_PI.pdf](https://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf).

1 Likewise, Defendant’s website provides a warning only for women who already have, or might have,  
2 cancer.<sup>3</sup>

3 7. Prior to 2015, Defendant went a step further, telling doctors and patients in Mirena’s  
4 prescribing information that “[t]wo observational studies *have not provided evidence* of an increased  
5 risk of breast cancer during the use of Mirena.” MIRENA SUPPLEMENTAL NEW DRUG APPLICATION,  
6 at 3 (emphasis added).<sup>4</sup>

7 8. In other words, Defendant has long told patients and doctors in materials distributed  
8 to both that there is no risk of breast cancer associated with the Products where the patient did not  
9 currently have or previously have breast cancer, or who had no suspicion of breast cancer.

10 9. Defendant provided no other warnings to Plaintiffs, Class Members, or their doctors  
11 that Mirena use would lead to a statistically significant increased risk of breast cancer.

12 **II. STUDIES SHOW THAT USING THE MIRENA IUD RESULTS IN A**  
13 **STATISTICALLY SIGNIFICANT INCREASED RISK OF BREAST**  
14 **CANCER**

15 10. Contrary to Defendant’s representations to doctors and patients, studies point to a  
16 statistically significant increased risk of breast cancer among Mirena users. Specifically, Mirena  
17 users have approximately 20-30% excess risk for breast cancer as compared with non-users of  
18 hormonal contraceptives. And, despite its knowledge of these studies, Defendant failed to update  
19 the FDA with this newly acquired information, or to otherwise update the Products’ warnings.

20 11. In 2010, a case-control study compared 329 women users of LNG-IUS with 708  
21 controls of the same age.<sup>5</sup> The study showed an increased risk for breast cancer for post-  
22 menopausal women in the LNG-IUS population with an odds rate of 1.53 at a 95% confidence  
23 interval.

24 12. In 2016, a Finnish study found a statistically significant increase in breast cancer

25 <sup>3</sup> WHO SHOULD NOT USE MIRENA?, <https://www.mirena-us.com/>.

26 <sup>4</sup> Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2015/021225orig1s031.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/021225orig1s031.pdf).

27 <sup>5</sup> See generally Heli K. Lyytinen, Heli K. et al., *A Case-Control Study On Hormone Therapy As A*  
28 *Risk Factor For Breast Cancer In Finland: Intrauterine System Carries A Risk As Well*, 126 INT’L  
J. CANCER 483 (2010), <https://onlinelibrary.wiley.com/doi/epdf/10.1002/ijc.24738>.

1 risk in postmenopausal women using an LNG-IUS such as the Mirena IUD.<sup>6</sup> Specifically, the  
 2 study found “positive associations with BC risk” at an odds ratio of 1.48 at a 95% confidence  
 3 interval “when compared to never-users of any hormonal contraceptive.”

4 13. In 2016, a study found that using an LNG-IUS, such as the Product, “is not only  
 5 related to an excess risk of lobular breast cancer but also, in contrary to previous assumptions, to an  
 6 excess risk of ductal breast cancer.”<sup>7</sup> Specifically, the study examined “women aged 30-49 who  
 7 had used LNG-IUS,” and found that these women

8 had an increased risk for both ductal breast cancer [standardized incidence  
 9 ratio (SIR) 1.20, 95% confidence interval (CI) 1.14–1.25] and for lobular  
 10 breast cancer (SIR 1.33, 95% CI 1.20–1.46), as compared with the general  
 11 female population. The highest risk was found in LNG-IUS users who  
 12 purchased the device at least twice, whose SIR for lobular cancer was 1.73  
 13 (95% CI 1.37–2.15).

14 This study was particularly reliable because it made use of data maintained by the Finnish Cancer  
 15 Registry (as opposed to volunteers or self-reporting), which avoids any potential bias due to non-  
 16 responsiveness and allows for the examination of a much larger number of cases than other studies.

17 14. In 2017, a Danish study found that, among 1.8 million women aged 15 to 49 who  
 18 used the LNG-IUS intrauterine system, the relative risk of breast cancer was 1.21 at 95%  
 19 confidence interval.<sup>8</sup>

20 15. The Mørch study was particularly reliable for a number of reasons. *First*, like the  
 21 Soini study discussed above, the Mørch study made use of data provided to the Danish Cancer  
 22 Registry, which avoids any potential bias due to non-responsiveness and allows for the  
 23 examination of a much larger number of cases than other studies. *See* Mørch at 2230.

24 16. *Second*, Mørch compared the risk of breast cancer in women who had used an LNG-

25 <sup>6</sup> Sanna Heikkinen et al., *Use Of Exogenous Hormones And The Risk Of Breast Cancer: Results*  
 26 *From Self-Reported Survey Data With Validity Assessment*, 27 *CANCER CAUSES & CONTROL* 249,  
 27 249 (2016), <https://pubmed.ncbi.nlm.nih.gov/26667320/>.

28 <sup>7</sup> Tuuli Soini, et al., *Levonorgestrel-Releasing Intrauterine System and the Risk Of Breast Cancer: A*  
*Nationwide Cohort Study*, 55 *ACTA ONCOLOGICA* 188, 188 (2016), [https://](https://www.tandfonline.com/doi/full/10.3109/0284186X.2015.1062538)  
[www.tandfonline.com/doi/full/10.3109/0284186X.2015.1062538](https://www.tandfonline.com/doi/full/10.3109/0284186X.2015.1062538).

<sup>8</sup> Lina S. Mørch et al., *Contemporary Hormonal Contraception And The Risk Of Breast Cancer*. 377  
*NEW ENGLAND J. MED.* 2228, 2228 (2017), [https://www.nejm.org/doi/full/10.1056/nejmoa](https://www.nejm.org/doi/full/10.1056/nejmoa1700732)  
 1700732.

1 IUS device like the Product to “women who had never used hormonal contraception.” *Id.* at 2228.  
 2 This is important because all hormonal contraceptives carry with them at least some risk of breast  
 3 cancer.<sup>9</sup> Thus, if a study were to compare the increased risk of breast cancer in women use whose  
 4 used the Product as compared to the *general population*, the results would likely be skewed  
 5 because most women in the general population use some form of hormonal contraception. By  
 6 contrast, Mørch examined the increased risk of breast cancer in women who used LNG-IUD  
 7 products like Mirena to *never-users*, which gives more reliable results of the increased risk. And  
 8 Mørch found that increased risk to be statistically significant (21%), higher than the risk caused by  
 9 other forms of birth control.

10 17. In 2020, a systematic review of existing studies found that “LNG-IUS users have an  
 11 increased breast cancer risk regardless of age and indication.”<sup>10</sup> Specifically, the Conz meta-  
 12 analysis found “increased breast cancer risk in LNG-IUS users: for all women, odds ratio (OR) =  
 13 1.16 (95% CI 1.06-1.28[]) ... for women aged <50 years, OR = 1.12 (95% CI 1.02-1.22[]) ... and  
 14 for women aged ≥ 50 years, OR = 1.52 (95% CI 1.34-1.72[]). Conz at 970. The study further  
 15 emphasized that, regardless of the risk, “it is difficult to believe that LNG-IUS use may be devoid  
 16 of any oncological risk” and that “[u]sers of LNG-IUS should therefore be aware of these trends.”  
 17 *Id.* at 981.

18 18. In 2023, another systematic review of existing studies similarly concluded that there  
 19 is “an increased BC risk in LNG-IUS users.”<sup>11</sup>

20 19. Finally, another study and meta-analysis from 2023 found “there is a relative increase  
 21

22 <sup>9</sup> See, e.g., NATIONAL CANCER INSTITUTE, ORAL CONTRACEPTIVES AND CANCER RISK,  
 23 [https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-](https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet)  
 24 sheet (“An analysis of data from more than 150,000 women who participated in 54 epidemiologic  
 studies showed that, overall, women who had ever used oral contraceptives had a slight (7%) increase  
 in the relative risk of breast cancer compared with women who had never used oral contraceptives.”).

25 <sup>10</sup> Livia Conz et al., *Levonorgestrel-Releasing Intrauterine System And Breast Cancer Risk: A*  
 26 *Systematic Review And Meta-Analysis*, 99 ACTA OBSTET GYNECOL SCANDINAVIA 970, 971 (2020),  
<https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/aogs.13817>.

27 <sup>11</sup> Aline Zürcher et al., *Influence of the Levonorgestrel-Releasing Intrauterine System on the Risk of*  
 28 *Breast Cancer: A Systematic Review*, 307 ARCH GYNECOL OBSTET. 1747 (June 2023), <https://pubmed.ncbi.nlm.nih.gov/35716207/>.

1 of around 20% to 30% in breast cancer risk associated with current or recent use of either combined  
2 oral or progestogen only contraceptives” such as Mirena.<sup>12</sup>

3 20. Although certain studies have come to the opposite conclusion, those studies had  
4 significant flaws, such as failing to use registry data (which yielded a smaller and more biased sample  
5 size) or compared the increased risk to the general female population (which skews risk analysis  
6 because it includes other users of hormonal contraceptives in the comparison group). Other studies  
7 were also funded by Defendant, as opposed to neutral third parties. Finally, a 2021 meta-analysis  
8 that Defendant relies on included only four studies in the meta-analysis (as opposed to seven in Conz)  
9 and *excluded* three studies that had found an increased risk of breast cancer (unlike Conz, which  
10 included these studies).<sup>13</sup>

11 21. The statistically significant increased risk of breast cancer in users of the Product  
12 (approximately 20-30%) presents a serious safety hazard that renders the Product unsuitable for its  
13 intended purpose. Women should not have to incur a 20-30% increased risk of breast cancer when  
14 selecting a birth control product, and neither Plaintiffs nor any member of the putative Class would  
15 have taken that risk, particularly when safer birth control alternatives are available. Further, although  
16 drug products often carry risks, there is a stark difference between, for instance, a product that makes  
17 a user feel bloated or nauseous and a product that increases a user’s risk of breast cancer by a  
18 statistically significant amount. Thus, the statistically significant increased risk of breast cancer  
19 caused by Mirena renders it unsafe and unsuitable for its intended purpose.

20 **III. DEFENDANT FAILED TO UPDATE THE FDA WITH NEWER STUDIES**  
21 **SHOWING A STATISTICALLY SIGNIFICANT INCREASED RISK OF**  
22 **BREAST CANCER, AND FAILED TO CHANGE THE WARNING**  
23 **INFORMATION FOR MIRENA IN LIGHT OF THIS NEWLY ACQUIRED**  
24 **INFORMATION**

25 22. Based on the increasing evidence of a statistically significant increased risk of breast  
26  
27

25 <sup>12</sup> DANIELLE FITZPATRICK ET AL., COMBINED AND PROGESTAGEN-ONLY HORMONAL  
26 CONTRACEPTIVES AND BREAST CANCER RISK: A UK NESTED CASE–CONTROL STUDY AND META-  
27 ANALYSIS at 3 (2023), <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004188>.

28 <sup>13</sup> Fabio R. Silva et al., *Meta-Analysis of Breast Cancer Risk in Levonorgestrel-Releasing Intrauterine System Users*, 21 CLINICAL BREAST CANCER, 497, 502-03 (2021).

1 cancer in users of the Product (20-30%), Defendant should have changed the labeling or prescribing  
2 information on the Product to reflect this, or presented this newly acquired information to the FDA  
3 to change its labeling to the extent this was required. Defendant did not do so.

4 23. The Product was first approved for use in the United States in 2000. In the prescribing  
5 information for the Product that is provided to doctors, Defendant included the following language:

6 Women who currently have or have had breast cancer, or have a  
7 suspicion of breast cancer, should not use hormonal contraception  
because some breast cancers are hormone-sensitive.

8 MIRENA PRESCRIBING INFORMATION, at § 5.9.

9 24. As to women who do not currently have or have had breast cancer, or who do not  
10 have a suspicion of breast cancer, Defendant has made several updates to the prescribing information  
11 distributed to doctors regarding the risk of breast cancer in these women. First, in 2009, and  
12 following the publication of a study entitled “European Active Surveillance Study for Intrauterine  
13 Devices,” Defendant updated the prescribing information to add the following language:

14 Spontaneous reports of breast cancer have been received during  
15 postmarketing experience with Mirena. Because spontaneous reports  
16 are voluntary and from a population of uncertain size, *it is not possible*  
to use postmarketing data *to reliably estimate the frequency or*  
*establish causal relationship to drug exposure.* Two observational  
studies *have not provided evidence* of an increased risk of breast  
cancer during the use of Mirena.

17 MIRENA SUPPLEMENTAL NEW DRUG APPLICATION, at 3 (emphasis added). As noted above, this  
18 statement incorrectly told doctors and patients that there is *no increased risk* (or no evidence of  
19 increased risk) of breast cancer in women who use Mirena who never had breast cancer or never had  
20 a suspicion of having breast cancer.

21 25. Then, in December 2015, Defendant submitted a Supplemental New Drug  
22 Application to the FDA following the publication of “two new studies addressing the risk of breast  
23 cancer in Mirena users.” *Id.*, at 38. The SNDA resulted in an update to the warnings section of the  
24 prescribing information provided to doctors, which came to read and still reads:

25 *Observational studies of the risk of breast cancer with the use of a*  
26 *LNG-releasing IUS do not provide conclusive evidence of increased*  
*risk.*

27 MIRENA PRESCRIBING INFORMATION, at § 5.9.(emphasis added); *see also* MIRENA SUPPLEMENTAL  
28 NEW DRUG APPLICATION, at 38. Again, this told doctors there is *no evidence of increased risk* of

1 breast cancer in women who use Mirena who never had or never had a suspicion of having breast  
2 cancer.

3 26. Notably, during the submission of its SNDA, Defendant “declined to add” this  
4 different language, “stating that the available data do not establish an association between breast  
5 cancer and Mirena use in women < 50 years old, and expressing concern that a labeling revision  
6 would imply there has been a change in the interpretation of available evidence.” MIRENA  
7 SUPPLEMENTAL NEW DRUG APPLICATION, at 38.

8 27. December 2015 was the last time Defendant submitted an SNDA to the FDA  
9 regarding the risks of breast cancer associated with Mirena. Since that time, several studies have  
10 come out finding a statistically increased risk of breast cancer (approximately 20-30%): the 2016  
11 Soini study, the 2017 Mørch study, the 2020 Conz meta-analysis, the 2023 Zürcher systematic  
12 review, and the 2023 Fitzpatrick meta-analysis. Each of these studies constitutes “newly acquired  
13 information” because they are (i) “data, analyses, or other information [that were] not previously  
14 submitted to the [FDA], (ii) are “data derived from new clinical studies ... or new analyses of  
15 previously submitted data (e.g., meta-analyses),” and (iii) the studies reveal[ed] risks of a different  
16 type or greater severity or frequency than previously included in submissions to FDA.” 21 C.F.R. §  
17 314.3(b).

18 28. Despite the fact that each of these studies post-dates Defendant’s 2015 SNDA and  
19 constitutes “newly acquired information” as alleged above, Defendant did not and has not provided  
20 these studies to the FDA for evaluation, did not and has not submitted a new SNDA in light of those  
21 studies, and did not and has not taken steps to change its prescription information to provide stronger  
22 warnings regarding the statistically significant increased risk of breast cancer from the Product in  
23 women of all ages and who have never had any exposure to or suspicion of breast cancer.

24 29. Defendant is the manufacturer of Mirena and Mirena is under Defendant’s exclusive  
25 control. Defendant thus could have taken steps to change the labeling of the Product, with or without  
26 FDA approval, based on this newly acquired information to accurately reflect the known or  
27 scientifically knowable risk, incidence, symptoms, scope, or severity of breast cancer stemming from  
28 Mirena to doctors and patients. Indeed, Defendant had a duty to do so because a change in labeling

1 is warranted “to include a warning about a clinically significant hazard as soon as there is reasonable  
2 evidence of a causal association with a drug; a causal relationship need not have been definitely  
3 established.” 21 C.F.R. § 201.57(c)(6)(i). As alleged above, the studies provide reasonable evidence  
4 of a causal association between Mirena and a statistically significant increased risk of breast cancer,  
5 and breast cancer is certainly a clinically significant hazard.

6 30. It is clear Defendant had knowledge of these studies. Defendant, as one of the largest  
7 pharmaceutical corporations in the world, reads literature and studies concerning its products.  
8 Furthermore, the prescribing language for Mirena and the SNDA indicate that Defendant reviews  
9 studies concerning the Product, as Defendant continuously pushes back on the findings of the studies  
10 and commented to the FDA about what it believed studies had shown in December 2015. MIRENA  
11 SUPPLEMENTAL NEW DRUG APPLICATION, at 38.

12 31. Notably, Defendant has a history of directly marketing Mirena to consumers and  
13 overstating the benefits while minimizing the Products’ risks. For instance, in 2009, the FDA sent a  
14 warning letter to Bayer, stating that Bayer’s online marketing materials “make representations and/or  
15 suggestions about the efficacy of ... Mirena [] but fail to communicate *any* risk information.”<sup>14</sup>  
16 Although this warning letter did not concern the risks of breast cancer, Defendant’s conduct has  
17 clearly continued.

18 **IV. PLAINTIFFS AND CLASS MEMBERS WERE INJURED BY THE**  
19 **MISREPRESENTATIONS AND OMISSIONS DEFENDANT MADE TO**  
20 **DOCTORS AND PATIENTS**

21 32. The preceding allegations are summarized as follows. *First*, various studies—  
22 particularly studies published after December 2015—found a statistically significant increased risk  
23 of breast cancer (approximately 20-30%) in women who use LNG-IUD products like Mirena.  
24 *Second*, Defendant failed to update its prescribing information, product labeling, or other literature  
25 provided to doctors and patients to reflect this “newly acquired information,” nor did Defendant  
26 bring these newer studies to the FDA’s attention in a SNDA. And *third*, Defendant told doctors and  
27 patients and has continued to tell doctors and patients in its prescribing information, product labeling,

28 <sup>14</sup> FDA WARNING LETTER, <https://www.yumpu.com/en/document/read/48525663/warning-letter-food-and-drug-administration>, at 3 (emphasis in original).

1 or other literature provided to doctors and patients that there was no evidence of an increased risk of  
2 breast cancer in women who have not had breast cancer or do not have a suspicion of breast cancer.  
3 As a result of these actions, Mirena users were harmed.

4 33. As a result of Defendant's conduct, Plaintiffs, Class Members, and their doctors were  
5 not aware that Mirena carries with it a statistically significant increased risk of breast cancer of  
6 approximately 20-30%. Nor did they have a reason to doubt Bayer's statement that there was no  
7 evidence of such a risk. Indeed, members of the medical community, including doctors and other  
8 healthcare professionals, relied upon the representations and warranties of the Defendant for the use  
9 of Mirena in recommending, prescribing, and/or implanting Mirena. Had Plaintiffs' and Class  
10 Members' doctors known that Mirena carried with it a statistically significant increased risk of breast  
11 cancer of 20-30%, or had Defendant disclosed the same to doctors, they would not have prescribed  
12 Mirena to Plaintiffs. Similarly, had Defendant not misrepresented that there was no evidence of an  
13 increased risk of breast cancer in women who have not had breast cancer or do not have a suspicion  
14 of breast cancer, Plaintiffs' and Class Members' doctors would not have prescribed Mirena to  
15 Plaintiffs and Class Members.

16 34. In addition, because Plaintiffs' doctors were not told of Mirena's breast cancer risk,  
17 they did not inform Plaintiffs of that risk. Nor were Plaintiffs or Class Members aware of that risk  
18 independently doctors because Defendant's marketing materials—such as in patient brochures and  
19 on Mirena's website—did warn about that risk. Instead, Defendant told Plaintiffs and Class  
20 Members through its marketing materials not to take the Product *only if* the patient previously had  
21 or currently has breast cancer.<sup>15</sup> Plaintiffs and Class Members would not have paid out-of-pocket or  
22 used the Product had Defendant not misrepresented the risk of breast cancer associated with Mirena,  
23 or failed to disclose those risks to doctors and/or patients.

24 35. In short, therefore, Defendant did not provide doctors prescribing Mirena with  
25 adequate warnings and instructions concerning the use of Mirena. Doctors therefore did not have  
26 sufficient information to properly inform Plaintiffs and Class Members of the risks and dangers

27 \_\_\_\_\_  
28 <sup>15</sup> SAFETY CONSIDERATIONS FOR MIRENA, <https://www.mirena-us.com/mirena-side-effects-and-safety>.

1 associated with the Mirena, specifically the statistically significant increased risk of breast cancer  
2 (approximately 20-30%). Plaintiffs and Class Members therefore did not have the same knowledge  
3 as Defendant because no adequate warning was communicated to them or their doctors, and doctors  
4 thus did not warn their patients.

5 36. As a direct and proximate result of the Defendant's advertising and widespread  
6 promotional activity, doctors, including Plaintiffs' and Class Member's doctors, began prescribing  
7 Mirena as safe and effective without warning patients or being aware themselves of the statistically  
8 significant increased risk of breast cancer. This caused Plaintiffs and Class Members to incur out-  
9 of-pocket costs, including the payment for the Product itself and/or the insertion thereof.

10 37. Defendant knew or should have known that doctors, including Plaintiffs' and Class  
11 Members' doctors, began commonly prescribing Mirena as a safe and effective contraceptive,  
12 despite the fact that Mirena had been linked to a statistically significant increased risk of breast.

13 38. Plaintiffs and Class Members thus suffered monetary damages as a result of  
14 Defendant's deceptive and fraudulent misrepresentations and omissions to doctors and patients alike.

15 39. A number of women, including Plaintiffs, paid out-of-pocket as a result of being  
16 prescribed Mirena due to Defendant's misrepresentations and omissions. The Affordable Care Act  
17 ("ACA") requires insurers to provide birth control without cost sharing in *some* instances. 29 C.F.R.  
18 § 2590.715-2713(a)(iv); 80 Fed. Reg. 41318, 41318 (July 14, 2015). However, many women still  
19 pay out-of-pocket to purchase Mirena, including but not limited to Plaintiffs. Further, the ACA does  
20 *not* cover the cost of having Mirena inserted, which all women must necessarily have done in order  
21 to use the Mirena IUD. *See* MIRENA COST AND INSURANCE SUPPORT (noting that "patients may still  
22 be responsible for the cost of the product and/or product-related costs, such as insertion or removal  
23 procedure fees.").<sup>16</sup> And, although Bayer ostensibly offers a "co-pay savings program," women will  
24 still pay for Mirena, even if it is "as little as \$20 out of pocket." *Id.*

25 40. Plaintiffs brings this action on behalf of themselves and the Class for equitable relief  
26 and to recover damages and restitution for: (i) breach of implied warranty; (ii) fraud;

27  
28 <sup>16</sup> Available at <https://www.mirena-us.com/cost-support>.

1 and (iii) violation of California’s Consumers Legal Remedies Act (“CLRA”), Cal. Civil Code  
2 §§ 1750, *et. seq.*

3 **PARTIES**

4 41. Plaintiff Travette Copeland is a resident and citizen of San Jose, California. In July  
5 2020, Ms. Copeland was prescribed and had the Mirena IUD inserted in California. Ms. Copeland  
6 paid \$35 for products and services that included payment for the Mirena IUD and insertion thereof  
7 out-of-pocket as a result of being prescribed the Mirena IUD. Ms. Copeland’s doctor who prescribed  
8 Mirena to her was not aware of the statistically significant increased risk of breast cancer  
9 (approximately 20-30%) caused by Mirena, nor did Defendant inform Ms. Copeland’s doctor of that  
10 risk. Instead, Ms. Copeland’s doctor reviewed the prescribing information, product pamphlet, and  
11 other materials provided by Defendant, which stated there that there was no evidence of an increased  
12 risk of breast cancer for women like Ms. Copeland who never had breast cancer, nor ever had a  
13 suspicion of having breast cancer. Because Ms. Copeland’s doctor was not told by Defendant of the  
14 statistically significant increased risk of breast cancer caused by Mirena—and, in fact, was told by  
15 Defendant there was no such increased risk—and was not otherwise aware of this increased risk, Ms.  
16 Copeland’s doctor never conveyed any warnings to Ms. Copeland and prescribed Mirena to Ms.  
17 Copeland based on Defendant’s representations and omissions in the information Defendant  
18 provided to Ms. Copeland’s doctor.

19 42. Further, when Ms. Copeland first had the Mirena IUD inserted, Defendant did not  
20 disclose to her the statistically significant increased risk of developing breast cancer from using the  
21 Mirena IUD. Similarly, Ms. Copeland’s doctor did not tell her and was not otherwise aware of any  
22 increased risk of breast cancer associated with Mirena. Accordingly, Defendant’s representations  
23 and omissions were part of the basis of the bargain, in that Ms. Copeland would not have paid out-  
24 of-pocket for the Mirena IUD had Defendant not failed to disclose the statistically significant  
25 increased risk of developing breast cancer from using the Mirena IUD. Similarly, had Defendant not  
26 misrepresented to Ms. Copeland’s doctor there was no evidence of an increased risk of breast cancer  
27 from using Mirena for patients who never had breast cancer, and had Defendant not failed to disclose  
28 to Ms. Copeland’s doctor the statistically significant increased risk of developing breast cancer from

1 using the Mirena IUD, Ms. Copeland's doctor would not have prescribed or instructed Ms. Copeland  
2 to use Mirena, meaning Ms. Copeland would not have incurred any out-of-pocket costs. At no time  
3 did Defendant or anyone else warn Ms. Copeland or her doctor about the significantly elevated breast  
4 cancer risk associated with the Product.

5 43. Plaintiff Lila Chu is a resident and citizen of Los Angeles, California. In June 2020,  
6 Ms. Chu was prescribed and had the Mirena IUD inserted in California. Ms. Chu paid \$8 out-of-  
7 pocket for the insertion of the Mirena IUD. Ms. Chu's doctor who prescribed Mirena to her was not  
8 aware of the statistically significant increased risk of breast cancer (approximately 20-30%) caused  
9 by Mirena, nor did Defendant inform Ms. Chu's doctor of that risk. Instead, Ms. Chu's doctor  
10 reviewed the prescribing information, product pamphlet, and other materials provided by Defendant,  
11 which stated there that there was no evidence of an increased risk of breast cancer for women like  
12 Ms. Chu who never had breast cancer, nor ever had a suspicion of having breast cancer. Because  
13 Ms. Chu's doctor was not told by Defendant of the statistically significant increased risk of breast  
14 cancer caused by Mirena—and, in fact, was told by Defendant there was no such increased risk—  
15 and was not otherwise aware of this increased risk, Ms. Chu's doctor never conveyed any warnings  
16 to Ms. Chu and prescribed Mirena to Ms. Chu based on Defendant's representations and omissions  
17 in the information Defendant provided to Ms. Chu's doctor.

18 44. Further, when Ms. Chu first had the Mirena IUD inserted, Defendant did not disclose  
19 to her the statistically significant increased risk of developing breast cancer from using the Mirena  
20 IUD. Similarly, Ms. Chu's doctor did not tell her and was not otherwise aware of any increased risk  
21 of breast cancer associated with Mirena. Accordingly, Defendant's representations and omissions  
22 were part of the basis of the bargain, in that Ms. Chu would not have paid out-of-pocket for the  
23 Mirena IUD had Defendant not failed to disclose the statistically significant increased risk of  
24 developing breast cancer from using the Mirena IUD. Similarly, had Defendant not misrepresented to  
25 Ms. Chu's doctor there was no evidence of an increased risk of breast cancer from using Mirena for  
26 patients who never had breast cancer, and had Defendant not failed to disclose to Ms. Chu's doctor  
27 the statistically significant increased risk of developing breast cancer from using the Mirena IUD,  
28 Ms. Chu's doctor would not have prescribed or instructed Ms. Chu to use Mirena, meaning Ms. Chu

1 would have not incurred any out-of-pocket costs. At no time did Defendant or anyone else warn Ms.  
2 Chu or her doctor about the significantly elevated breast cancer risk associated with the Product.

3 45. Defendant Bayer Healthcare Pharmaceuticals Inc. is a Delaware corporation with its  
4 headquarters at 100 Bayer Boulevard, Whippany, New Jersey 07981. Bayer markets, distributes,  
5 sells, and makes the Product available for prescription throughout the United States and the State of  
6 California, and provides the same prescribing information and marketing materials to doctors who  
7 prescribe Mirena throughout the United States and the State of California.

### 8 **JURISDICTION AND VENUE**

9 46. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332(d)(2)(a)  
10 because this case is a class action where the aggregate claims of all members of the proposed class  
11 are in excess of \$5,000,000.00, exclusive of interest and costs, there are over 100 members of the  
12 putative class, and Plaintiffs, as well as most members of the proposed class, are citizens of states  
13 different from Defendant.

14 47. This Court has personal jurisdiction over Defendant because Plaintiffs were  
15 prescribed and used the Product in California and Defendant conducts substantial business within  
16 California, such that Defendant has significant, continuous, and pervasive contacts within the State  
17 of California.

18 48. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant  
19 transacts significant business within this District and because Plaintiff Copeland was prescribed and  
20 used the Product in this District.

### 21 **CLASS ALLEGATIONS**

22 49. Plaintiffs seek to represent a class defined as all persons in the United States who paid  
23 an out-of-pocket for a Mirena IUD or for a procedure to insert a Mirena IUD (the “Nationwide  
24 Class”).

25 50. Plaintiffs also seek to represent a class defined as all persons who reside in the state  
26 of California paid an out-of-pocket for a Mirena IUD or for a procedure to insert a Mirena IUD (the  
27 “California Subclass”) (collectively with the Nationwide Class, the “Class”).

28 51. Specifically excluded from the Class are persons who made such purchase for the

1 purpose of resale, Defendant, Defendant's officers, directors, agents, trustees, parents, children,  
2 corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or  
3 entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities  
4 related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge  
5 assigned to this action, and any member of the judge's immediate family.

6 52. Subject to additional information obtained through further investigation and  
7 discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or  
8 amended complaint.

9 53. **Numerosity.** The members of the Class are geographically dispersed throughout the  
10 United States and are so numerous that individual joinder is impracticable. Plaintiffs reasonably  
11 estimate that there are hundreds of thousands of members in the Class. Although the precise number  
12 of Class Members is unknown to Plaintiffs, the true number of Class Members is known by  
13 Defendant and may be determined through discovery. Class Members may be notified of the  
14 pendency of this action by mail and/or publication through the distribution records of Defendant and  
15 third-party retailers and vendors.

16 54. **Existence and predominance of common questions of law and fact.** Common  
17 questions of law and fact exist as to all members of the Class and predominate over any questions  
18 affecting only individual Class members. These common legal and factual questions include, but  
19 are not limited to, the following:

- 20 (a) whether the Product manufactured, distributed, and sold by  
21 Defendant subjected consumers to a statistically significantly  
22 increased risk (approximately 20-30%) of developing breast  
23 cancer, thereby breaching implied warranties made by  
24 Defendant and making the Product unfit for its intended  
25 purpose;  
26 (b) whether Defendant knew or should have known that the  
27 Product subjected consumers to a statistically significantly  
28 increased risk (approximately 20-30%) of developing breast  
cancer prior to selling the Product, thereby constituting fraud  
and/or fraudulent omission;  
(c) whether Plaintiffs and the Class have sustained monetary loss  
and the proper measure of that loss;

- 1 (d) whether Plaintiffs and the Class are entitled to declaratory and  
2 injunctive relief;
- 3 (e) whether Plaintiffs and the Class are entitled to restitution and  
4 disgorgement from Defendant; and
- 5 (f) whether the marketing, advertising, packaging, labeling, and  
6 other promotional materials for Product are deceptive.

7 55. **Typicality.** The claims of the representative Plaintiffs are typical of the claims of the  
8 Class in that the representative Plaintiffs, like all members of the Class, were prescribed and used  
9 the Product, Defendant misrepresented or otherwise failed to disclose to both Plaintiffs and their  
10 doctors the statistically significantly increased risk (approximately 20-30%) of developing breast  
11 cancer, and Plaintiffs paid an out-of-pocket cost as a result of Defendant's misrepresentations and  
12 omissions. The representative Plaintiffs, like all members of the Class, have been damaged by  
13 Defendant's misconduct in the very same way as the members of the Class. Further, the factual bases  
14 of Defendant's misconduct are common to all members of the Class and represent a common thread  
15 of misconduct resulting in injury to all members of the Class.

16 56. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the  
17 interests of the Class. Plaintiffs have retained counsel that is highly experienced in complex  
18 consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf  
19 of the Class. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class.

20 57. **Superiority.** A class action is superior to all other available means for the fair and  
21 efficient adjudication of this controversy. The damages or other financial detriment suffered by  
22 individual Class members are relatively small compared to the burden and expense of individual  
23 litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class, on  
24 an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore,  
25 even if Class members could afford such individualized litigation, the court system could not.  
26 Individualized litigation would create the danger of inconsistent or contradictory judgments arising  
27 from the same set of facts. Individualized litigation would also increase the delay and expense to all  
28 parties and the court system from the issues raised by this action. By contrast, the class action device  
provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and

1 comprehensive supervision by a single court, and presents no unusual management difficulties under  
2 the circumstances.

3 58. In the alternative, the Class may also be certified because:

- 4 (a) the prosecution of separate actions by individual Class  
5 members would create a risk of inconsistent or varying  
6 adjudications with respect to individual members that would  
7 establish incompatible standards of conduct for the Defendant;
- 8 (b) the prosecution of separate actions by individual Class  
9 members would create a risk of adjudications with respect to  
10 them that would, as a practical matter, be dispositive of the  
11 interests of other Class members not parties to the  
12 adjudications, or substantially impair or impede their ability to  
13 protect their interests; and/or
- 14 (c) Defendant has acted or refused to act on grounds generally  
15 applicable to the Class as a whole, thereby making appropriate  
16 final declaratory and/or injunctive relief with respect to the  
17 members of the Class as a whole.

## 18 CAUSES OF ACTION

### 19 COUNT I

#### 20 **Breach Of Implied Warranty Of Merchantability**

21 59. Plaintiffs incorporate by reference the allegations contained in all preceding  
22 paragraphs of this complaint.

23 60. Plaintiffs bring this claim individually and on behalf of the members of the proposed  
24 Class against Defendant.

25 61. This claim is brought under the laws of the State of California.

26 62. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller,  
27 impliedly warranted that the Product was suited for use as a birth control device and that it would  
28 not cause a statistically significantly increased risk (approximately 20-30%) of developing breast  
cancer. Defendant breached the warranty implied in the contract for the sale of the Product because  
the Product could not “pass without objection in the trade under the contract description,” the Product  
was not “of fair average quality within the description,” the Product was not “adequately contained,  
packaged, and labeled as the agreement may require,” and the Product did not “conform to the  
promise or affirmations of fact made on the container or label.” *See* U.C.C. § 2-314(2) (listing

1 requirements for merchantability). As a result, Plaintiffs and Class Members did not receive the  
2 goods as impliedly warranted by Defendant to be merchantable.

3 63. Plaintiffs and Class Members purchased the Product in reliance upon Defendant's  
4 skill and judgment.

5 64. The Product was not altered by Plaintiffs and Class Members.

6 65. The Product was not fit for its intended purpose when it left the exclusive control of  
7 Defendant because the Product carried with it statistically significantly increased risk (approximately  
8 20-30%) of developing breast cancer. This risk constitutes an unreasonable safety hazard for  
9 consumers, particularly when other, safer birth control options are available.

10 66. Defendant knew that the Product would be purchased and used without additional  
11 testing by Plaintiffs and Class Members.

12 67. The Product was defectively designed and unfit for its intended purpose, and Plaintiffs  
13 and Class Members did not receive the Product as warranted. Defendant should have designed  
14 Mirena in such a way that it largely minimized or eliminated the risk of breast cancer, and the Product  
15 should not have been released given that it carries a statistically significantly increased risk  
16 (approximately 20-30%) of developing breast cancer.

17 68. Plaintiffs and Class Members were injured as a direct and proximate result of  
18 Defendant's breach because (i) they would not have paid an out-of-pocket cost for the Product or its  
19 insertion had they known that the Product carried with it a statistically significantly increased risk  
20 (approximately 20-30%) of developing breast cancer from using the Product, and (ii) their doctors  
21 would not have prescribed the Product had Defendant not misrepresented there was no "evidence"  
22 or "conclusive evidence" of this risk, and had Defendant not failed to disclose there was a statistically  
23 significantly increased risk (approximately 20-30%) of developing breast cancer from using the  
24 Product, meaning Plaintiffs and Class Members would not have incurred any out-of-pocket costs.

25 69. On February 1, 2022, prior to the filing of this action, Defendant was served with a  
26 notice letter on behalf of the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607.  
27 Plaintiffs' counsel sent Defendant a letter advising Defendant that it breached an implied warranty  
28 and demanded that Defendant cease and desist from such breaches and make full restitution by

1 refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as

2 **Exhibit 1.**

3 **COUNT II**  
4 **Fraud**

5 70. Plaintiffs incorporate by reference the allegations contained in all preceding  
6 paragraphs of this complaint.

7 71. Plaintiffs bring this claim individually and on behalf of the members of the proposed  
8 Class against Defendant.

9 72. This claim is brought under the laws of the State of California.

10 73. As discussed above, Defendant failed to disclose to Plaintiffs and Class Members that  
11 the Product carried with it a statistically significantly increased risk (approximately 20-30%) of  
12 developing breast cancer. Likewise, Defendant misrepresented to doctors that there was no  
13 “evidence” or “conclusive evidence” of an increased risk of developing breast cancer in women who  
14 never had breast cancer, and failed to disclose to doctors that there is a statistically significantly  
15 increased risk (approximately 20-30%) of developing breast cancer from using the Product.

16 74. Defendant had knowledge of these misrepresentations omissions and therefore acted  
17 with scienter. Specifically, several studies documenting the statistically significantly increased risk  
18 (approximately 20-30%) of developing breast cancer associated with the Product have been  
19 published since 2010. Nonetheless, Defendant continued to sell the Product without disclosing the  
20 same to Plaintiffs and Class Members, who used the Product without knowledge of this statistically  
21 significantly increased risk. Similarly, Defendant failed to disclose this risk to doctors, while also  
22 misrepresenting to doctors there was no evidence of an increased risk of developing breast cancer in  
23 women who never had breast cancer. Further, Defendant was capable of altering the labeling and  
24 warnings for the Product, with or without FDA approval. The studies published after 2015  
25 constituted “newly acquired information” that Defendant should have used to change its labeling and  
26 warnings or brought to the FDA’s attention in a SNDA for evaluation, but Defendant never did either.  
27 Thus, Plaintiffs’ and Class Members’ doctors prescribed and continue to prescribe Mirena to patients  
28 without knowledge of this statistically significantly increased risk.



1           84. The purchases by the Plaintiffs and California Subclass Members constitute  
2 “transactions,” as defined by California Civil Code § 1761(e).

3           85. The unlawful methods, acts or practices alleged herein to have been undertaken by  
4 Defendant were all committed intentionally and knowingly. The unlawful methods, acts or practices  
5 alleged herein to have been undertaken by Defendant did not result from a *bona fide* error  
6 notwithstanding the use of reasonable procedures adopted to avoid such error.

7           86. Defendant’s methods, acts and/or practices, including Defendant’s  
8 misrepresentations omissions, active concealment, and/or failures to disclose, violated and continue  
9 to violate the CLRA in ways including, but not limited to, the following:

- 10           (a) Defendant misrepresented that its products had characteristics,  
11 benefits, or uses that they did not have (Cal. Civ. Code  
12 § 1770(a)(5));  
13           (b) Defendant misrepresented that its products were of a particular  
14 standard, quality, grade, or of a particular style or model when the  
15 products were of another (Cal. Civ. Code § 1770(a)(7)); and  
16           (c) Defendant advertised its products with an intent not to sell them as  
17 advertised (Cal. Civ. Code § 1770(a)(9)).

18           87. Specifically, Defendant (i) misrepresented to doctors that there was no “evidence” or  
19 “conclusive evidence” of the increased risk of breast cancer associated with the Product for women  
20 who never had or never had a suspicion of having present cancer, (ii) failed to disclose to doctors  
21 that there is a statistically significant increased risk (approximately 20-30%) of developing breast  
22 cancer associated with the Product, and (iii) failed to disclose to Plaintiffs and California Subclass  
23 Members that there is a statistically significant increased risk (approximately 20-30%) of developing  
24 breast cancer associated with the Product.

25           88. Defendant at all relevant times had a duty to disclose the information in question  
26 because, *inter alia*: (i) Defendant had superior knowledge of material information that was not known  
27 to Plaintiffs, the California Subclass, and their doctors; (ii) Defendant concealed material information  
28 from Plaintiffs, the California Subclass, and their doctors; and/or (iii) Defendant made partial  
representations to Plaintiffs, the California Subclass, and their doctors, which were false and  
misleading absent the omitted information.

1           89. Defendant's misrepresentations and nondisclosures deceive and have a tendency and  
2 ability to deceive the general public and doctors who prescribe Mirena.

3           90. Defendant's misrepresentations and nondisclosures are material, in that a reasonable  
4 person would attach importance to the information Defendant failed to disclose and would have acted  
5 differently had Defendant disclosed the statistically significantly increased risk (~20-30% on  
6 average) of developing of breast cancer.

7           91. Similarly, Defendant's misrepresentations and nondisclosures are material, in that a  
8 reasonable doctor would attach importance to the information Defendant failed to disclose and would  
9 have acted differently had Defendant disclosed the statistically significantly increased risk  
10 (approximately 20-30%) of developing breast cancer.

11           92. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent  
12 conduct, Plaintiffs and the California Subclass suffered injury-in-fact and lost money because they  
13 paid for the Mirena IUD and/or the insertion of the Mirena IUD.

14           93. But for Defendant's omissions of material facts, Plaintiffs and the California Subclass  
15 would not have paid out-of-pocket for the Product or its insertion. Similarly, but for Defendant's  
16 misrepresentations and omissions of material facts, Plaintiffs' and the California Subclass's doctors  
17 would not have prescribed the Product, meaning Plaintiffs and California Subclass Members would  
18 not have paid any out-of-pocket for the Product or its insertion.

19           94. Defendant's conduct as alleged herein caused substantial injury to Plaintiffs,  
20 California Subclass Members, and the public.

21           95. On February 1, 2022, more than thirty days prior to the commencement of an action  
22 under this section, Defendant was served with a notice letter on behalf of the California Subclass that  
23 complied in all respects with Cal. Civ. Code § 1782. Plaintiffs' counsel sent Defendant a letter  
24 advising Defendant of the specific acts and practices it committed in violation of the CLRA, and  
25 which particular sections of CLRA Defendant breach. Plaintiffs' counsel also demanded that  
26 Defendant cease and desist from such breaches and make full restitution by refunding the monies  
27 received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1**.

28

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendant, as follows:

- (a) For an order certifying the nationwide Class under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiffs as the representative of the Class, and naming Plaintiffs’ attorneys as Class Counsel to represent the Class;
- (b) For an order declaring the Defendant’s conduct violates the statutes referenced herein;
- (c) For an order finding in favor of Plaintiffs and the Class on all counts asserted herein;
- (d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;
- (e) For prejudgment interest on all amounts awarded;
- (f) For an order of restitution and all other forms of equitable monetary relief;
- (g) For injunctive relief as pleaded or as the Court may deem proper; and
- (h) For an order awarding Plaintiffs and the Class their reasonable attorneys’ fees and expenses and costs of suit.

**DEMAND FOR TRIAL BY JURY**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: May 20, 2024

**BURSOR & FISHER, P.A.**

By:           /s/ L. Timothy Fisher          

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*Attorneys for Plaintiff*

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February 1, 2022

**Via Certified Mail - Return Receipt Requested**

Bayer U.S. LLC  
100 Bayer Boulevard  
Whippany, New Jersey 07981

*Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607;  
Cal. Civ. Code § 1782; N.Y. Gen. Bus. Law §§ 349 and 350;  
and all other relevant state and local laws*

To Whom It May Concern,

This letter serves as a preliminary notice and demand for corrective action by Bayer U.S. LLC (“Bayer” or “You”) pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws, including but not limited to subsections (a)(5), (7), and (9) of the Consumers Legal Remedies Act, Civil Code § 1770 and New York General Business Law §§ 349 and 350 – related to our clients, Priya Sidhu and Casey Overton, and a class of all similarly situated purchasers (the “Class”) of defective and falsely labeled Mirena intrauterine device (“Mirena IUD” or the “Product”) manufactured and sold by Bayer.

Ms. Sidhu first purchased the Mirena IUD in California in February 2019, and has continued to use the Product since that time. Ms. Sidhu pays \$50 out of pocket each time she purchases the Product. Likewise, Ms. Overton first purchased the Mirena IUD in New York in April 2015, and continued to do so until October 2020. Ms. Overton paid \$25-30 out of pocket each time she purchased the Product. Although both Ms. Sidhu and Ms. Overton received marketing materials (*i.e.*, a pamphlet from You) when they purchased the Product, the materials failed to warn Ms. Sidhu and Ms. Overton that the Product carried with it an increased risk of breast cancer. Yet the risk was prominently there. A recent study found that patients using the Product have a have a 20% increased risk of developing breast cancer.<sup>1</sup> Had you disclosed this fact, Ms. Sidhu and Ms. Overton would not have purchased the Product, or would have paid significantly less for it, based on the incumbent risk of developing breast cancer.

In short, our clients and the Class overpaid for the Product based on your failure to disclose the heightened risk of developing breast cancer. Your failure to disclose these material facts constitutes a breach of the express and implied warranties made to our clients and the Class regarding the quality and safety of the Mirena IUDs they purchased. *See* U.C.C. §§ 2-313, 2-314.

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<sup>1</sup> Tuuli Soini et al., *Levonorgestrel-Releasing Intrauterine System and the Risk Of Breast Cancer: A Nationwide Cohort Study*, 55 ACTA ONCOLOGICA 188 (2016), <https://www.tandfonline.com/doi/full/10.3109/0284186X.2015.1062538>

This letter also serves as notice of violation of the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* You violated the CLRA by (1) representing that the Product had certain characteristics that it did not have, in violation of Cal. Civ. Code § 1770(5); (2) representing that the Product was of a certain standard or quality when it was not, in violation of Cal. Civ. Code § 1770(7); and (3) advertising the Product with an intent not to sell it as advertised, in violation of Cal. Civ. Code § 1770(9). As a result of Your violation of the California Consumers Legal Remedies Act, Ms. Sidhu sustained injury.

Finally, this letter serves as notice of violation of the New York General Business Law (“GBL”) §§ 349 and 350, and all other relevant state and local laws. You violated GBL §§ 349 and 350 by failing to disclose that the Product carried with it a heightened risk of breast cancer. You knew or should have known about these facts. As a result of Your violation of the GBL §§ 349 and 350, Ms. Overton and a subclass of all purchasers of the Product in New York sustained injury and are entitled to statutory damages of \$550 per violation.

On behalf of our clients and the Class, we hereby demand that You immediately make full restitution to all purchasers of the defective and falsely labeled Mirena IUDs of all purchase money obtained from sales thereof, in addition to statutory damages as appropriate.

We also demand that You preserve all documents and other evidence which refers or relates to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for the Mirena IUDs;
2. All documents concerning the design, development, supply, production, extraction, and/or testing of the Mirena IUDs;
3. All tests of the Mirena IUDs;
4. All documents concerning the pricing, advertising, marketing, and/or sale of the Mirena IUDs;
5. All communications with customers involving complaints or comments concerning the Mirena IUDs;
6. All documents concerning communications with any pharmacy or physician involved in the marketing or sale of the Mirena IUDs;
7. All documents concerning communications with federal or state regulators;
8. All documents concerning any testing or screening for the increased risk of breast cancer stemming from the Mirena IUDs; and
9. All documents concerning the total revenue derived from sales of the Mirena IUDs.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,



Joshua Arisohn