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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

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

NATURE OF THE ACTION

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

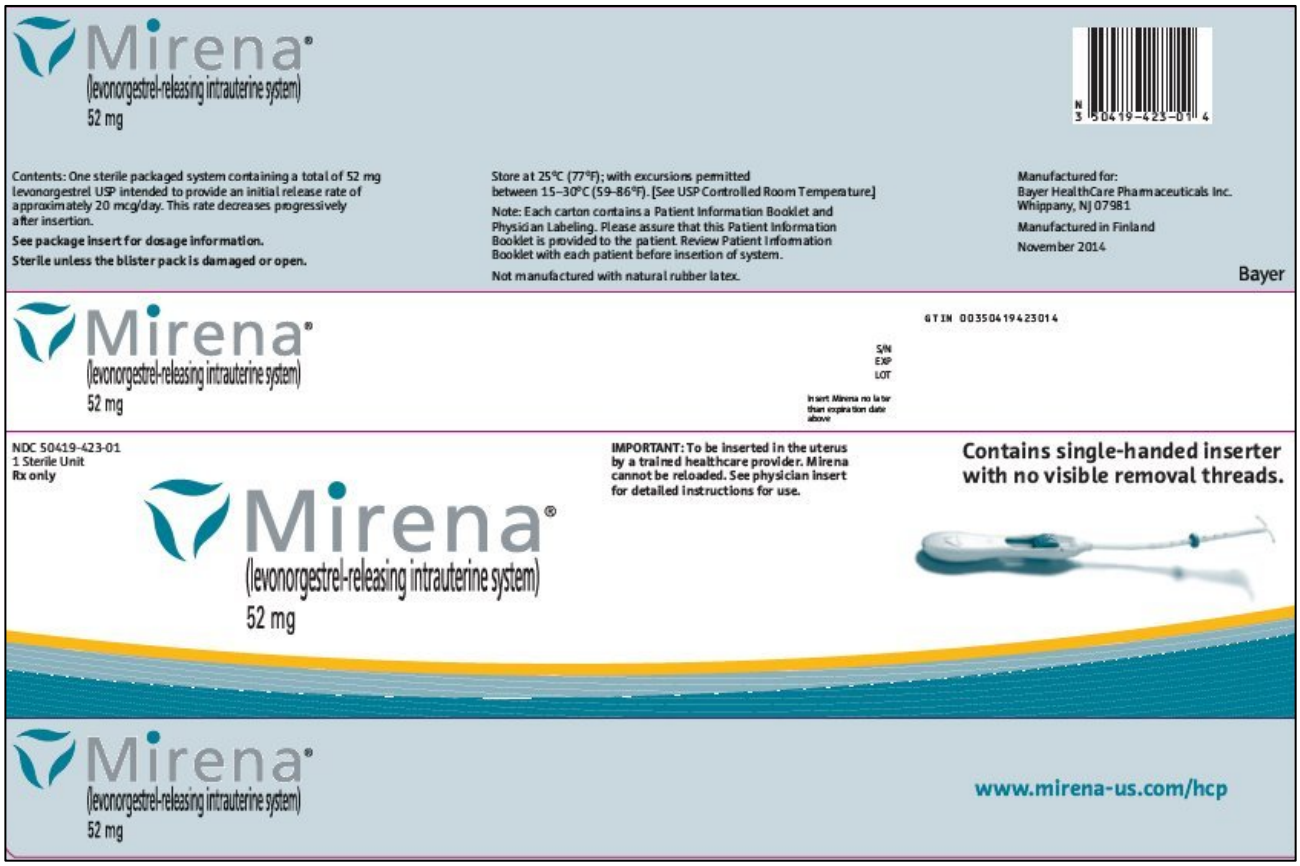
1. This is a putative class action lawsuit on behalf of women who paid an out-of-pocket cost as a result of being prescribed Bayer's Mirena intrauterine device (the "Mirena IUD," "Mirena," or the "Product"). Defendant markets and sells the Products as suitable for use as birth control, but Mirena IUDs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

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

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

[1] SAFETY CONSIDERATIONS FOR MIRENA, https://www.mirena-us.com/mirena-side-effects-and-safety.

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



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

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

[2] Available at https://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf.

Likewise, Defendant's website provides a warning only for women who already have, or might have, cancer.[3]

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

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

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

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

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

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

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

[3] WHO SHOULD NOT USE MIRENA?, https://www.mirena-us.com/.

[4] Available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/021225orig1s031.pdf.

[5] *See generally* Heli K. Lyytinen, Heli K. et al., *A Case-Control Study On Hormone Therapy As A 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.

risk in postmenopausal women using an LNG-IUS such as the Mirena IUD.[6] Specifically, the study found "positive associations with BC risk" at an odds ratio of 1.48 at a 95% confidence interval "when compared to never-users of any hormonal contraceptive."

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

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

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

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

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

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

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

[7] 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://www.tandfonline.com/doi/full/10.3109/0284186X.2015.1062538.

[8] 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/nejmoa1700732.

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

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

18. In 2023, another systematic review of existing studies similarly concluded that there is "an increased BC risk in LNG-IUS users."[11]

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

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[9] *See*, *e.g.*, NATIONAL CANCER INSTITUTE, ORAL CONTRACEPTIVES AND CANCER RISK, https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-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.").

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

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

of around 20% to 30% in breast cancer risk associated with current or recent use of either combined oral or progestogen only contraceptives" such as Mirena.[12]

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

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

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

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

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

[13] 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).

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

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

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

MIRENA PRESCRIBING INFORMATION, at § 5.9.

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

> Spontaneous reports of breast cancer have been received during postmarketing experience with Mirena. Because spontaneous reports 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[15] SAFETY CONSIDERATIONS FOR MIRENA, https://www.mirena-us.com/mirena-side-effects-and-safety.

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

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

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

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

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

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

[16] Available at https://www.mirena-us.com/cost-support.

and (iii) violation of California's Consumers Legal Remedies Act ("CLRA"), Cal. Civil Code §§ 1750, *et. seq*.

PARTIES

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

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

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

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

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

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

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

JURISDICTION AND VENUE

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

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

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

CLASS ALLEGATIONS

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

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

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

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

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

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

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

(a) whether the Product manufactured, distributed, and sold by Defendant subjected consumers to a statistically significantly increased risk (approximately 20-30%) of developing breast cancer, thereby breaching implied warranties made by Defendant and making the Product unfit for its intended purpose;

(b) whether Defendant knew or should have known that the Product subjected consumers to a statistically significantly 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;

(d) whether Plaintiffs and the Class are entitled to declaratory and injunctive relief;

(e) whether Plaintiffs and the Class are entitled to restitution and disgorgement from Defendant; and

(f) whether the marketing, advertising, packaging, labeling, and other promotional materials for Product are deceptive.

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

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

57. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all 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

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

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

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I
Breach Of Implied Warranty Of Merchantability

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

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

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

62. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the Product was suited for use as a birth control device and that it would 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

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

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

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

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

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

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

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

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

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

COUNT II
Fraud

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

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

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

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

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

75. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiffs and Class Members and their doctors reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and Class Members to pay out-of-pocket for and use the Product—including payments for the Product itself and/or insertion thereof—and to induce doctors to prescribe the Product to their patients.

76. Defendant had a duty to disclose the significantly increased risk of developing breast cancer to Plaintiffs and Class Members, and Plaintiffs' and Class Members' doctors, because (i) Defendant had superior knowledge of material facts not known to Plaintiffs and Class Members and their doctors, (ii) Defendant actively concealed this material fact from Plaintiffs and Class Members and their doctors, and (iii) Defendant made partial representations to Plaintiffs and Class Members and their by representing some of the risks that the Mirena IUD carries with it, but not the statistically significantly increased risk (approximately 20-30%) of developing breast cancer, or the risk posed to women who never had or never had a suspicion of having breast cancer.

77. The fraudulent actions of Defendant caused damage to Plaintiffs and Class Members, who are entitled to damages and other legal and equitable relief as a result.

78. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT III
Violation of California's Consumers Legal Remedies Act
California Civil Code §§ 1750, *et seq.*

79. Plaintiffs incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

80. Plaintiffs bring this claim individually and on behalf of the members of the California Subclass against Defendant.

81. Defendant is a "person," as defined by California Civil Code § 1761(c).

82. Plaintiffs and California Subclass Members are "consumers," as defined by California Civil Code § 1761(d).

83. The Product purchased and used by the Plaintiffs and California Subclass Members are "goods" as defined by California Civil Code § 1761(a).

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

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

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

(a) Defendant misrepresented that its products had characteristics, benefits, or uses that they did not have (Cal. Civ. Code § 1770(a)(5));

(b) Defendant misrepresented that its products were of a particular standard, quality, grade, or of a particular style or model when the products were of another (Cal. Civ. Code § 1770(a)(7)); and

(c) Defendant advertised its products with an intent not to sell them as advertised (Cal. Civ. Code § 1770(a)(9)).

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

88. Defendant at all relevant times had a duty to disclose the information in question because, *inter alia*: (i) Defendant had superior knowledge of material information that was not known to Plaintiffs, the California Subclass, and their doctors; (ii) Defendant concealed material information 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.

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

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

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

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

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

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

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

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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