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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PRIYA SIDHU, individually and on behalf of all others similarly situated, Plaintiff, v. BAYER U.S. LLC, Defendant.	Case No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Priya Sidhu ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendant Bayer U.S. LLC ("Defendant" or "Bayer"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based upon personal knowledge.

NATURE OF THE ACTION

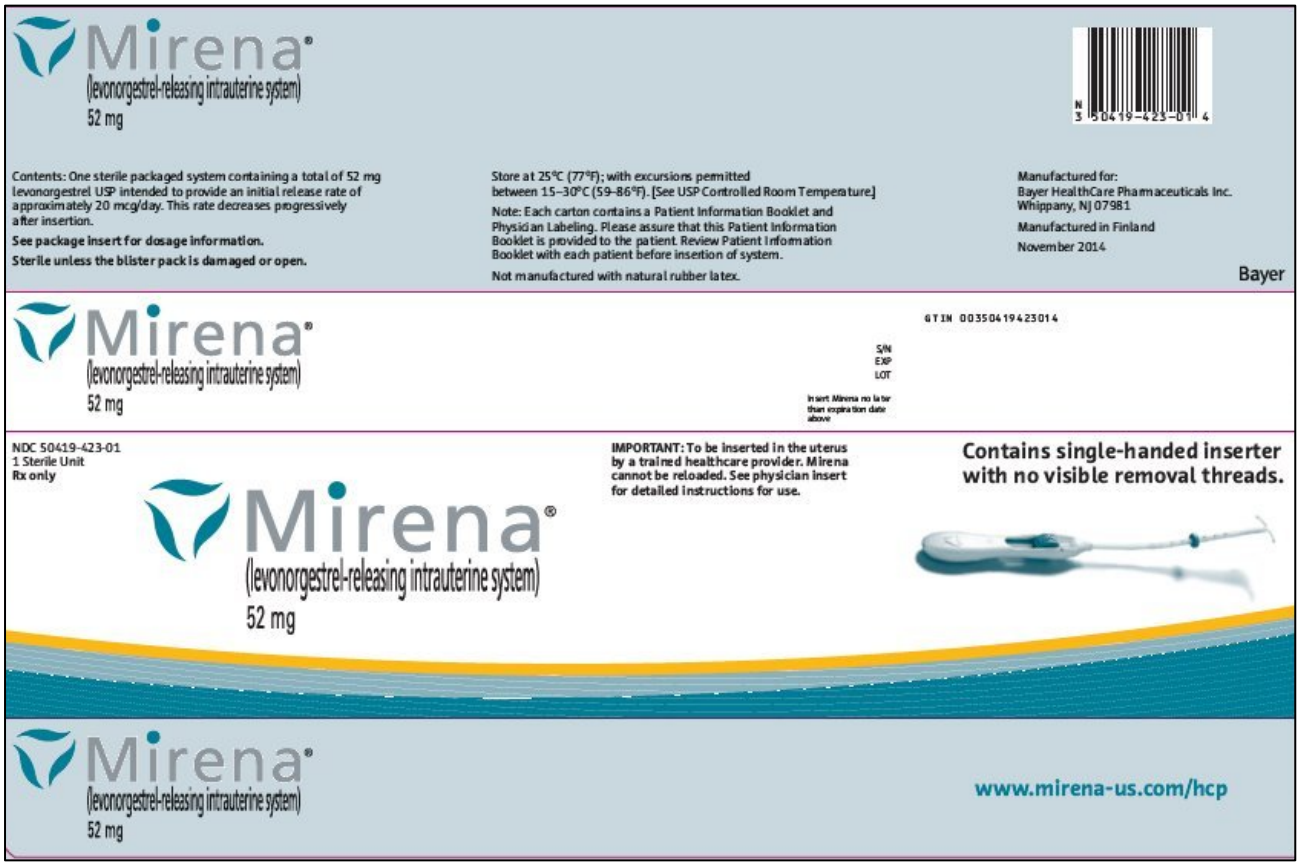
1. This is a putative class action lawsuit on behalf of purchasers of Bayer's Mirena intrauterine devices (the "Mirena IUD" or the "Product"). Defendant markets and sells the Products as suitable for use as birth control, but Mirena IUDs are not suitable for that use because they significantly increase the risk of breast cancer in users.

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 significantly increased risk of breast cancer caused by the Product.

4. Likewise, the packaging of the Product does not disclose that it significantly increases the risk of breast cancer:

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



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

6. But Defendant has long known that the Product significantly increases the risk of breast cancer.

7. In 2010, a case-control study compared 329 women users of LNG-IUS with 708 controls of the same age.[2] The study showed an increased risk for breast cancer in the LNG-IUS population with an odds rate of 1.53 at a 95% confidence interval.

[2] 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.

8. In 2015, a Finnish study found a statistically significant increase in breast cancer risk in postmenopausal women using a LNG-IUS such as the Mirena IUD.[3] Specifically, the study found an odds ratio of 1.48 at a 95% confidence interval.

9. In 2016, a study found that patients using an LNG-IUS, such as the Product, have a significantly elevated risk of developing breast cancer.[4] Specifically, the study found that women who used the LNG-IUS

> 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).

According to the study, "[t]he results imply that intrauterine administration of levonorgestrel 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."

10. In 2017, a Danish study found that, among women who used the LNG-IUS intrauterine system, the relative risk of breast cancer was 1.21 at 95% confidence interval.[5]

11. In 2020, a systematic review of existing studies found that "LNG-IUS users have an increased breast cancer risk regardless of age and indication."[6]

12. Plaintiff and Class Members purchased the Product designed, marketed, manufactured, distributed, and sold by Defendant. Plaintiff and Class Members relied on

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[3] 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 (2016), https://pubmed.ncbi.nlm.nih.gov/26667320/.

[4] Soini, Tuuli 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.

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

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

Defendant's representations concerning the Product, including Defendant's specific enumeration of risks that the Product carried. Plaintiff and Class members would not have purchased the Product—or, at minimum, would have paid significantly less for the Product—had Defendant disclosed that the Product carried with it a significantly elevated risk of breast cancer.

13. Plaintiff and Class Members thus suffered monetary damages as a result of Defendant's deceptive and fraudulent omissions.

14. Plaintiff brings this action on behalf of herself and the Class for equitable relief and to recover damages and restitution for: (i) breach of implied warranty; (ii) unjust enrichment; (iii) fraud; (iv) negligence; (v) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*; (vi) violation of California's Consumers Legal Remedies Act ("CLRA"), Civil Code §§ 1750, *et. seq.*; and (vii) violation of California's False Advertising Law ("FAL"), Cal. Bus & Prof Code § 17500.

PARTIES

15. Plaintiff Priya Sidhu is a resident of San Jose, California and has an intent to remain there, and is therefore a domiciliary of California. Between February 2019 and February 2022, Ms. Sidhu was prescribed and used the Mirena IUD in California. Ms. Sidhu paid $50 out-of-pocket for the Mirena IUD. Upon first using the Mirena IUD, Ms. Sidhu received and reviewed the patient brochure distributed by Defendant, which did not disclose the significantly elevated risk of developing breast cancer from using the Mirena IUD. Ms. Sidhu relied on Defendant's representations and warranties in deciding to purchase and use the Mirena IUD. Accordingly, Defendant's representations and warranties were part of the basis of the bargain, in that she would not have purchased the Mirena IUD, or would have paid significantly less for it, had Defendant disclosed that the Mirena IUD carried with it a significantly elevated risk of developing breast cancer. At no time did Defendant or anyone else warn Plaintiff or her physician about the significantly elevated breast cancer risk associated with the Product.

16. Defendant Bayer U.S. LLC 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.

JURISDICTION AND VENUE

17. 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 Plaintiff, as well as most members of the proposed class, are citizens of states different from Defendant.

18. Defendant is an "unincorporated association" under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), and Defendant is therefore "a citizen of the State where it has its principal place of business [New Jersey] and the State under whose laws it is organized [Delaware]." *See* 28 U.S.C. § 1332(d)(10).

19. This Court has personal jurisdiction over Defendant because Plaintiff was prescribed and used the Product in California, was exposed to Defendant's fraudulent omissions in California, and Defendant conducts substantial business within California, such that Defendant has significant, continuous, and pervasive contacts within the State of California.

20. 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 was prescribed and used the Product in this District.

CLASS ALLEGATIONS

21. Plaintiff seeks to represent a class defined as all persons in the United States who were prescribed and used the Mirena IUD (the "Nationwide Class").

22. Plaintiff also seeks to represent a class defined as all persons who reside in the state of California and who were prescribed and used the Mirena IUD (the "California Subclass") (collectively with the Nationwide Class, the "Class").

23. 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.

24. 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.

25. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, 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.

26. **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 significantly elevated risk 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 significantly elevated risk of developing breast cancer prior to selling the Product, thereby constituting fraud and/or fraudulent omission;

(c) whether Defendant is liable to Plaintiff and the Class for unjust enrichment;

(d) whether Plaintiff and the Class have sustained monetary loss and the proper measure of that loss;

(e) whether Plaintiff and the Class are entitled to declaratory and injunctive relief;

(f) whether Plaintiff and the Class are entitled to restitution and disgorgement from Defendants; and

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

27. **Typicality.** The claims of the representative Plaintiffs are typical of the claims of the Classes in that the representative Plaintiff, like all members of the Class, was prescribed and used the Product and was not told of the significantly increased risk of developing breast cancer by Defendant. The representative Plaintiff, like all members of the Class, has 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.

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

29. **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.

30. 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

31. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

32. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

33. 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 significantly elevated risk of 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, Plaintiff and Class Members did not receive the goods as impliedly warranted by Defendant to be merchantable.

34. Plaintiff and the Class Members purchased the Product in reliance upon Defendant's skill and judgment in properly packaging and labeling the Tests.

35. The Product was not altered by Plaintiff and Class Members.

36. The Product was not fit for its intended purpose when it left the exclusive control of Defendant.

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

38. The Product was defectively designed and unfit for its intended purpose, and Plaintiff and Class Members did not receive the Product as warranted.

39. Plaintiff and Class Members were injured as a direct and proximate result of Defendant's breach because (i) they would not have purchased the Product if they had known that the Product carried with it a significantly elevated risk of breast cancer, and (ii) they overpaid for the Product on account of Defendant's failure to disclose that the Product carried with it a significantly elevated risk of developing breast cancer.

40. On February 1, 2022, prior to the filing of this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's 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
Unjust Enrichment

41. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

42. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

43. Plaintiff and the Class conferred a benefit on Defendant in the form of monies paid to purchase the Product.

44. Defendant voluntarily accepted and retained this benefit.

45. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for the Product while failing to disclose the significantly elevated risk of developing breast cancer unfit for the purpose in which they were sold, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT III
Fraud

46. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

47. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

48. As discussed above, Defendant failed to disclose to Plaintiff and Class Members that the Product carried with it a significantly increased risk of breast cancer.

49. Defendant had knowledge of these omissions and therefore acted with scienter. Specifically, several studies documenting the significantly increased risk of breast cancer associated with the Product have been published since 2010. Nonetheless, Defendant continued to sell the Product without disclosing the same to Plaintiff and Class Members, who used the Product without knowledge of this significantly increased risk.

50. The omissions of material fact made by Defendant, upon which Plaintiff and Class Members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class Members to purchase and use the Product.

51. Defendant had a duty to disclose the significantly increased risk of developing breast cancer to Plaintiff and Class Members because (i) Defendant had exclusive knowledge of material

facts not known to Plaintiff and Class Members, (ii) Defendant actively concealed this material fact from Plaintiff and Class Members, and (iii) Defendant made partial representations to Plaintiff and Class Members by representing some of the risks that the Mirena IUD carries with it, but not the significantly elevated risk of breast cancer.

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

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

COUNT IV
Negligence

54. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

55. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

56. Defendant, as the designer, manufacturer and distributor of the Product owed Plaintiff and the public a duty to use reasonable care in designing and testing the Mirena IUD.

57. Defendants breached its duty of care owed to Plaintiff and other consumers because it did not use the amount of care in designing and testing the Product that a reasonably careful designer of similar products would use in similar circumstances to avoid exposing others to a foreseeable risk of harm. If Defendant had properly tested the product, it would have discovered that it results in a significantly elevated risk of breast cancer.

As a direct and proximate cause of Defendant's negligence, Plaintiff and Class have been injured and harmed in the form of an economic loss. Specifically, had Plaintiff and the Class known that the Product was negligently designed so that it causes a significantly elevated risk of breast cancer, they would not have purchased the Product or only agreed to pay significantly less for it.

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COUNT V
Violation of California's Unfair Competition Law
California Business and Professions Code § 17200 *et seq*.

58. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

59. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

60. By committing the acts and practices alleged herein, Defendant has violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*, as to the California Subclass, by engaging in unlawful, fraudulent, and unfair conduct.

61. Defendant has violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of the CLRA, FAL, and by committing fraud, unjust enrichment, negligence, and breaching implied warranties, as alleged herein.

62. Defendant's acts and practices described above also violate the UCL's proscription against engaging in fraudulent conduct. As more fully described above, Defendant's failure to disclose that the Product carries with it a significantly increased risk of developing breast cancer is likely to deceive reasonable consumers.

63. Plaintiff and the other California Subclass members suffered a substantial injury by virtue of buying the Product that they would not have purchased absent Defendant's unlawful, fraudulent, and unfair omissions about significantly increased risk of developing breast cancer, or by virtue of paying an excessive premium price for the Product as a result of Defendant's unlawful, fraudulent, and unfair omissions.

64. There is no benefit to consumers or competition from failing to disclose that the Product carries with it a significantly increased risk of developing breast cancer.

65. Plaintiff and the other California Subclass members had no way of reasonably knowing that the Product they purchased and used carried with it a significantly increased risk of developing breast cancer. Thus, they could not have reasonably avoided the injury each of them suffered.

66. The gravity of the consequences of Defendant's conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiff and the other members of the California Subclass.

67. Plaintiff, on behalf of herself and the California Subclass, seeks injunctive relief to require Defendant to: (1) provide notice to every class member that the Product carries with it significantly increased risk of developing breast cancer; (2) provide a refund to Plaintiff and the California Subclass for their Product test in an amount to be determined at trial; (3) subsidize the costs of screening for breast cancer for Plaintiff and California Subclass Members.

68. Defendant's conduct has caused substantial injury to Plaintiff, California Subclass Members, and the public. Defendant's conduct is ongoing and will continue absent a permanent injunction. Accordingly, Plaintiff seeks an order enjoining Defendant from committing such unlawful, unfair, and fraudulent business practices. Plaintiff further seeks an order granting restitution to Plaintiff and the California Subclass members in an amount to be proven at trial. Plaintiff further seeks an award of attorneys' fees and costs under Cal. Code Civ. Proc. § 1021.5.

69. Plaintiff and the general public lack an adequate remedy at law to remedy and/or mitigate the totality of the injuries and misconduct described herein.

70. Absent injunctive relief, Defendant will continue to injure Plaintiff and the California Subclass members. Defendant's conduct and omissions of material fact are ongoing. And, even if such conduct were to cease, it is behavior that is capable of repetition or reoccurrence by Defendant yet evades review.

71. In order to prevent injury to the general public, Plaintiff, in her individual capacity, seeks a public injunction requiring Defendant to disclose to consumers that the Product carries with it a significantly increased risk of developing breast cancer.

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

72. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

73. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

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

75. Plaintiff and members of the California Subclass are "consumers," as defined by California Civil Code § 1761(d).

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

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

78. 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.

79. With regard to this count of the pleading which alleges one or more violations of the CLRA, venue is proper in the state or federal court having jurisdiction over Santa Clara County, California (the county in which this action has been commenced) pursuant to Section 1780(d) of the California Civil Code because, without limitation, Santa Clara County is a county in which Defendant is doing business and is the county in which a substantial portion of the events that gave rise to this cause of action occurred. A declaration establishing that this Court has proper venue for this count is attached hereto as **Exhibit 2**.

80. Defendant's methods, acts and/or practices, including Defendant's 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)).

81. Specifically, Defendant failed to disclose that the Product carried with it a significantly increased risk of developing breast cancer.

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

83. Defendant's misrepresentations and nondisclosures deceive and have a tendency and ability to deceive the general public.

84. 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 significantly increased risk of breast cancer.

85. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent conduct, Plaintiff and the California Subclass suffered injury-in-fact and lost money.

86. But for Defendant's omissions of material facts, Plaintiff and the California Subclass would not have purchased the Product tests and/or would have paid significantly less for the Product.

87. Defendant's conduct as alleged herein caused substantial injury to Plaintiff, California Subclass Members, and the public. Defendant's conduct is ongoing and will continue and recur absent a permanent injunction. Accordingly, Plaintiff and the California Subclass seek an order enjoining Defendant from committing such practices.

88. If not enjoined by order of this Court, Defendant will continue to omit crucial information and injure Plaintiff and consumers through the misconduct alleged herein once more. Defendant has a duty to speak truthfully or in a non-misleading manner.

89. Plaintiff will be harmed if, in the future, they are left to guess as to whether Defendant's representations are accurate and whether there are omissions of material facts regarding the features or specifications of the Product.

90. In order to prevent injury to the general public, Plaintiff, in her individual capacity, seeks a public injunction requiring Defendant to disclose that the Product carries with it a significantly increased risk of developing breast cancer.

91. The balance of the equities favors the entry of permanent injunctive relief against Defendant. Plaintiff and the general public will be irreparably harmed absent the entry of permanent injunctive relief against Defendant. Plaintiff and the general public lack an adequate remedy at law. A permanent injunction against Defendant is in the public interest. Defendant's unlawful behavior is capable of repetition or re-occurrence absent the entry of a permanent injunction.

92. 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 Plaintiff and the California Subclass that complied in all respects with Cal. Civ. Code § 1782. Plaintiff's 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. Plaintiff's counsel also demanded that Defendant t 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 VII
Violation of California's False Advertising Law
California Business and Professions Code § 17500, *et seq.*

93. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

94. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

95. California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.* ("FAL"), makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, … in any advertising device … or in any other manner or means whatever, including over the Internet, any statement, concerning … personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

96. Defendant committed acts of false advertising, as defined by §17500, by failing to disclose that the Product carries with it a significantly increased risk of developing breast cancer.

97. Defendant knew, or should have known through the exercise of reasonable care, that its failure to disclose this material fact was substantially likely to mislead to consumers.

98. Defendant's actions in violation of § 17500 were false and misleading such that the general public is and was likely to be deceived.

99. Plaintiff and the California Subclass lost money or property as a result of Defendants' FAL violations because: (a) they would not have purchased the Product on the same terms if the true facts were known about the Product; (b) they paid a price premium for the Product due to Defendant's failure to disclose that the Product carried with it a significantly increased risk of developing breast cancer; and (c) the Product did not have the characteristics as promised by Defendant.

PRAYER FOR RELIEF

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

(a) For an order certifying the nationwide Class under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as representative of the Class, and naming Plaintiff's 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 Plaintiff 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 Plaintiff 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), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: March 14, 2022

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ L. Timothy Fisher*
L. Timothy Fisher

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EXHIBIT 1

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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.[1] 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.

[1] 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

EXHIBIT 2

CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, L. Timothy Fisher, declare as follows:

1. I am counsel for Plaintiff, and I am a partner at Bursor & Fisher, P.A.. I make this declaration to the best of my knowledge, information, and belief of the facts stated herein.

2. The complaint filed in this action is filed in the proper place for trial under California Civil Code Section 1780(d) because a substantial part of the events or omissions giving rise to these claims occurred in this District.

3. Plaintiff Priya Sidhu alleges that between February 2019 and February 2022, she was prescribed and used the Mirena IUD in San Jose, California. *See* Compl. ¶ 15. Plaintiff alleges she paid $50 out-of-pocket for the Mirena IUD. *Id*. Plaintiff further alleges that she received and reviewed the patient brochure distributed by Defendant, which did not disclose the significantly elevated risk of developing breast cancer from using the Mirena IUD. *Id.* Plaintiff relied on Defendant's representations and warranties in deciding to purchase and use the Mirena IUD. Accordingly, Defendant's representations and warranties were part of the basis of the bargain, in that she would not have purchased the Mirena IUD, or would have paid significantly less for it, had Defendant disclosed that the Mirena IUD carried with it a significantly elevated risk of developing breast cancer.

I declare under the penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct. Executed on March 14, 2022 in Walnut Creek, California.

/s/ L. Timothy Fisher
L. Timothy Fisher