IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION

SHERRI HOWELL PLAINTIFF V. ORGANON USA, INC., N.V. ORGANON SCHERING CORP., MERCK & CO., INC., AND MERCK SHARP & DOHME, CORP. DEFENDANTS	CASE NO. 12-cv-0087-LRR JUDGE

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff Sherri Howell, (hereinafter "Plaintiff"), by and through undersigned counsel, and for her Complaint against Organon USA, Inc., N.V. Organon, Schering Corporation, Merck & Co., and Merck Sharp and Dohme, Corp. states as follows:

PARTIES AND JURISDICTION

1. Plaintiff is a resident and citizen of the Cedar Rapids, Iowa, located in Linn County.

2. Defendant Organon USA, Inc. is a New Jersey corporation with its principal place of business at 56 Livingston Ave., Roseland, New Jersey 07068. Defendant Organon USA, Inc. is a sales unit of the healthcare group of Akzo Nobel NV and Defendant Organon International, Inc. At all times relevant, Organon USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate

commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing®. At relevant times, Defendant Organon USA, Inc. conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Iowa.

3. Defendant N.V. Organon is a foreign corporation with a principal place of business at Molenstraat 110, 5342 OCC Oss in the Netherlands. Defendant N.V. Organon conducted research and contributed to the development, the design, testing and manufacturer, as well as marketing and distribution of NuvaRing® in the United States. Defendant N.V. Organon conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Iowa.

4. Defendant Schering Corporation (herein after "Defendant Schering") is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Defendant Schering conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Iowa.

5. Defendant Schering acquired Organon BioSciences NV (OBS), in November 2007 and assumed the liabilities attendant thereto, including the liabilities of Defendant Organon USA, Inc. Organon BioSciences, NV, is comprised of Organon, a human health business (which includes Organon USA, Inc.), Intervet, an animal health business, Nobilon, a human vaccine development unit, and Diosynth, a third party manufacturing arm of Organon.

6. In 2008, Defendant Schering acquired Organon Pharmaceuticals USA, Inc., and caused it to be dissolved as a corporation; and made it a subsidiary. In so doing, Schering assumed the liabilities of Organon Pharmaceuticals USA, Inc. Upon information and believe,

Organon Pharmaceuticals, Inc. was the United States pharmaceutical arm of Defendant Organon International, Inc. Until dissolution Organon Pharmaceuticals USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, packaging, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing®. Upon information and belief, Organon Pharmaceuticals USA, Inc. was at all times relevant to this Complaint part of the Akzo Nobel, NV business unit of Organon.

7. Defendant Schering expressly and/or impliedly assumed the liabilities and obligations of Organon USA, Inc. and Organon International, Inc., including the injuries and damages associated with NuvaRing® and alleged herein.

8. Hereinafter, Defendants Organon USA, Inc., N.V. Organon and Schering Corporation will be referred to collectively as “Organon” or “Organon Defendants”.

9. In or about November 2009, Defendant Merck & Co., Inc., completed the merger with Schering Corporation, which included Organon and the liabilities and assets associated with NuvaRing®. Defendant Merck & Co., Inc. is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, NJ, 08889-0100. Defendant Merck Sharp & Dohme is a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, NJ, 08889-0100. Defendants Merck & Co., Inc. and Merck Sharp & Dohme conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Iowa.

10. In the merger, Schering Corporation acquired all of the shares of Merck & Co., Inc., which became a wholly-owned subsidiary of Schering-Plough Corporation and was

renamed Merck Sharp & Dohme Corp. Schering continued as the surviving public company and was renamed Merck & Co., Inc.

11. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. expressly and/or impliedly assumed the liabilities and obligations of Schering-Plough and the named Organon defendants for the injuries and damages alleged herein resulting from Plaintiff's use of NuvaRing®.

12. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. have continued the business and operation of Schering-Plough Corporation and the named Organon Defendants, including, but not necessarily limited to the NuvaRing®.

13. Therefore, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. are liable to Plaintiff for the injuries and damages alleged herein as a successor in interest and/or successor corporations of Schering-Plough Corporation and the Organon defendants named herein.

14. This Court has personal jurisdiction over the defendants in that the prescription drug at issue, NuvaRing®, was marketed, sold, or otherwise distributed within the State of Iowa.

15. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.00 exclusive of interest and costs.

16. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district, as the Defendants collectively have marketed, sold, distributed or otherwise distributed NuvaRing® within the Northern District of Iowa.

TAG-ALONG ACTION

17. This is a potential tag-along action and in accordance with 28 U.S.C. §1407, it should be transferred to the United States District Court for the Eastern District of Missouri for inclusion in *In re: NuvaRing Products Liability Litigation*, MDL 1964, Case No. 08-md-1964 (Hon. Rodney W. Sippel).

FACTUAL BACKGROUND

18. Upon information and belief, upon the merger of Defendant Merck and Defendant Schering into Defendant Corporation Sharp & Dohme, Corp., Defendants Merck & Co., Inc. and Defendant Merck Sharp & Dohme, Corp. assumed the liabilities and obligations of Defendants Organon associated with NuvaRing®, including the liabilities associated with the damages and injuries alleged herein by Plaintiff. Therefore, all named Defendants are liable to Plaintiff who was injured due to her use of the said NuvaRing® product, either by virtue of being the corporation which engages in the conduct stated herein, or as successor corporations having assumed the liability through the purchase of a predecessor corporation.

19. Defendants market NuvaRing® as the first and only, once-a-month vaginal birth control ring, and further markets NuvaRing® as providing the same efficacy as birth control pills or the patch in preventing pregnancy, but with more convenience because it offers “month-long protection against pregnancy, so women who use NuvaRing® don't have to think about contraception every day.”

20. At all times material hereto, Defendants failed to properly disclose the known safety hazards associated with NuvaRing®.

21. The package insert accompanying NuvaRing® stated that the vaginal ring is expected to be associated with similar risks to that of birth control pills and that the safety information they provide to consumers is derived primarily from studies of birth control pills.

22. Therefore, the safety information provided to the consumer was not derived primarily from studies of NuvaRing® and, therefore, the package insert accompanying NuvaRing® is misleading.

23. However, Etonogestrel, a synthetic, third-generation progestin, that Defendants Organon use in the NuvaRing® as a starting agent, was not the subject of sufficient and adequate testing. Defendants Organon knew or should have known that information conveying potential adverse events involving DVT, PE, and death should be set forth in the package insert.

24. The safety information provided to the consumer was not derived primarily from studies of NuvaRing®.

25. Defendants, including by and through their predecessor and affiliate corporations, failed to warn of the extent of the risk of venous thromboembolism, including Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), and death associated with use of the novel combined contraceptive vaginal route of administration, the NuvaRing®.

26. Pharmaceutical drugs are subject to the federal statutory requirement that their labeling carry adequate warnings. 21 U.S.C. § 352(f)(2).

27. Pre-marketing clinical trials of branded drugs are typically quite small, involving only carefully selected patients taking the drug for limited periods of time, many serious risks associated with a drug are not discovered until the drug has been on the market for a number of

years.[1] Often, as in this case, risks do not fully emerge until long after a drug has entered the market and captured a large percentage of sales.

28. Knowledge about a drug's benefits and risks grows over time, especially after a drug has begun to be marketed The FDA has procedures by which drug manufacturers can make changes to a drug's approved labeling or other changes to an approved application. Drug manufacturers may submit either "Prior Approval Supplements" to their NDA or ANDA—which, as the name implies, require FDA approval before the proposed change may be implemented—or "Changes Being Effected" ("CBE") Supplements, under which the proposed change may be implemented before the FDA has acted on the supplemental application. *See* 21 C.F.R. §§ 314.70(b), (c).

29. While most changes to a drug's approved labeling must be requested through a Prior Approval Supplement, 21 C.F.R. § 314.70(b), FDA regulations permit a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" through a CBE supplement. 21 C.F.R. § 314.70(c).

30. Drug companies may also communicate information concerning their drugs to doctors and pharmacists by other means. For instance, they may publish their approved labeling in the Physician's Desk Reference (PDR) and may also issue "Dear Health Care Professional" ("DHCP") letters. Nothing in the FDCA or FDA regulations prohibits pharmaceutical drug companies from communicating in these ways, though they rarely if ever choose to do so. However, FDA regulations do consider such communications to constitute "labeling;" therefore, such communications "must be consistent with and not contrary to [the drug's] approved . . . labeling." 21 C.F.R. § 201.100(d)(1).

[1] . Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medicines*, 287 JAMA 2215 (May 1, 2002) (finding that half of all black box warnings on drugs introduced after 1975 were added after the drug had been on the market for seven or more years).

31. Defendants knew, but failed to disclose, in violation of federal law, that the NuvaRing® had a higher risk of thromboembolic complications than oral contraceptives, due to the markedly potentiated androgenic effects caused by the synthetic, third-generation progestin used in the NuvaRing®.

32. Defendants negligently and/or recklessly marketed NuvaRing® as a novel vaginal delivery system, and placed the product into the stream of commerce without conducting adequate tests to regulate the exposure and/or release rates of estrogen and Progestin to a user, including Plaintiff, of such product.

33. At all times material hereto, Defendants Organon, by and through their agents, servants and/or employees, negligently, recklessly, carelessly and/or grossly negligently marketed, distributed and/or sold NuvaRing® without adequate instructions or warnings of its known serious side effects and unreasonably dangerous risks.

34. Instead, Defendants Organon market NuvaRing® as having a low risk of side effects and continues to minimize NuvaRing's® side effects by focusing on the incidence of minor side effects, stating, "[w]ith NuvaRing® there is a low incidence of side effects, such as headaches, nausea, and breast tenderness."

35. As a result of the claims of Defendants Organon regarding the effectiveness and safety of NuvaRing®, Plaintiff began using the NuvaRing® contraceptive in or about February 2011. While on the NuvaRing®, on March 30, 2011, at age 26, Plaintiff experienced shortness of breath and chest pain.

36. As a result of her chest pain and shortness of breath Plaintiff was admitted to Mercy Medical Center on March 30, 2011 where a Chest CT revealed she was suffering from a pulmonary embolism.

37. Plaintiff was immediately placed on Lovenox then Coumadin and was hospitalized as a result of her pulmonary embolism. Plaintiff was also placed on Warfarin for a minimum of six months due to her injuries.

38. As a direct and proximate result of using the NuvaRing®, Plaintiff suffered injuries and continues with regular follow-up care.

39. Prior to Plaintiff's use of NuvaRing®, Defendants Organon knew or should have known that use of their products created a venous thromboembolism, including Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), and death than oral contraceptives.

40. Despite the fact that Defendants Organon knew or should have known of the serious health risks, including venous thromboembolism associated with the use of the NuvaRing® particularly to Plaintiff, Defendants failed to warn Plaintiff of said serious risks before she used the product and failed to conduct appropriate testing prior to the NuvaRing® being prescribed to Plaintiff.

41. Additionally, at all times material hereto, Defendants failed to properly disclose the known safety hazards associated with NuvaRing®.

42. Had Plaintiff known the risks and dangers associated with NuvaRing®, she would not have used NuvaRing® and would not have suffered the aforementioned injuries.

43. As a direct and proximate result of Plaintiff's use of NuvaRing®, Plaintiff suffered intense and excruciating physical pain and suffering from the initial onset of her injuries until she ultimately required hospitalization, including but not limited to the fact that she was unable to breathe during that time and was hospitalized.

44. Further, as a direct and proximate result of Plaintiff's use of NuvaRing®, Plaintiff has suffered economic and non-economic losses, has incurred hospital expenses and will incur future medical expenses.

45. Defendants' actions and omissions as identified in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of damages based on aggravating circumstances.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DEFECTIVE MANUFACTURING

46. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of NuvaRing® and were responsible for marketing, labeling, and/or selling the NuvaRing® and otherwise putting it into the stream of commerce.

48. The NuvaRing® manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury and death to consumers, including Plaintiff.

49. As a direct and proximate result of Plaintiff's use of NuvaRing® as manufactured, designed, sold, supplied and/or introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

37. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law strict products liability. Further, Defendants' actions and omissions

as identified in this Complaint constitute a willful and wanton disregard for the rights and safety of Plaintiff, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT

50. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

51. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of NuvaRing® and were responsible for marketing, labeling, and/or selling the NuvaRing® and otherwise putting it into the stream of commerce.

52. The NuvaRing® manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect and less safe than oral contraceptives.

53. The foreseeable risks associated with the design or formulation of NuvaRing®, include, but are not limited to, the fact that the design or formulation of NuvaRing® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner and more dangerous than oral contraceptives.

54. NuvaRing® was defective in that it was not properly designed or prepared and/or was not accompanied by proper warnings regarding the prevalence and severity of adverse side effects associated with its use.

55. NuvaRing® was further defective in that its design and manufacture contained unnecessarily dangerous hormones and released uneven amount of the said hormones.

56. The foreseeable risks associated with the design of the NuvaRing® include, but are not limited to, the fact that NuvaRing® is more dangerous and presents a greater risk of

injury than an ordinary consumer would reasonably expect when using this type of product in an intended or reasonably foreseeable manner.

57. At the time the NuvaRing® left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, including use of a second generation progestin, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

58. As a direct and proximate result of Plaintiff's use of NuvaRing® as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

59. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law. Further, Defendants' actions and omissions as identified in this Complaint constitute a willful and wanton disregard for the rights and safety of Plaintiff, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILTY – DEFECT DUE TO INADEQUATE WARNING

60. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

61. The NuvaRing® manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed

to adequately warn consumers and/or their health care providers of such risks, including the extent of risk of the types of injuries Plaintiff suffered as a result of using NuvaRing®.

62. The NuvaRing® manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of NuvaRing®, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

63. Defendants marketed, promoted and advertised their NuvaRing® product to physicians and to the public as more effective and safe than the oral contraceptive pill, at a time that the Defendants had actual and/or constructive knowledge that the NuvaRing® was less safe than oral contraceptives.

64. Defendants failed to warn prescribing physicians and the public that the NuvaRing® was associated with increased risk of cardiovascular thromboembolic complications than oral contraceptives.

65. Defendants knew, but failed to disclose that NuvaRing® had a higher risk of cardiovascular thromboembolic complications than oral contraceptives, due to the markedly potentiated androgenic effects caused by the synthetic progestin used in the NuvaRing®.

66. Defendants failed to provide proper and full information as to the safety of the NuvaRing® to the U.S. Food and Drug Administration, which regulates the sale of the NuvaRing®.

67. Defendants did not reasonably warn the medical profession of precautions and known potential complications of NuvaRing® to enable physicians and other healthcare

providers to reasonably assess the risks versus the benefits of the use of the NuvaRing® for contraception.

68. Defendants failed to adequately warn prescribing physicians, pharmacists, and users of the NuvaRing® of the refrigerated storage requirements.

69. Plaintiff and her prescribing physician were unaware of the increased risks and danger of harm inherent in NuvaRing®, as above described, and would have used and prescribed other methods for birth control if they had been so informed.

70. Defendants' failure to warn of the increased risks and danger of harm inherent in NuvaRing®, as described above, created an unreasonable danger to users of this product, and the product was unreasonably dangerous at the time it was prescribed to Plaintiff.

71. Plaintiff was prescribed and used the NuvaRing® for its intended purpose and as reasonably anticipated without knowledge of its characteristics, and could not have discovered any defect in the product through the exercise of reasonable care.

72. The warnings that were given by Defendants were not accurate, clear and/or were ambiguous.

73. As a direct and proximate result of Plaintiff's use of NuvaRing® as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

74. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law. Further, Defendants' actions and omissions as identified in this Complaint constitute a willful and wanton disregard for the rights and safety of Plaintiff, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY DUE TO NON CONFORMANCE WITH REPRESENTATIONS

75. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

76. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of NuvaRing® and made representations regarding the character or quality of NuvaRing®.

77. The NuvaRing® manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

78. Defendants had an economic interest in all transactions involving sales and prescriptions of NuvaRing®.

79. Plaintiff justifiably relied upon Defendants' representations regarding NuvaRing® when they used NuvaRing®.

73. As a direct and proximate result of Plaintiff's use of NuvaRing® and her reliance on Defendants' representations regarding the character and quality of NuvaRing®, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

74. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law. Further, Defendants' actions and omissions as identified in this Complaint constitute a willful and wanton disregard for the rights and safety of Plaintiff, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION
NEGLIGENCE

80. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

81. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of NuvaRing® into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

82. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of NuvaRing® into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

83. Defendants also failed to exercise ordinary care in the labeling of NuvaRing® and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of NuvaRing®.

84. Despite the fact that Defendants knew or should have known that NuvaRing® posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market NuvaRing® for use by consumers.

85. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result Defendants' failure to exercise ordinary care as described above.

86. Defendants deliberately bypassed confining its promotion of NuvaRing® to learned intermediaries and instead engaged in extensive and expensive direct-to-consumer advertising, including over the internet, in which promotional material adequate warnings were not given, thereby assumed a direct duty to the user.

87. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the negligence of Defendants as follows:

a) In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of NuvaRing®, including Plaintiff, of its known dangerous and defective characteristics;

b) In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for NuvaRing®;

c) In its promotion of NuvaRing® in an overly aggressive, deceitful and fraudulent manner, despite knowledge of the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

d) In representing that NuvaRing® was safe for its intended use when, in fact, the product was unsafe for its intended use;

e) In utilizing dangerous levels of progestins which was never used before as a starting agent in contraceptives and without first conducting adequate testing;

f) In utilizing combined contraceptives in a vaginal route of administration without first conducting adequate testing as to the release and/or exposure rates of such contraceptives;

g) In failing to perform appropriate pre-market testing of NuvaRing®;

h) In failing to perform appropriate post-market testing of NuvaRing®;

i) In failing to perform appropriate post-market surveillance of NuvaRing®;

j) In failing to properly ship, transport, and deliver NuvaRing® in the required refrigerated storage;

k) In failing to adequately instruct its employees and/or agents and medical professionals of the necessity to store NuvaRing® in refrigerated containers; and

l) In failing to have uniform labels on contraindications of use of the product.

88. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

89. Defendants' conduct as described above, including but not limited to its failure to adequately test NuvaRing®, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

90. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

91. Defendants expressly warranted that NuvaRing® was a safe and effective prescription contraceptive.

92. Defendants promoted NuvaRing® to the FDA, prescribing doctors, the public and Plaintiff, as "safe," "favorable safety profile," "low side effects," "less side effects," "low hormones" and other similar terms.

93. Defendants deliberately promoted what it called "low estrogen" in its said product as a means of avoiding reference to the dangerous progestin which it used in the product, and

used the dangerous progestin as compared to other, safer progestins to save money since they owned the patent to the progestin which they used.

94. Members of the consuming public, including Plaintiff, were intended beneficiaries of the warranty.

95. The NuvaRing® manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

96. Defendants breached their express warranty in one of more of the following ways:

a) NuvaRing®, as designed, innovated, marketed, manufactured, and/or sold and distributed by Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition.

b) Defendants failed to warn of the likelihood and severity of adverse side effects of NuvaRing®, and/or did not provide adequate warnings and instructions on the product, nor did they employ other reasonable means to inform doctors and patients of the risks of the drug.

c) Defendants failed to adequately test NuvaRing® and to monitor its effects.

d) Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the true risks of injury from NuvaRing®.

97. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

98. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

99. At the time Defendants designed, manufactured, marketed, sold, and distributed NuvaRing® for use by Plaintiff, Defendants knew of the use for which NuvaRing® was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

100. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether NuvaRing® was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

101. Contrary to such implied warranty, NuvaRing® were not of merchantable quality or safe for its intended use, because the product was unreasonably dangerous as described above.

102. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

EIGHTH CAUSE OF ACTION
NEGLIGENT AND/OR INTENTIONAL REPRESENTATION

103. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

104. Defendants knew or were aware or should have been aware that NuvaRing® had not been sufficiently tested, and was unsafe, defective in design and manufacture, unreasonably dangerous and/or that it lacked adequate and/or sufficient warnings.

105. Defendants knew and were aware or should have been aware that NuvaRing® promoted more risks of clotting than other contraceptives demonstrating that further testing was needed.

106. Defendants knew or should have known that NuvaRing® had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

107. Defendants knew or should have known the safety profile in the U.S. label was misleading to prescribing doctors and users of NuvaRing®, including Plaintiff, as the label contained contraindications different than that of other NuvaRing® labels.

108. Plaintiff reasonably relied upon Defendants' representations to Plaintiff and/or her health care providers that NuvaRing® was safe for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

109. As a direct and proximate result of Defendants' fraudulent and/or negligent actions and omissions, Plaintiff used NuvaRing® and suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

110. Defendants' actions and omissions as identified in this Complaint demonstrate a willful and wanton disregard for the rights and safety of Plaintiff, so as to warrant the imposition of punitive damages.

NINETH CAUSE OF ACTION
UNJUST ENRICHMENT

111. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

112. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and use of NuvaRing® by Plaintiff.

113. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving products of the quality, nature, or fitness that had been represented by Defendants, or that the Plaintiff, as a reasonable consumer, expected to receive.

114. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiff, who is entitled in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

TENTH CAUSE OF ACTION
FALSE ADVERTISING

115. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

116. Defendants knowingly misrepresented NuvaRing® as a safe and effective contraceptive and knowingly made false statements and omissions of material fact concerning the properties, ingredients, characteristics, qualities, benefits, uses, efficacy, safety, and/or testing of NuvaRing® to the Plaintiff and the general public.

117. In its labeling, marketing, direct-to-consumer advertising, promotion, sale, and distribution of NuvaRing®, Defendants made untrue, deceptive, and/or misleading material assertions, representations, and/or statements downplaying risks associated with NuvaRing® and exaggerating the drug's safety to the Plaintiff and the general public when Defendants had

actual knowledge of the serious, adverse health effects associated NuvaRing® including, but not limited to, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, cardiovascular thromboembolic complications and even death.

118. Defendants intended to increase the sale and consumption of NuvaRing® by falsely marketing NuvaRing® as safe and effective, and by concealing facts regarding the dangerous properties of NuvaRing®, to thereby induce Plaintiff's physicians to prescribe NuvaRing® and to ultimately cause Plaintiff to purchase and consume NuvaRing®.

119. In purchasing and consuming NuvaRing®, Plaintiff reasonably relied upon Defendants' false and misleading assertions and omissions of material fact that NuvaRing® was a safe and effective contraceptive option.

120. As a direct and proximate result of Defendants' false statements as herein alleged, Plaintiff ingested NuvaRing® and suffered severe and debilitating injuries and economic loss, including but not limited to, cost of medical care, rehabilitation, lost income, permanent health conditions, and pain and suffering.

ELEVENTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DUE TO FAILURE TO ADEQUATELY TEST

121. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

122. Defendants repeatedly advised consumers and the medical community that NuvaRing® contained the same safety profile as oral hormonal birth control pills. Defendants failed to adequately test the safety of NuvaRing® versus oral hormonal birth control pills.

123. Had Defendants adequately tested the safety of NuvaRing® versus oral hormonal birth control pills and disclosed those results to the medical community or the public, Plaintiff would not have undertaken birth control therapy with NuvaRing®.

124. As a direct and proximate result of Defendants' failure to adequately test the safety of NuvaRing® versus oral hormonal birth control pills, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

125. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

TWELFTH CAUSE OF ACTION
IOWA CONSUMER PROTECTION ACT
PURSUANT TO IOWA CODE SECTION 714.16

126. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

127. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of NuvaRing®.

128. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for NuvaRing®, and would not have incurred related medical costs.

129. Specifically, Plaintiff, her physicians, and their staff were misled by the deceptive conduct described herein.

130. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

131. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for NuvaRing® that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

132. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of:

a) Iowa Code §§ 714.16 *et seq.*

133. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell NuvaRing®. Each aspect of Defendants' conduct combined to artificially create sales of NuvaRing®.

134. The medical community relied upon Defendants' misrepresentations and omissions in determining which form of contraception to utilize.

135. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

136. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for NuvaRing®.

137. As a direct and proximate result of Defendants' violations of Iowa's unfair trade practice acts, Plaintiff has sustained economic losses and other damages for which she is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

THIRTEENTH CAUSE OF ACTION
PUNITIVE DAMAGES

138. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

139. At all times material hereto, the Defendant knew or should have known that NuvaRing® was inherently more dangerous with respect to the risks of deep vein thrombosis, pulmonary embolism, heart attacks, stroke, cardiovascular thromboembolic complications, and even death than other birth control medications including oral contraceptives.

140. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety and efficacy of NuvaRing®.

141. Defendant's misrepresentation included intentionally withholding material information from the medical community and the public, including Plaintiff, regarding the safety of NuvaRing®.

142. Notwithstanding the foregoing, Defendant continued to aggressively market NuvaRing® to consumers, including Plaintiff, without disclosing the aforesaid side effects when there were safer alternative birth control medications including oral contraceptives.

143. The Defendant knew of NuvaRing's® defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by NuvaRing®.

144. Defendants fraudulently, intentionally, and/or recklessly concealed and failed to disclose to the public, including Plaintiff, the potentially life threatening side effects of NuvaRing® in order to ensure continued and increased sales.

145. Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff of the necessary information to enable the Plaintiff to weigh the true risk of using NuvaRing® against its benefits.

146. The aforesaid conduct of Defendant in the license, approval process, design, manufacturing, assembly, packaging, warning, marketing, advertising, promotion, distribution and sale of NuvaRing® was fraudulent, knowing misconduct, willful and/or conduct undertaken to recklessly and with conscious disregard for the safety of Plaintiff such as to constitute despicable conduct, and oppression, fraud and malice, and at all times relevant, such conduct was ratified by the corporate Defendant herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish and set an example to Defendant, and to deter them from similar conduct in the future.

147. Plaintiff seeks actual and punitive damages from the Defendant as alleged herein pursuant to all appropriate state statutes and common law. The injuries and damages alleged herein are permanent and will continue into the future.

FOURTEENTH CAUSE OF ACTION
SUCCESSOR LIABILITY
AS TO DEFENDANT MERCK

148. In or about November 2009, Defendant Merck, a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 completed the acquisition and merger with Schering-Plough Corporation, which included Organon and the liabilities and assets associated with NuvaRing®.

149. In the Merger, Schering-Plough Corporation acquired all of the shares of Merck & Co., Inc., which became a wholly-owned subsidiary of Schering-Plough Corporation and was renamed Merck Sharp & Dohme Corp. Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc.

150. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. expressly and/or impliedly assumed the liabilities and obligations of Schering-Plough and the named Organon defendants for the injuries and damages alleged herein resulting from Plaintiff's use of NuvaRing®.

151. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. have continued the business and operation of Schering-Plough Corporation and the named Organon Defendants, including, but not necessarily limited to NuvaRing®.

152. Therefore, Defendant Merck & Co., Inc. and Merck Sharp & Dohme Corp. is liable to Plaintiff for the injuries and damages alleged herein as a successor in interest and/or successor corporations of Schering-Plough Corporation and the Organon defendants named herein.

PRESERVATION CLAIMS

153. Plaintiff hereby incorporates by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

154. Many States have recently enacted tort reform statutes with "exclusive remedy" provisions. Courts have yet to determine whether these exclusive remedy provisions eliminate or supersede, to any extent, state common law claims. If during the pendency of this action this Court makes any such determination, Plaintiff hereby specifically makes claim to and preserves any State claim based upon any exclusive remedy provision, under any state law this Court may apply, to the extent not already alleged above.

155. To the extent that Defendant(s) may claim that one or more of Plaintiff's claims are barred by the applicable statute of limitations, Plaintiff asserts that the statute of limitations is and has been tolled by Plaintiff's discovery that her injury(ies) was/were caused by

Defendants' defective product and failure to properly and adequately warn of the products' risks, all as more fully set forth in this Complaint, after the injury sustained by Plaintiff.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent health conditions, and pain and suffering.

3. Punitive damages in excess of twice the compensatory damages award;

4. Attorneys' fees, expenses, and costs of this action;

5. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

6. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,

/s/ Brian Galligan
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Attorney for Plaintiff

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

/s/ Brian Galligan
Brian Galligan (AT 0002632)