

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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KACI DUKE AND MATTHEW DUKE

Plaintiffs,

Civil Action No. _____

vs.

ORGANON USA, INC.
56 Livingston Avenue
Roseland, NJ 07068

COMPLAINT AND
JURY DEMAND

ORGANON PHARMACEUTICALS USA, INC.
56 Livingston Avenue
Roseland, NJ 07068

ORGANON INTERNATIONAL, INC.
56 Livingston Avenue
Roseland, NJ 07068

AKZO NOBEL NV

SCHERING-PLOUGH CORPORATION
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

Defendants.

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Plaintiffs, by and through counsels, and for their complaint against Defendants, allege as follows:

PARTIES AND JURISDICTION

1. Plaintiffs are the citizens of the state of Texas.
2. Plaintiffs seek an amount in controversy in excess of \$75,000.00, exclusive of interest and costs.
3. Defendant, ORGANON USA, INC., is a global pharmaceutical company engaged in the business of creating, manufacturing, marketing, distributing, labeling,

researching, developing and selling medicines in the field of women's health, including the contraceptive, NuvaRing.

4. Defendant, ORGANON USA, INC., is or at pertinent time was a wholly owned subsidiary and the largest pharmaceutical business unit of Defendant, AKZO NOBEL NV.

5. Defendant, ORGANON PHARMACEUTICALS USA, INC., is a foreign corporation authorized to and actually transacting business in the State of New Jersey, with its principal place of business located at 56 Livingston Avenue, Roseland, New Jersey 07068.

6. Defendant, ORGANON PHARMACEUTICALS USA, INC., is a global pharmaceutical company engaged in the business of creating, manufacturing, marketing, distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NuvaRing.

7. Defendant, ORGANON PHARMACEUTICALS USA, INC., is or at pertinent time was a wholly owned subsidiary and a pharmaceutical business unit of Defendant, AKZO NOBEL NV.

8. Defendant, ORGANON INTERNATIONAL, INC., is a foreign corporation authorized and actually transacting business in the State of New Jersey, with its principal place of business located at 56 Livingston Avenue, Roseland, New Jersey 07068.

9. Defendant, ORGANON INTERNATIONAL, INC., is a global pharmaceutical company engaged in the business of creating, manufacturing, marketing, distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NuvaRing.

10. Defendant, ORGANON INTERNATIONAL, INC., is or at pertinent time was a wholly owned subsidiary and a pharmaceutical business unit of Defendant, AKZO NOBEL NV.

11. Defendant, AZKO NOBEL NV, is a global Fortune 500 Company incorporated and existing under the laws of The Netherlands.

12. Defendant, AZKO NOBEL NV, individually and through its wholly owned subsidiaries, including Defendants herein, and the trading of its stock on NASDAQ regularly transacts or solicits business, engages in a persistent course of conduct, and derives substantial revenue from goods used or consumed in the State of New Jersey.

13. Defendant, AZKO NOBEL NV, individually and through its wholly owned subsidiaries, including Defendants herein, is a company engaged in the business of creating, manufacturing, marketing, distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NuvaRing.

14. Defendant SCHERING-PLOUGH Corporation acquired the above named defendants in 2007 and assumed the liabilities attendant thereto, and has its principal place of doing business in New Jersey.

14a. In 2008, defendant SCHERING-PLOUGH acquired defendant ORGANON PHARMACEUTICAL USA, INC.; caused it to be dissolved as a corporation; and made it a subsidiary. In so doing, defendant SCHERING-PLOUGH assumed the liabilities of ORGANON PHARMACEUTICAL USA, INC., as pleaded in this complaint.

15. This court has 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 defendants have their principal places of doing business here.

FACTUAL BACKGROUND

17. Pursuant to prescription, plaintiff, KACI DUKE, utilized defendants' ring product from approximately May 2003 to October 2006.

18. Defendants marketed, promoted and advertised the ring product to physicians and to the public as equally or more safe than oral contraceptive pills, whereas it was less safe than the pill, as defendants knew.

19. Defendants marketed, promoted and advertised the ring product as presenting less of a risk of thrombotic side effects than other means of contraception because of its relatively low amount of estrogen in an attempt to disguise the fact that it had a high level of a dangerous third-generation progestin, capable to causing thrombotic side effects.

20. Defendants failed to warn prescribing physicians and the public that the ring product was associated with more thrombotic events than the pill.

21. Defendants failed to provide proper and full information as to safety to the Food and Drug Administration, which regulated the sale of the ring, and thereby avoided having appropriate warnings and cautions added to its labeling and advertising.

22. Defendants obtained permission to market the ring product by presenting safety data derived from studies on the pill and failed to do proper clinical investigation with actual users of the ring product.

23. In actuality, as defendants knew but failed to disclose, the ring product released a continuous stream of hormones (progestin and estrogen) into the body of the user, and at a higher level than the pill provided, and more than defendants stated were being released into the blood stream in its promotional literature.

24. Plaintiff, KACI DUKE, on or about October 10, 2006, sustained an injury due to her use of the ring, namely pulmonary embolism.

25. As a further result plaintiff incurred damages, both special and general.

26. Plaintiff and her prescribing health care providers were unaware of the increased risk of the use of the ring and would have used and prescribed other methods for birth control if they had been so informed.

27. Up until the time that plaintiff was injured, the Food and Drug Administration had never forbidden the defendants from mentioning the subjects about enhanced risks stated above, nor had it ever prevented defendants from enlarging on their warnings about thrombotic risks associated with the use of the ring product.

FIRST CAUSE OF ACTION - STRICT PRODUCT LIABILITY

28. The said ring product was defective and unreasonably dangerous when defendants placed it into the stream of commerce.

29. The defects in the ring product were a proximate cause of the injuries suffered by plaintiff and the damages thereby incurred.

30. By engaging in the said conduct, defendants have become strictly liable to plaintiff.

31. Defendants' ring product was defective and unreasonably dangerous when Defendants placed it into the stream of commerce, in violation of the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1 et seq.

32. Said conduct of defendants was so willful, wanton, malicious, reckless and in such disregard for the consequences as to reveal a conscious indifference to the clear risk of death or serious bodily injury and merits the imposition of punitive damages.

SECOND CAUSE OF ACTION - BREACH OF WARRANT

33. Plaintiffs repeat and reallege paragraphs of the Complaint designated 28-32.

34. Defendants have breached applicable warranties, express and implied, including safety and are therefore liable to plaintiffs.

THIRD CAUSE OF ACTION - NEGLIGENCE

35. Plaintiffs repeat and reallege paragraphs of the Complaint designated 28-32 and 34.

36. Defendants were negligent in designing, manufacturing, inspecting, testing, labeling, monitoring, promoting, distributing and selling the product.

37. Defendants are therefore liable to plaintiffs.

38. The conduct of defendants was so willful, wanton, malicious, reckless and in such disregard for the consequences as to reveal a conscious indifference to the clear risk of death or serious bodily injury and merits the imposition of punitive damages.

FOURTH CAUSE OF ACTION – FRAUD AND MISREPRESENTATION

39. Plaintiffs repeat and reallege paragraphs of the Complaint designated 28-32, 34, 36-38.

40. Defendants deliberately and carelessly made false and misleading statements about the safety of the product, on which plaintiff and their prescribing doctor relied to her detriment.

41. Defendants concealed research which it did or had done for it, or changed it before presentation to the FDA or for publication so as to minimize health hazard, and caused to be published articles unjustifiably representing the safety of the product.

FIFTH CAUSE OF ACTION—CONSUMER FRAUD

42. Plaintiffs repeat and reallege paragraphs of the Complaint designated 28-32, 34, 36-38, 40-41.

43. Defendants, through their agents, servants and/or employees violated the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq.*, through their design, manufacture, testing, distribution, promotion and sale of the ring product by engaging in one or more of the following unlawful practices: unconscionable commercial practices, deception, fraud, false pretenses, false promises, misrepresentations, and/or the knowing concealment, suppression or omission of material facts with the intent that Plaintiffs herein and other users would rely upon such concealment, suppression or omission.

44. As a direct and proximate result of the wrongful acts and conduct of the Defendants, as described above, plaintiff was caused to suffer serious and permanent injuries; was caused to suffer great pain and will in the future be caused to suffer great pain; was caused to incur medical expenses and will in the future be caused to incur medical expenses; was caused to lose time from her employment and will in the future be caused to lose time from her employment; and was caused to suffer and will in the future continue to suffer an adverse and material change in her quality of life.

SIXTH CAUSE OF ACTION - LOSS OF CONSORTIUM

45. Plaintiffs repeat and reallege paragraphs of the Complaint designated 28-32, 34, 36-38, 40-41, 43-44.

46. As a proximate result of the injuries and losses sustained by his wife/spouse KACI, Plaintiff, MATTHEW DUKE, has been and will continue to be deprived of her love, companionship, affection, society, consortium, comfort, marital relations, services and support which he previously received.

47. This Plaintiff, MATTHEW DUKE, has rendered and will for the indefinite future be required to render nursing care, medical and other services to his wife/spouse in connection with and due to her injuries.

WHEREFORE, Plaintiffs demand Judgment on this Court against the Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

WHEREFORE, plaintiffs demand judgment against defendants, severally and jointly:

- a. Compensatory damages on all Causes of Action;
- b. Punitive damages against on all Causes of Action;
- c. All together with interest, costs and disbursements;
- d. Such other and further relief as this Court deems just and proper.

JURY DEMAND


Plaintiffs request trial by jury for all issues.

Dated: November 26, 2008

**RHEINGOLD, VALET, RHEINGOLD,
SHKOLNIK & McCARTNEY LLP**

By: _____

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-and-

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