

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION**

MICHELLE SMITH

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,
and TEVA PHARMACEUTICAL INDUSTRIES
LIMITED

Defendants.

I. COMPLAINT

1. Plaintiff Michelle Smith, (“Plaintiff” or “Smith”), by and through her attorneys, Schlesinger Law Offices, P.A., complains against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (“Defendants” or “Teva”) as follows:

II. NATURE OF THE CASE

2. Seasonique and Seasonale, oral contraceptives made, manufactured, marketed and sold by Defendants, was defective, dangerous to human health, and lacked proper warnings as to the dangers associated with its use when Plaintiff took it from 2004-2013. Plaintiff seeks redress for the severe and permanent injuries she sustained when a liver tumor, caused by these drugs, ruptured and hemorrhaged.

III. PARTIES

3. Plaintiff resides in Broward County, Florida and is a citizen of the State of Florida.

4. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North

Wales, PA 19454. Teva Pharmaceuticals USA, Inc. at all material times, is in the business of designing, creating, manufacturing, assembling, testing, labeling, supplying, packaging, warning, promoting, marketing, developing, selling and/or distributing the pharmaceutical drugs Seasonique and Seasonale.

5. Defendant Teva Pharmaceutical Industries Limited is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel. Teva Pharmaceutical Industries Limited, at all material times, is in the business of designing, creating, manufacturing, assembling, testing, labeling, supplying, packaging, warning, promoting, marketing, developing, selling and/or distributing the pharmaceutical drugs Seasonique and Seasonale.

6. Upon information and belief, Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Limited.

IV. JURISDICTION AND VENUE

7. The Court has jurisdiction under 28 U.S.C. § 1332 because the lawsuit is between citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of costs and interest.

8. Venue is proper in the Southern District of Florida because Defendants committed tortious acts within the state of Florida and the Southern District of Florida out of which acts these causes of action arise.

V. FACTUAL ALLEGATIONS

A. Seasonique & Seasonale

9. Seasonique and Seasonale are oral contraceptives.

10. Defendants aggressively promote these drugs as an “extended regimen birth control option” that allows woman to have four scheduled periods a year, instead of twelve.

11. Under the regimen, Defendants claim that Seasonique, for example, lessens the withdrawal symptoms that result from a “sudden, sharp decrease in hormones” as compared with other oral contraceptives.

12. Teva claims that Seasonique is “backed by extensive clinical trials and real-world experience” and that the drug “offers less frequent menses and is both safe and effective.”

13. According to Teva, seven out of ten women prefer fewer periods a year. Teva’s Senior Director of Global Marketing Women’s Health has said: “Many women may not be aware that they can space their periods. Seasonique will offer women a new choice in contraception to achieve greater freedom and confidence in their birth control.”

14. In 2013 – the year that masses on Plaintiff’s liver hemorrhaged, requiring surgery and causing permanent injuries – Seasonique sales helped Teva net \$20.3 billion in revue.

B. Teva’s Labels Do Not Adequately Warn Health Providers About Hepatic Adenomas

15. Hepatic adenomas are liver tumors. They could be benign, they could turn malignant, and they can rupture and hemorrhage. Patients with large hepatic adenomas, over 5 cm, often require surgical intervention.

16. Patients diagnosed with hepatic adenomas are usually female of reproductive age with a history of oral contraceptive use.

17. Defendants have known that there is a proved association between the use of oral contraceptives and the development of hepatic adenoma. Evidence indicates that estrogen

consumption is the primary risk factor for their development.¹

18. Defendants have also known that the longer the duration of use, the greater the risk for developing a hepatic adenoma.

19. A 5-fold increased risk exists with 5-7 years of oral contraceptive exposure, and a 25-fold increased risk exists with longer than 9 years of oral contraceptive exposure.²

20. But Defendants do not adequately convey this information to prescribing physicians.

21. Rather, Defendants downplay the fact that the hepatic adenoma risk exponentially increases with long-term use.

22. For example, the Seasonale label of 2003 and the Seasonique label of 2006 stated: “Benign hepatic adenomas are associated with oral contraceptive use, although their occurrence is rare in the United States. Indirect calculations have estimated the attributable risk to be in the range of 3.3 cases/100,000 for users, a risk that increases after four or more years of use.” (emphasis added).

23. In 2010, however, the labels were modified. They state: “Hepatic adenomas are associated with [oral contraceptive] use. An estimate of the attributable risk is 3.3 cases/100,000 [oral contraceptive] users.” That warning also states: “Studies have shown an increase risk of developing hepatocellular carcinoma in long-term (>8 years) [oral contraceptive] users. However, the attributable risk of liver cancers in [oral contraceptive] users is less than one care per million

¹ Lizardi-Cervera, Javier, et al. “Focal nodular hyperplasia and hepatic adenoma: A Review,” *Annals of Hepatology* 2006; 5 (3): July-September: 206-211 (available at <http://www.annalsofhepatology.com/revista/numeros/2006/ah063s.pdf> (last visited, May 25 2017)

² Id.

users.”

24. These labels are deficient. The 2003 and 2006 labels downplay the seriousness of the association by stating that the occurrence is “rare.” The 2010 labels also downplay the seriousness of the risk by removing the fact that the hepatic-adenoma risk increases with long-term use. While the 2010 label mentions hepatocellular carcinoma (cancer) it is silent on hepatic adenomas caused by long-term use.

25. The 2010 labels are also confusing and ambiguous. For example, Teva mentions “studies” but then downplays their significance with the word, “however,” which is used to contrast or contradict the studies.

26. In other product literature, Teva has characterized the risk of hepatic adenomas as “extremely rare.” This signifies to prescribing physicians that such adverse events should not be made a priority when conducting a risk-benefit analysis, and prescribing physicians are less likely to warn and monitor for them.

27. Thus, Teva’s labels fail to adequately warn of the true risk of contracting hepatic adenomas with long-term use of the drug.

28. Since at least 2006, Teva knew or should have known that the risk increases exponentially over time. Since at least 2006, Teva knew or should have known there is a 5-fold increased risk exists with 5-7 years of oral contraceptive exposure, and a 25-fold increased risk exists with longer than 9 years.

29. The labels, however, fail to warn physicians of this fact. Prescribing physicians, relying on Teva’s warning, are not informed of when hepatic adenomas are likelier to occur. Prescribing physicians are also not told of the multiplied risk after 5 years and 9 years.

30. Information on timing is crucial because oral contraceptives, like Seasonique and Seasonale, are offered and intended for long-term use.

31. Teva could improve its labels by, for example, better emphasizing the long-term risk association of hepatic adenomas and by instructing physicians to conduct routine imaging exams to rule out the formation and existence of hepatic adenomas with long-term use.

C. Plaintiff's Prescribing Physician Was Not Aware of the Increased Risk of Contracting Hepatic Adenomas Caused by Long-term Use of Seasonale and Seasonique

32. Plaintiff began taking Seasonale in 2003. Her prescribing physician, at all times relevant, was Dr. Tara A. Solomon.

33. Plaintiff began taking Seasonique in 2009.

34. Dr. Solomon prescribed these oral contraceptives because of the very "benefits" that Teva touted: fewer periods.

35. Dr. Solomon did not warn of the risk of contracting hepatic adenomas, and did not warn of the increased risk with long-term use.

36. Dr. Solomon did not warn because Teva did not adequately inform her of the increased risk with long-term use.

37. Upon information and belief, Dr. Solomon did not know there is a 5-fold increased risk exists with 5-7 years of oral contraceptive exposure, and a 25-fold increased risk exists with longer than 9 years. Upon information and belief, she did not know this information because Teva failed to inform her.

38. Upon information and belief, Dr. Solomon did not order medical imaging exams to rule out the development or existence of hepatic adenomas because Teva failed to advise her to do

so.

39. Based on what Dr. Solomon knew when she prescribed Seasonique and Seasonale, she believed their side-effect profiles were acceptable for Plaintiff.

40. Had Teva told Dr. Solomon that the risk of contracting hepatic adenomas increased exponentially, as stated above, with long-term use of these contraceptives, Dr. Solomon would have communicated these risks to Plaintiff, and Plaintiff would not have chosen to take these drugs.

41. Considering what Dr. Solomon now knows about Seasonique and Seasonale, she would not have prescribed the drug.

D. Plaintiff Sustained Serious and Permanent Physical Injuries Caused By Her Long-Term Use of Seasonique and Seasonale

42. Plaintiff's long-term use of these oral contraceptives caused or substantially contributed to causing hepatic adenomas.

43. On or about June 1, 2013, Plaintiff was admitted to Cleveland Clinic in Weston, Florida because of severe abdominal pain. Medical testing showed that Plaintiff had multiple adenomas on her liver and surrounding tissue, the largest of which was approximately the size of a football. That hepatic adenomas ruptured and was hemorrhaging.

44. Plaintiff required surgical intervention – a liver resection – to remove the largest of the hepatic adenomas.

45. Plaintiff's suffered and continues to suffer from physical and mental pain and anguish, and she sustained severe and permanent abdominal scarring.

E. Defendants Consciously or Recklessly Disregarded the Rights and Safety of Patients Like Plaintiff

46. Defendants knew that these oral contraceptives cause debilitating and potentially

lethal side effects, or recklessly disregarded that fact, and continued to market Seasonique and Seasonale to consumers, including Plaintiff, without disclosing the true risk of side effects.

47. Defendants knew of Seasonique's and Seasonale's defective nature, as set forth herein, but, in conscious and/or reckless disregard of the foreseeable harm caused by them, continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

48. Defendants acted with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter it from similar conduct in the future.

CLAIMS FOR RELIEF

COUNT I

PRODUCTS LIABILITY – DEFECTIVE DESIGN

49. Plaintiff incorporates by reference all other paragraphs of the Complaint as if fully set forth herein and further alleges:

50. At all material times, Defendants engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting the drugs Seasonique and Seasonale, which are defective and unreasonably dangerous to consumers, including Plaintiff.

51. At all material times, Defendants sold, distributed, supplied, manufactured, marketed and/or promoted Seasonique and Seasonale.

52. At all material times, Seasonique and Seasonale were expected to reach, and did reach, consumers in the State of Florida, including Plaintiff, without substantial change in the condition they were sold.

53. At all material times, Defendants sold, distributed, supplied, manufactured, marketed and/or promoted Seasonique and Seasonale in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce in ways that include:

- a. When placed in the stream of commerce, Seasonique and Seasonale contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;
- b. When placed in the stream of commerce, Seasonique and Seasonale were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect; they were defective in design and formulation because these drugs contained an amount of estrogen that leads to and increases the risk of contracting hepatic adenomas; other oral contraceptives for patient use contain less estrogen, and therefore, less risk of contracting hepatic adenomas;
- c. Seasonique and Seasonale were insufficiently tested;
- d. Seasonique and Seasonale caused harmful side effects that outweighed any potential utility;
- e. Seasonique and Seasonale were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use;

54. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries.

55. As a further direct and proximate result of the design defect and Defendants'

misconduct as set forth herein, Plaintiff incurred expense of medical care, hospitalization, treatment, expense of nursing care and treatment, and expense of rehabilitative care and treatment. Those losses are permanent and continuing in nature and Plaintiff will suffer these losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT II

PRODUCTS LIABILITY – FAILURE TO WARN

56. Plaintiff incorporates by reference all other paragraphs of the Complaint as if fully set forth herein and further alleges:

57. Seasonique and Seasonale were defective and unreasonably dangerous when it left Defendants' possession in that it contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with the drug, including the propensity to cause hepatic adenomas.

58. Plaintiff could not have discovered any defect in the drug through the exercise of reasonable care.

59. Defendants, as manufacturers and/or distributors of a prescription drug, are held to the level of knowledge of an expert in the field.

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

61. Plaintiff, individually and through her physician, reasonably relied upon

Defendants' skill, superior knowledge and judgment. Defendants, however, failed to adequately warn that the risk of contracting hepatic adenomas increases exponentially, as described above, with long-term use of Seasonique and Seasonale.

62. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Seasonique and Seasonale.

63. Had Plaintiff received adequate warnings regarding the risks of Seasonique and Seasonale, she would not have used the drug.

64. As a direct and proximate cause of the inadequate warning and Defendants' misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries.

65. As a further direct and proximate result the inadequate warning and Defendants' misconduct as set forth herein, Plaintiff incurred expense of medical care, hospitalization, treatment, expense of nursing care and treatment, and expense of rehabilitative care and treatment. Those losses are permanent and continuing in nature and Plaintiff will suffer these losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT III

NEGLIGENCE

66. Plaintiff incorporates by reference all other paragraphs of the Complaint as if fully set forth herein and further alleges:

67. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Seasonique and Seasonale.

68. Defendants failed to exercise such reasonable care under the circumstances and therefore breached their duty by:

- a. Failing to properly and thoroughly test Seasonique and Seasonale before releasing it to the market;
- b. Failing to properly and thoroughly analyze the data resulting from the pre-market tests of Seasonique and Seasonale;
- c. Failing to conduct sufficient post-market testing and surveillance of Seasonique and Seasonale;
- d. Designing, manufacturing, marketing, advertising, distributing, and selling Seasonique and Seasonale to consumers, Plaintiff, without adequate warnings of the significant and dangerous risks of Seasonique and Seasonale, and without proper instructions to avoid the harm which could foreseeably occur as a result of using Seasonique and Seasonale;
- e. Negligently continuing to manufacture, market, advertise, and distribute Seasonique and Seasonale after Defendants knew or should have known of its adverse effects.

69. As a direct and proximate cause of the Defendants' negligence Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries.

70. As a further direct and proximate result of the Defendants' negligence as set forth herein, Plaintiff incurred expense of medical care, hospitalization, treatment, expense of nursing

care and treatment, and expense of rehabilitative care and treatment. Those losses are permanent and continuing in nature and Plaintiff will suffer these losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT IV

NEGLIGENT FAILURE TO WARN

71. Plaintiff incorporates by reference all other paragraphs of the Complaint as if fully set forth herein and further alleges:

72. Defendants owed consumers, including Plaintiff, a duty to warn of the foreseeable risks associated with the use of the drugs, Seasonique and Seasonale.

73. Defendants did not warn of or reveal the true risk of contracting hepatic adenomas as alleged herein.

74. Defendants' failure to warn of these risks was a breach of Defendants' duty because such risks and dangers of the product were known, or in the exercise of reasonable care, should have been known to Defendants, and in the exercise of reasonable care, such risks should have been relayed to consumers, including Plaintiff, by an enhanced and more descriptive warning.

75. As a result of Defendants' negligent failure to warn, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff's risk for contracting hepatic adenomas was exponentially increased.

76. As a direct and proximate cause of the Defendants' negligent failure to warn,

Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries.

77. As a further direct and proximate result of the Defendants' negligent failure to warn as set forth herein, Plaintiff incurred expense of medical care, hospitalization, treatment, expense of nursing care and treatment, and expense of rehabilitative care and treatment. Those losses are permanent and continuing in nature and Plaintiff will suffer these losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

78. Plaintiff hereby demands a trial by jury on all counts as to all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above referenced claims and causes of action as follows:

1. Awarding compensatory damages to Plaintiff;
2. Awarding punitive and/or exemplary damages, in an amount to be determined at trial;
3. Awarding Plaintiff's attorney's fees;
4. Awarding Plaintiff the costs of the proceedings; and
5. Awarding such other and further relief the Court deems just and proper.

May 26, 2017

By: s/Jeffrey L. Haberman
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JS 44 (Rev. 07/16) FLSD Revised 07/01/2016

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.) NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.

I. (a) PLAINTIFFS Michelle Smith

DEFENDANTS Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Limited

(b) County of Residence of First Listed Plaintiff Broward (EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Montgomery (IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (Firm Name, Address, and Telephone Number) Jeffrey L. Haberman, Schlesinger Law Offices, P.A. 1212 S.E. 3rd Ave., Fort Lauderdale, FL 33316 - Phone: 954-467-8800

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED. Attorneys (If Known)

(d) Check County Where Action Arose: MIAMI-DADE MONROE BROWARD PALM BEACH MARTIN ST. LUCIE INDIAN RIVER OKEECHOBEE HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- 1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

- Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1
2 2
3 3
4 4
5 5
6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
2 Removed from State Court
3 Re-filed (See VI below)
4 Reinstated or Reopened
5 Transferred from another district (specify)
6 Multidistrict Litigation Transfer
7 Appeal to District Judge from Magistrate Judgment
8 Multidistrict Litigation - Direct File
9 Remanded from Appellate Court

VI. RELATED/ RE-FILED CASE(S) (See instructions): a) Re-filed Case YES NO b) Related Cases YES NO JUDGE: DOCKET NUMBER:

VII. CAUSE OF ACTION 28 USC sec 1332 - Products liability Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause (Do not cite jurisdictional statutes unless diversity):

LENGTH OF TRIAL via days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$ 75,000.00+ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE DATE May 26, 2017 SIGNATURE OF ATTORNEY OF RECORD s/Jeffrey L. Haberman

FOR OFFICE USE ONLY RECEIPT # AMOUNT IFP JUDGE MAG JUDGE