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TINA J. STEWART and MICHAEL STEWART, *Plaintiffs*, v. SANDOZ, INC., *Defendant*.	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION - MIDDLESEX COUNTY DOCKET NO.:_____ CIVIL ACTION **COMPLAINT & JURY DEMAND**

Plaintiffs Tina J. Stewart and Michael Stewart, by and through Plaintiffs' undersigned counsel, bring this civil action against Defendant for personal injuries suffered by Plaintiff Tina J. Stewart, and for Michael Stewart's loss of consortium, and allege as follows:

INTRODUCTION

1. Plaintiffs Tina J. Stewart and Michael Stewart were injured as a result of her exposure to brand-name drug products Taxotere, Docefrez, Docetaxel Injection Concentrate, and Docetaxel Injection—products also known as docetaxel—(and collectively referred to herein as "Taxotere (docetaxel)"). The products at issue that were approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Defendant Sandoz Inc. is liable to Plaintiffs for damages and such other relief deemed just and proper.

2. Taxotere (docetaxel) is a chemotherapy drug administered to many who suffer primarily from breast cancer. Defendant, as well as other brand-name drug sponsors, manufacturers, labelers, and distributors of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, have known for years that these drugs cause permanent hair loss, a now well-documented side effect that for years has been publicized in numerous scientific studies, articles, and presentations. Despite this, these brand-name entities failed to warn patients and healthcare providers of the risk of permanent hair loss and report this risk to the Food and Drug Administration ("FDA"). Instead, Defendant hid this devastating side effect. In fact, some brand-name entities still fail to disclose that permanent hair loss is a common side effect.

3. As a result, there are thousands of women, like the Plaintiff in this case, who underwent chemotherapy using Taxotere (docetaxel) and now suffer from permanent hair loss, a side effect for which they were not warned and were wholly unprepared. Had these women and their healthcare providers known that permanent hair loss could result, they would have selected a different treatment option—effective alternatives to these drugs that do not lead to this devastating side effect are used regularly. *See In re: Taxotere (docetaxel) Products Liability Litigation*, 2:16-md-02740-KDE-MBN (E.D. La.) (MDL No. 2740) (currently pending multidistrict litigation

involving thousands of women alleging permanent, disfiguring hair loss due to Taxotere (docetaxel)).

4. As a result of this undisclosed side effect, Plaintiff has struggled to return to normalcy, even after surviving cancer. An integral element of her identity—her hair—never returned. Plaintiff is stigmatized with the universal cancer signifier—baldness—long after she underwent cancer treatment. Her hair loss acts as a permanent reminder that she is a cancer victim. She defeated cancer yet the image she sees in the mirror each day is that of a cancer patient. This permanent change has altered Plaintiff's self-image, negatively impacted her relationships, and others' perceptions of her, leading to social isolation and depression even long after fighting cancer.

5. Defendant failed, and still fails, to adequately warn that permanent or irreversible hair loss is a common side effect of Taxotere (docetaxel). As such, Plaintiff was unable to weigh the devastating possibility of permanent hair loss when deciding among a variety of treatment options. Plaintiff seeks recovery for her mental and physical suffering stemming from permanent and irreversible hair loss.

THE PARTIES

A. Plaintiffs.

6. Plaintiff Tina J. Stewart was at all relevant times a resident of Del Norte, Rio Granda, Colorado.

7. Plaintiff Michael Stewart was at all relevant times a resident of Del Norte, Rio Granda, Colorado.

8. Plaintiff has suffered personal injuries as a result of the use of Taxotere (docetaxel), including permanent disfigurement and hair loss.

9. Plaintiff Michael Stewart has suffered loss of consortium as a result of his wife's

use of Taxotere (docetaxel).

10. Plaintiff was administered Taxotere (docetaxel) that had been designed, developed, manufactured, sold, distributed, labeled, packaged, promoted, advertised, marketed, tested, and otherwise produced by Defendant Sandoz, Inc.

11. Plaintiff was administered Taxotere (docetaxel) between August 3, 2015 and November 16, 2015, in the State of Colorado at the Heart of the Rockies Regional Medical Center in Salida, Colorado.

B. Initial Taxotere (Docetaxel) Development.

12. Upon information and belief, at the direction of Sanofi S.A., Aventis Pharma S.A. licensed the patents for Taxotere (docetaxel) to Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC (collectively "Sanofi").

13. Sanofi S.A. and Aventis Pharma S.A., through Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., marketed Taxotere throughout the United States by providing marketing information regarding Taxotere (docetaxel) to health care providers and similarly soliciting purchases for the drug.

14. Sanofi S.A. and Aventis Pharma S.A., through Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., distributed and sold Taxotere (docetaxel) to healthcare providers and patients throughout the United States.

15. In addition to the Sanofi-related entities, other brand-name entities obtained approval to market new drugs with the proprietary names Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate. Their new drug applications were approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 355(b)(2).

16. A 505(b)(2) application is a subset of NDA, and it is subject to the NDA approval

requirements set out in section 505(b) and (c) of the FDCA. As such, it must satisfy the requirements for safety and effectiveness information.

17. A 505(b)(2) application contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

18. Accordingly, a 505(b)(2) applicant may rely on the findings of safety and effectiveness of a listed drug to the extent the new product seeking approval and the listed drug are the same. Otherwise, to the extent the products are different, a 505(b)(2) application, like a 505(b)(1) application, must include sufficient data to demonstrate that the product with those different aspects meets the statutory approval standard for safety and effectiveness.

19. A drug approved under the 505(b)(2) approval pathway is not a generic copy of a brand-name drug. Section 505(b)(2) is not an appropriate approval pathway for an application for a duplicate drug eligible for approval under section 505(j) of the FDCA (the Abbreviated New Drug Application process).

C. Sandoz.

20. Defendant Sandoz Inc. ("Sandoz") is a pharmaceutical company organized and existing under the laws of the State of Colorado with a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

21. Defendant Sandoz has transacted and conducted business throughout the United States, including the State of New Jersey.

22. Defendant Sandoz has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States, including the State of New Jersey.

23. At all relevant times, Defendant Sandoz has been in the business of designing,

testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under New Drug Application ("NDA") #201525.

24. The proprietary name for Defendant Sandoz's branded drug is Docetaxel Injection.

25. Defendant Sandoz expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

26. Defendant Sandoz filed NDA application #201525 on September 16, 2010, under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

27. Sandoz's formulation of Docetaxel Injection, however, is different from Taxotere in that it contains less polysorbate 80 and more 96 percent ethanol. Also, it contains polyethylene glycol 300 as a solubizer and anhydrous citric acid for pH adjustment.

28. Sandoz received FDA approval for NDA #201525 on June 29, 2011 and began marketing the drug in the United States on August 15, 2011.

29. When the drug was approved, a portion of the Patient Counseling Information read as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel administration." It also stated that one of the "most common side effects of Docetaxel Injection" is "hair loss." Neither of these statements refer to permanent hair loss.

30. Since approval, Sandoz has submitted multiple Changes Being Effected Supplemental New Drug Applications ("CBE sNDA") to update labeling. It submitted a CBE sNDA (S-002) on July 29, 2011 that was approved on March 15, 2012, and a CBE sNDA (S-003) on August 15, 2013 that was approved on April 23, 2014. Neither submission, however, updated labeling concerning hair loss.

31. On October 21, 2016, the FDA approved Sandoz's CBE sNDA, submitted on

March 7, 2016, "to include information on permanent or irreversible alopecia to Section 6.2 (Post-marketing Experience), Section 17 (Patient Counseling Information) of the Package Insert, and the Patient Package Insert (PPI) labeling."

32. As of December 2015, under "Post-Marketing Experiences," the labeling states: "Cases of permanent alopecia have been reported." Its Patient Counseling Information states that "side effects such as […] hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Its patient information also states that the "most common side effects" include "hair loss, in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed."

33. There is no mention of the risk of permanent or irreversible hair loss, however, in the Warnings and Precautions or Adverse Reactions portions of its labeling.

34. The facility which administered Taxotere (docetaxel) to Plaintiff confirmed that the Taxotere (docetaxel) administered to Plaintiff between August 3, 2015 and November 16, 2015, was from Defendant Sandoz, Inc.

35. Defendant is a corporation organized under the laws of the state of New Jersey of the United States of America that was or is doing business within the State of New Jersey. The aforementioned Defendant designed, marketed, sold, distributed, packaged, promoted, labeled, researched, tested or manufactured the Taxotere (docetaxel) product(s) which was administered to Plaintiff.

JURISDICTION AND VENUE

36. At all times relevant to this action, the Defendant has been engaged either directly or indirectly in the business of marketing and promoting Taxotere (docetaxel) within the State of New Jersey, with a reasonable expectation that the products would be used or consumed in this

state, and thus regularly solicited or transacted business in this state and across the United States.

37. At all times relevant to this action, the Defendant has been engaged either directly or indirectly in the business of distributing Taxotere (docetaxel) within the State of New Jersey, with a reasonable expectation that the products would be used or consumed in this state and across the United States, and thus have regularly solicited or transacted business in this state.

38. At all times relevant to this action, the Defendant has been engaged either directly or indirectly, in the business of selling Taxotere (docetaxel) within the State of New Jersey, with a reasonable expectation that the products would be used or consumed in this state and across the United States, and thus have regularly solicited or transacted business in this state.

39. At all times relevant to this action, the Defendant was engaged in disseminating inaccurate, false, and misleading information about the Taxotere (docetaxel) to physicians in all states in the United States, including the State of New Jersey, with a reasonable expectation that the misleading information would be used and relied upon by physicians throughout the United States, including the State of New Jersey.

40. Defendant Sandoz Inc. is a resident of New Jersey because its principal place of business is in the state.

41. Venue is proper in this county pursuant to Rule 4:3-2 because the Defendant is doing business within Middlesex County, including the sale, marketing, promotion and distribution of the Taxotere (docetaxel) products relevant to this action.

FACTUAL BACKGROUND

I. Plaintiff

42. Plaintiff Tina J. Stewart has suffered personal injuries as a result of the use of Taxotere (docetaxel), including permanent disfigurement, permanent hair loss.

43. Plaintiff was administered Taxotere (docetaxel) between August 3, 2015 and November 16, 2015, in the State of Colorado at the Heart of the Rockies Regional Medical Center in Salida, Colorado.

44. Plaintiff was administered Taxotere (docetaxel) that had been designed, developed, manufactured, sold, distributed, labeled, packaged, promoted, advertised, marketed, tested, and otherwise produced by Defendant.

45. Plaintiff has suffered personal injuries as a direct and proximate result of Defendant's conduct and misconduct as described herein and in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere (docetaxel).

46. Plaintiffs file this lawsuit within the applicable statute of limitations period of first suspecting that these drugs made by these particular Defendant caused the appreciable harm she sustained and alleges herein. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of her injuries as the cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did they have reason to suspect that Plaintiff had been injured, the cause of her injuries, or the tortious nature of the conduct causing her injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

47. Additionally, Plaintiffs were prevented from discovering this information at an earlier date because: (1) Defendant misrepresented to the public, the FDA, and the medical profession that Taxotere (docetaxel) are free from permanent side effects; (2) Defendant failed to disclose to the public, the FDA, and the medical profession their knowledge of the risk of permanent side effects; and (3) Defendant fraudulently concealed facts and information that could have led Plaintiffs to discover the liability of Defendant.

48. None of Plaintiff's injuries were warned of. Neither Defendant nor the healthcare providers who administered Taxotere (docetaxel) to Plaintiff had informed them that Plaintiff's hair loss would be permanent. To the contrary, Defendant had made representations, assertions, suggestions, and/or warnings that any hair loss suffered would be temporary in nature.

49. Plaintiffs believed Defendant's representations that her hair loss was temporary.

50. Plaintiff would not have used Taxotere (docetaxel) had the Defendant properly disclosed the risks associated with its use.

II. Development, Approval, and Labeling Changes for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

51. Taxotere (docetaxel) is a drug used in the treatment of various forms of cancer, including breast cancer, and is a part of a family of cytotoxic drugs referred to as taxanes.

52. Taxanes are derived from yew trees, and unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell reproduction. They are widely used as chemotherapy agents.

53. The development of taxanes began in the 1960s. Bristol-Myers Squibb developed, manufactured, and distributed the first commercially available taxane in the United States, known as Taxol (paclitaxel).

54. Taxol is the main competitor drug to Taxotere, and has been on the market since 1993.

55. Both docetaxel (Taxotere) and paclitaxel (Taxol) disrupt the microtubular network in cells that is essential for mitotic and interphase cellular function in the cell multiplication process.

56. Taxotere began as a two-vial product. One vial is called a concentrate, and it

contains docetaxel, along with polysorbate 80 and residual amounts of ethanol. The other vial is a diluent, containing water and ethanol.

57. The concentrate vial and the diluent vial are combined to form a "premix." A premix can be added to an intravenous bag to make a prefusion.

58. Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez are not purchased by patients at a pharmacy; rather, patients use of these drugs occurs via administration through injection and/or intravenously at a physician's office or medical treatment facility.

59. In the 1980s scientists at Rhône-Poulenc Rorer S.A., Sanofi S.A.'s predecessor-in-interest, began developing Taxotere with the intention of making a more potent taxane. Since that time, Sanofi S.A., Aventis Pharma S.A., Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and their affiliates and predecessors-in-interest (collectively "Sanofi") have controlled the development and been the owner, holder, or assignee of the patents related to Taxotere.

60. Phase I clinical testing of Taxotere began in 1990 (called the "TAX 001" study) and continued until 1992. Sanofi reported the results of clinical testing in May 1994.

61. Soon thereafter, on July 27, 1994, Sanofi applied for FDA approval for Taxotere under NDA #20449. The FDA's Oncologic Drugs Advisory Committee panel unanimously denied approval of the drug, requesting more data on toxicity, side effects, and phase III test results.

62. After additional clinical testing, the FDA approved Taxotere in May 14, 1996 for limited use—namely, for the treatment of patients with locally advanced or metastatic breast cancer that had either (1) progressed during anthracycline-based therapy or (2) relapsed during anthracycline-based adjuvant therapy.

63. After the initial approval, Sanofi sought and received FDA approval for additional

indications. Based on self-sponsored clinical trials, Sanofi claimed Taxotere's superiority over competing chemotherapy products approved for breast cancer treatment, including claiming superior efficacy over the lower potency paclitaxel (Taxol), its primary competitor.

64. On June 22, 1998, the FDA approved a slightly broader indication for Taxotere that extended its use to patients with locally advanced or metastatic breast cancer as treatment after "failure of prior chemotherapy."

65. That same year, Sanofi obtained FDA approval in December 1999 for use of Taxotere in treating "locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy."

66. As with all prior FDA-approved indications for Taxotere, the drug was approved at this time, and until late 2002, only as a second-line of treatment, meaning that Sanofi was prohibited from promoting Taxotere for use in patients who had not undergone and failed a specified first-line of treatment.

67. As of December 23, 1999, hair loss was listed as a "possible side effect[] of Taxotere." The label elaborated: "Loss of hair occurs in most patients taking Taxotere (including the hair on your head, underarm hair, pubic hair, eyebrows, and eyelashes) [… .] Once you have completed all your treatments, hair generally grows back."

68. Sanofi obtained FDA approval in November 2002 for use of Taxotere "in combination with cisplatin for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition."

69. Sanofi obtained FDA approval in May 2004 for use of Taxotere "in combination with prednisone as a treatment for patients with androgen independent (hormone refractory)

metastatic prostate cancer."

70. Later that year, Sanofi obtained FDA approval in August 2004 for use of Taxotere "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer."

71. In March 2006, Sanofi obtained FDA approval for use of Taxotere "in combination with cisplatin and fluorouracil for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease."

72. Sanofi obtained FDA approval in October 2006 for use of Taxotere "in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN)." In September 2007, FDA approved a broader SCCHN indication that removed the condition of inoperability.

73. The 2010 version of the prescribing information stated under "Patient Counseling Information" that "side effects such as […] hair loss are associated with docetaxel administration." "Patient Information" indicated that the "most common side effects of TAXOTERE include: […] hair loss." The document contains no mention of irreversible or permanent hair loss. The November 2014 version of this labeling information contains the same text.

74. Sanofi obtained FDA approval in May 2010 to add language related to pediatric safety and efficacy, including: "The overall safety profile of TAXOTERE in pediatric patients receiving monotherapy or TCF was consistent with the known safety profile for adults."

75. Sanofi submitted a CBE sNDA on November 24, 2015 concerning "permanent or irreversible alopecia."

76. On December 11, 2015, FDA approved the sNDA. Under "Patient Counseling

Information," the new label text reads: "Explain to patients that side effects such as […] hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Additionally, under "Patient Information," the label states that the "most common side effects of TAXOTERE include: […] hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." This is the latest and currently operative warning regarding permanent or irreversible alopecia in the Taxotere label. The label contains no mention of irreversible or permanent hair loss under "Warnings and Precautions" or "Adverse Reactions."

III. Defendant's Duties Under the FDCA and State Law.

77. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to prescription drugs rests with NDA holders/drug sponsors (such as manufacturers or labelers) and their assigns or agents; they have superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

78. To fulfill their essential responsibilities, these entities must vigilantly monitor all reasonably available information. They must closely evaluate the post-market clinical experience of their drugs and timely provide updated safety and efficacy information to the healthcare community and to consumers.

79. When monitoring and reporting adverse events, as required by both federal regulations and state law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to drug sponsors and the medical community that a public safety problem exists. If, for example, a manufacturer were to delay in reporting post-market information, that delay could mean that researchers, FDA, and the

medical community are years behind in identifying a public safety issue associated with the drug. In the meantime, more patients are harmed by using the product without knowing, understanding, and accepting its true risks. This is why drug sponsors must not only completely and accurately monitor, investigate and report post-market experiences, but they must also report the data in a timely fashion.

80. Because complete information about the safety of a drug cannot be known at the time of approval, and because the true picture of a product's safety profile emerges over time because of use by patients, it is a central premise of federal drug regulation that the NDA holders and their assigns or agents—not the FDA—bear responsibility for the content of its label at all times. Consequently, NDA holders are primarily responsible for crafting an adequate label and ensuring that warnings remain adequate as long as the drug is on the market.

81. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading, or does not provide adequate directions for use and adequate warnings. See 21 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacists sufficient information—including indications for use and "any relevant hazards, contraindications, side effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.100(c)(1).

82. As part of their responsibility to monitor post-market clinical experiences with the drug and provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant, whether under 505(b)(1) or (2), "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance

studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b). Any report of a "serious and unexpected" drug experience, whether foreign or domestic, must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii). Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a "history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.80(c)(2)(ii).

83. Federal law requires labeling to be updated as information accumulates: "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

84. All changes to drug labeling require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug sponsors, including those whose drugs were approved under Section 505(b)(2), may seek to change their approved labels by filing a supplemental application. 21 C.F.R. § 314.70.

85. One regulation, the "Changes Being Effected" (CBE) regulation, permits a manufacturer to unilaterally change a drug label to reflect "newly acquired information," subject to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes "new analyses of previously submitted data." 21 C.F.R. § 314.3(b). Thus, for instance, if a drug sponsor were to determine that a warning were insufficient based on a new analysis of previously existing data, it could submit a CBE and change its labeling.

86. The longer a drug sponsor delays updating its labeling so that it reflects current safety information, the more likely it is that medical professionals will continue to prescribe drugs without advising patients of harmful side effects, and the more likely it is that patients will suffer harmful side effects without the opportunity to evaluate risks for themselves.

IV. Sanofi and Sandoz Knew That Taxotere (docetaxel) May Cause Permanent Alopecia.

87. Beginning in 1998, Sanofi sponsored a trial entitled GEICAM 9805. It was initiated to compare the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC") with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC") in patients with high-risk, node-negative breast cancer. Between June 1999 and March 2003, a total of 1060 patients from 55 centers were randomly assigned to receive either TAC or FAC. By 2005, it knew that the GEICAM 9805 study demonstrated that 9.2 percent of patients who took Taxotere had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer.

88. In December 2006, an oncologist from Denver, Colorado, Dr. Scot Sedlacek, presented a study entitled "Persistent significant alopecia (PSA) from adjuvant docetaxel after doxorubicin/cyclophosphamide (AC) chemotherapy in women with breast cancer." Dr. Sedlacek tracked patients in three groups: Group A (doxorubicin regimen without a taxane); Group B (doxorubicin plus paclitaxel) and Group C (doxorubicin plus docetaxel). No women in Group A or Group B experienced persistent significant alopecia, but 6.3 percent of those in Group C did. Dr. Sedlacek concluded "that when docetaxel is administered after 4 doses of AC, there is a small but significant possibility of poor hair regrowth lasting up to 7 years. Such an emotionally devastating long term toxicity from this combination must be taken into account when deciding on adjuvant chemotherapy programs in women who likely will be cured of their breast cancer."

89. On November 21, 2008, Sanofi responded to an inquiry from a patient in the United

Kingdom concerning Taxotere and the incidence of permanent alopecia. That letter acknowledged that "one reference of non-reversible alopecia" had been identified. Its letter cited a paper published in the journal of Clinical Oncology for the proposition that "clinical studies … showed one case of non-reversible alopecia at the end of the study." The letter also cited another paper from the New England Journal of Medicine, which stated that "studies involving Taxotere in combination with doxorubicin and cyclophosphamide observed alopecia to be ongoing at the median follow-up time of 55 months in 3 percent of patients at the end of the chemotherapy."

90. In 2009, the British Journal of Dermatology published an article entitled "Irreversible and severe alopecia following docetaxel or paclitaxel cytotoxic therapy for breast cancer." That article reported a case in which a 58-year-old woman "developed diffuse and irreversible alopecia 7-years ago, after being treated with six cycles of docetaxel … every 3 weeks for a local occurrence." She did not have alopecia before administration of the chemotherapy. The article concluded "the irreversibility can be attributed only to the cytotoxic effect of docetaxel."

91. On March 4, 2010, The Globe and Mail published an article entitled "Women who took chemo drug say they weren't warned of permanent hair loss." The article explained: "Women who took a drug to fight breast cancer say they were never warned of a side effect—permanent hair loss—that left them looking sick long after they were treated for the disease." The article described this permanent hair loss as a "lasting side effect of the chemotherapy drug Taxotere, in combination with other drugs." The article included sufferers from Montreal, Canada; Brittany, France; and Oklahoma who had been treated with Taxotere. The article explained that the "side effect of persistent alopecia is suffered by about 3 percent of patients who take Taxotere with other chemotherapy drugs, according to the manufacturer's own studies," but that a "different study suggests that the incidence of persistent alopecia could be as high as 6 percent."

92. The Globe and Mail article also cited medical oncologist Dr. Hugues Bourgeois of Le Mans, France, "who presented research on 82 patients with persistent alopecia at the San Antonio Breast Cancer symposium this winter." Dr. Bourgeois described the choice he gives his patients—twelve cycles of Taxol or four cycles of Taxotere, where the risk of hair loss is higher. According to Dr. Bourgeois, most choose Taxol, which Dr. Bourgeois said "works just as well on breast cancer."

93. On March 6, 2010, CBS News published an article entitled "Sanofi's Latest Challenge: Women Who Say Its Chemotherapy Left Them Permanently Bald." The article described a group of women who called themselves "Taxotears" and encouraged women who have lost all their hair to report the adverse events to Sanofi and drug watchdog authorities. It also noted that "Taxotere's official prescribing information … makes no mention of permanent alopecia," and that "small studies suggest that as many as 6.3 percent of patients lose all their hair forever."

94. The CBS News article also mentioned that the Medicines and Healthcare products Regulatory Agency in the United Kingdom noted that "it was aware of one study in which 22 of 687 patients (about 3 percent) had persistent baldness after nearly five years."

95. On May 10, 2010, an article by Ben Tallon, MBChB, and others entitled "Permanent chemotherapy-induced alopecia: Case report and review of the literature" was published online. That article described "a case of permanent hair loss following standard dose chemotherapy with docetaxel, carboplatin, and trastuzumab for the treatment of breast carcinoma." There, the "lack of evidence for alopecia with trastuzumab, and the exposure to only a single infusion of standard dose carboplatin, suggests that docetaxel is the implicated agent." The article also explained: "Permanent [chemotherapy-induced alopecia] has been described following the use of … docetaxel."

96. In 2011, the American Journal of Dermatopathology published a study entitled "Permanent Alopecia After Systemic Chemotherapy: A Clinicopathological Study of 10 Cases," by Mariya Miteva, MD and others. The article discussed "the histological features of 10 cases of permanent alopecia after systematic chemotherapy with taxanes (docetaxel)," including 6 cases in which the patients took docetaxel for breast cancer. "All patients had moderate to very severe hair thinning … ."

97. On May 9, 2012, the Annals of Oncology published an article entitled "Permanent scalp alopecia related to breast cancer chemotherapy by sequential fluorouracil/epirubicin/cyclophosphamide (FEC) and docetaxel: a prospective study of 20 patients," by Nicolas Kluger, M.D.,Ph.D., among others. It reported that, since 2009, "nine cases of permanent scalp alopecia after systemic chemotherapy related to taxanes used to treat breast cancer have been reported … Docetaxel was almost always involved, alone in seven cases … or in association with carboplatin … and trastuzumab."

98. In October 2013, Drs. Nicola Thorp, Felicity Swift, Donna Arundell and Helen Wong presented at Clatterbridge Cancer Centre in the United Kingdom on "Long Term Hair Loss in Patients with Early Breast Cancer Receiving Docetaxel Chemotherapy." Their study was based on a questionnaire sent in October 2013 to patients who received docetaxel in 2010. Out of 189 questionnaires, 134 were returned. "Of those responding 21 (15.8 percent) had significant persistent scalp hair loss." The presentation concluded: "Long term significant scalp alopecia (hear lasting for up to 3.5 years following completion of chemotherapy) may affect 10-15 percent of patients following docetaxel for EBC. This appears to be unrelated to other patient and treatment characteristics … This risk should be discussed routinely (as part of the process of informed consent) with all patients embarking upon docetaxel as a component of management of EBC."

99. This Clatterbridge study was also published at the 2014 San Antonio Breast Cancer Symposium.

100. On November 10, 2015, the Journal of Clinical Oncology published an article entitled "Epirubicin Plus Cyclophosphamide Followed by Docetaxel Versus Epirubicin Plus Docetaxel Followed by Capecitabine As Adjuvant Therapy for Node-Positive Early Breast Cancer: Results From the GEICAM/2003-10 Study." This article reviewed and reiterated the connection between docetaxel and long-term alopecia:

> Patients who received [docetaxel] not only had to wear a wig for a longer period of time but also reported a significantly higher proportion of long-term incomplete scalp hair recovery and permanent wig use after therapy. This adverse effect, probably related to docetaxel … has previously been described by others. Sedlacek reported that approximately 6% of patients who received adjuvant docetaxel for early BC had persistent alopecia, whereas this toxicity was not seen in 384 patients receiving nondocetaxel adjuvant regimens. Kluger et al reported 20 patients with BC with persistent hair loss of androgenetic-like pattern after adjuvant treatment with CEF followed by docetaxel. Consequently, a prospective study of the efficacy of scalp hypothermia in the prevention of docetaxel-induced persistent alopecia is ongoing at one of the centers participating in the present trial.

101. Despite this, hair loss was listed as a "possible side effect[] of Taxotere" that "generally grows back" in a Patient Information Letter circulated by Sanofi beginning in December 23, 1999.

102. By contrast, the labeling for Taxotere approved by the European Medicines Agency in 2005 acknowledged that "[c]ases of persisting alopecia have been reported." It also stated in a tabulated list of adverse reactions in breast cancer that took into account node-positive breast cancer (from a study entitled TAX 316) and node-negative breast cancer (from GEICAM 9805) that alopecia is a "[v]ery common adverse reaction," with persisting alopecia occurring under three percent of the time.

103. In the September 28, 2007 version of the Highlights of Prescribing Information in

the United States, alopecia is listed as one of the most common adverse reactions. There is no mention of permanent alopecia.

104. The April 2010 version of Taxotere's United States labeling still stated that "hair generally grows back." That language does not appear in the 2011 version of Taxotere's label. Instead, the 2011 version of the prescribing information stated under "Patient Counseling Information" that "side effects such as … hair loss are associated with docetaxel administration." "Patient Information" indicated that the "most common side effects of TAXOTERE include: … hair loss." The document contains no mention of irreversible or permanent hair loss. Instead, it states that "alopecia" is one of the most common adverse reactions. The November 2014 version of this labeling information contains the same text.

105. In May 2015, Sanofi UK updated its Taxotere label. That version states that a "[v]ery common" side effect is "hair loss (in most cases normal hair growth should return)."

106. On June 12, 2015, Canada's Taxotere labeling changed. Its new labeling stated: "Hair loss may happen shortly after treatment has begun. Your hair should grow back once you've finished the treatment. However, some patients may experience persistent hair loss.

107. In August 2015, Australia's Taxotere labeling changed. Its new labeling stated that alopecia was "observed to be ongoing at the median follow-up time of 55 months."

108. In the United States, Sanofi submitted a CBE on November 24, 2015 concerning permanent alopecia.

109. On December 11, 2015, FDA approved the CBE. Under "Patient Counseling Information," the new text reads: "Explain to patients that side effects such as … hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Additionally, under "Patient Information," the label states that the "most common side effects of

TAXOTERE include: … hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The label contains no mention of irreversible or permanent hair loss under "Warnings and Precautions" or "Adverse Reactions."

110. Upon information and belief, Defendant failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80 by, among other things, failing to report each adverse drug experience concerning the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate products, whether foreign or domestic, including Plaintiff' injuries complained of herein, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by Defendant, failing to promptly investigate all adverse drug experiences concerning these drug products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by the FDA, and, if additional information is not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

111. Also, consistent with the Changes Being Effected regulations, Defendant had and continues to have a duty to initiate a change to the products' labels to reflect the true levels of risk, including the risk of developing Plaintiff' injuries complained of herein. To this day, Defendant has not adequately satisfied their duty to update the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate products' labeling or prescribing information to reflect their knowledge as to the true risks of developing the injuries complained of herein.

IV. Taxotere (docetaxel) Caused Permanent Alopecia in Many Breast Cancer Patients.

112. Chemotherapy is known to cause temporary and reversible hair loss. Hair loss occurs because chemotherapy targets rapidly dividing cells (both normal, healthy cells as well as cancer cells) including hair follicles. Hair follicles, the structures in the skin filled with tiny blood

vessels that make hair, are some of the fastest growing cells in the body, thus, hair follicles are some of the most likely cells to be damaged by chemotherapy.

113. There are 100,000 hair follicles on the scalp that typically grow about 0.3 to 0.4 mm a day or about six inches a year. For hair production, hair follicles undergo a cycle that consists of three phases: the anagen phase (growth), the catagen phase (transition), and the telogen phase (resting). During the anagen phase, the cells at the root of the hair follicle are dividing rapidly and an entire hair shaft from tip to root is formed. The matrix cells, which build the hair shaft, have a cell cycle length of approximately 18 hours. Approximately 90 percent of the hair on the scalp is normally in the anagen phase.

114. The catagen phase is a short transitional phase that occurs at the end of the anagen phase when growth of a hair stops. Only about 3 percent of hair follicles are in the catagen phase at any time.

115. The hair follicle is completely at rest during the telogen phase and, at the end of the telogen phase, the hair falls out and a new hair is supposed to start growing in the hair follicle beginning the hair cycle again with the anagen phase. Around 6 to 8 percent of all hair is regularly in the telogen phase.

116. Chemotherapy causes the matrix cells to stop dividing abruptly in the anagen phase. As a result, the portion of the hair shaft that is the closest to the skull narrows and subsequently breaks within the hair canal. For this reason, hair loss usually begins one to three weeks after the initiation of chemotherapy and hair may fall out very quickly in clumps or gradually.

117. Because the majority of hair on the scalp is in the anagen phase during any given period, the hair loss that results from chemotherapy can be quite significant and visible.

118. The effects of chemotherapy on hair follicles results in temporary hair loss that lasts

until the telogen phase is complete and a new hair cycle begins. According to the Mayo Clinic, hair can be expected to grow back after chemotherapy within three to six months. Dr. Ralph M. Trueb, the author of several articles related hair loss associated with chemotherapy, also states that hair regrowth following chemotherapy treatment will occur within three to six months after cessation of treatment.

119. Unlike the temporary and reversible alopecia that ordinarily results from chemotherapy, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate cause Permanent Chemotherapy Induced Alopecia, which is defined as an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy. The Permanent Chemotherapy Induced Alopecia caused by Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate is not limited to the scalp and can affect hair follicles throughout the body.

120. Patients who receive Taxotere without any other type of chemotherapy have experienced permanent hair loss all over their bodies. For example, one oncologist reported he was unlikely to prescribe Taxotere in early stage breast cancer patients because of the toxicity of the drug. When prescribing Taxotere in early stage breast cancer cases, he recommended lower dosage levels over a longer period of time. His patients who have received Taxotere have experienced permanent hair loss.

121. Also, the GEICAM 9805, a study sponsored by Sanofi produced evidence that over 9 percent of high risk breast cancer patients who were administered Taxotere suffered permanent alopecia with hair loss lasting, in some cases, over ten years.

122. Dr. Sedlacek's 2006 study, as described above, further demonstrates that Taxotere causes permanent hair loss. His study divided patients he treated from January of 1994 to

December of 2004 into three groups. The first group, which contained 258 patients, received Doxorubicin. None suffered permanent alopecia. The second group, which contained 126 patients, received Doxorubicin and Taxol. Again, none suffered permanent alopecia. The third group contained 112 patients who received Doxorubicin and Taxotere. Of those patiens, 6.3 percent suffered permanent alopecia with hair regrowth of less than 50 percent of the amount before chemotherapy.

123. In addition and as detailed above, Dr. Tallon's 2010 article concluded that, when a cocktail of Taxotere, Trastuzumab, and Carboplatin was administered and there was resulting permanent alopecia, Taxotere was the implicated agent. Its reasoning was that there was a lack of evidence linking alopecia with Trastuzumab and limited exposure to Carboplatin. Trastuzumab does not contain a component that causes hair loss and does not increase the rate of hair loss when combined with standard chemotherapy. Similarly, Carboplatin causes only mild temporary alopecia in 5 percent of users.

124. Likewise, the 2012 study by Dr. Kluger and others concluded that Taxanes were responsible for permanent scalp alopecia among patients who were administered a sequential regimen of FEC (fluorouracil, epirubicin, and cyclophosphamide) followed by docetaxel. They noted that no patients treated with only anthracycline regimens (and not docetaxel) suffered from permanent severe scalp alopecia.

125. Further, Drs. Thorp, Swift, Arundell and Wong in their 2014 presentation reported that 15.8 percent of Taxotere patients surveyed had significant persistent scalp hair loss for up to 3.5 years following completion of chemotherapy.

126. Finally, Sanofi's change to the Taxotere label in 2015, described above, acknowledges that Taxotere causes permanent hair loss but fails to do so adequately. Moreover,

some other Taxotere manufacturers have chosen not to adopt Sanofi's revised labeling. Under the "Patient Counseling Information" of the revised label, the new text reads: "Explain to patients that side effects such as … hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Additionally, under "Patient Information," the label states that the "most common side effects of TAXOTERE include: … hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The label contains no mention of irreversible or permanent hair loss under "Warnings and Precautions" or "Adverse Reactions."

127. By contrast, in a report issued on Taxotere on May 12, 2016, the European Medicines Agency ("EMA") concluded that "[b]ased on review of the Sanofi global pharmacovigilance database, worldwide scientific literature, clinical studies, and biological plausibility, the cumulative weighted evidence is sufficient to support a causal association between docetaxel and permanent/irreversible alopecia in the patients who received docetaxel."

128. Because NDA holders and their assigns or agents are held to the knowledge of an expert in the field concerning the products they sell, Defendant cannot plead ignorance of the scientific information publicly available or otherwise available to them that would have supported a label change, including the studies and information discussed herein.

V. Sanofi Marketed & Promoted Taxotere Despite Knowing It Caused Permanent Alopecia.

129. Sanofi, including its predecessors and affiliates, have designed, directed, and/or engaged in a marketing scheme to over promote Taxotere directly to consumers and for off-label uses not approved by the FDA. As a result, Sanofi has earned in excess of €7 billion in revenue on its sales of Taxotere in the United States:

Year	U.S. Sales as Reported by

	Sanofi S.A.
2000	€367,000,000
2001	€541,000,000
2002	€701,000,000
2003	€733,000,000
2004	Could not be located
2005	€695,000,000
2006	€708,000,000
2007	€691,000,000
2008	€737,000,000
2009	€827,000,000
2010	€786,000,000
2011	€243,000,000
2012	€53,000,000
2013	€42,000,000
2014	€8,000,000
2015	€-1,000,000
2016	€4,000,000
Total	**€7,135,000,000**

130. In or around 2000, Sanofi hired a marketing firm to conduct a study on the primary concerns of oncologists and breast cancer patients undergoing treatment. The results of the study revealed that breast cancer patients felt an innate need to stay 'connected' through various means.

131. As a result of the marketing study, Sanofi launched a new sales promotional campaign in 2000 known as "Connection Cards" in which gift packages were offered to breast cancer patients at their oncologist's office. These gift packages initially included ten custom designed note cards and envelopes; a 30-minute prepaid long-distance calling card; a reference card with contact information for nationally recognized breast cancer organizations; a reference card with contact information with the company's breast cancer support program; and most importantly, a brochure giving detailed information about Taxotere.

132. To maintain the effectiveness of the promotional campaign, Sanofi added coupons for wigs and vouchers for discounted taxi services to the gift packages provided to breast cancer patients. In 2002, Sanofi made available to U.S. patients approximately 60,000 "Connection

Cards" through 150 sales representatives.

133. Sanofi claimed the promotional campaign to be a success, adding the campaign to its permanent rotation of promotional materials.

134. Sanofi also promoted Taxotere for the following breast cancer treatments, which at the time, were neither approved by the FDA nor supported by the available drug compendia: adjuvant breast cancer, neo-adjuvant breast cancer, weekly dose for metastatic breast cancer.

135. Sanofi directed its U.S. sales force to misrepresent the safety and effectiveness of the off-label use of Taxotere to expand the market for Taxotere in unapproved settings, such as a first-line of treatment or for early-stage breast cancer.

136. On July 26, 2001, the FDA's Division of Drug Marketing, Advertising and Communications, now known as the Office of Prescription Drug Promotion, sent a letter to Sanofi identifying promotional activities that were in violation of the FDCA and its implementing regulations on off-label promotion.

137. In particular, FDA identified promotional brochures distributed at the American Society of Clinical Oncology Annual Meeting in May 2001 that stated that Taxotere was safe and effective for first-line treatment in combination with Adriamycin such as that it was "the only taxane combination approved for first-line treatment of locally advanced or metastatic breast cancer."

138. This was considered off-label promotion because Taxotere in combination with Adriamycin was approved by FDA only for second-line treatment—not first-line treatment—of locally advanced or metastatic breast cancer. Likewise, as explained by FDA, other taxane combinations, as well as other classes of drug combinations, were approved for this first-line treatment. FDA demanded that Sanofi "immediately cease the distribution of these and similar

promotional materials."

139. FDA sent a second warnings letter to Sanofi on December 18, 2002, concerning promotional materials at the 2002 Annual Meeting, which featured queen chess pieces and stated that Taxotere was "at the center of more strategies every day." According to FDA, these promotional materials constituted "false or misleading promotion" which could "compromise patient survival and safety." FDA focused on Sanofi's claim that Taxotere resulted in "significant survival advantages," noting that this statement was not supported by clinical trial results. FDA also noted that Sanofi underemphasized information concerning severe risks that can result from using Taxotere.

140. Sanofi responded to FDA on December 30, 2002, stating "we are discontinuing the use of these [ads], and any similar materials." Nonetheless, Sanofi continued its false and misleading promotional and marketing activities.

141. Despite Sanofi's assurances that these and similar promotional materials would be discontinued and destroyed, FDA sent Sanofi a third warnings letter on July 17, 2003, identifying two direct-to-consumer promotional pieces that raised "similar" concerns. These two promotional ads appeared on the back of People Magazine's circulation wrap and prominently featured the slogan "The Next Move May Be the Key to Your Survival" and "It's Your Move," which again featured the queen and chess piece theme.

142. FDA found these ads to be misleading because the headline suggests that, if cancer patients want to survive breast or lung cancer, their "next move" should include Taxotere, thus implying that Taxotere is "more effective than has been demonstrated by substantial evidence or substantial clinical experience." FDA concluded that Sanofi's ads "reinforce[] the message that treatment with Taxotere will result in significant survival advantages," when the clinical data "did

not necessarily represent longterm survival or a cure." FDA demanded that Sanofi submit a letter stating the status of these items (active or discontinued) as well a list of violative promotional materials.

143. Sanofi replied on August 1, 2003, assuring FDA that the two ads had been discontinued and identifying another direct-to-consumer promotional piece, similar to the two ads. The third ad, which featured the same Taxotere slogans, "The *Next Move May Be the Key to Your Survival,"* and *"It's Your Move,"* had been disseminated in "Coping," "MAAM," and "Cure" Magazines between March and July 2003 and was planned to be disseminated in these magazines in addition to "Y-Me" magazine through December 2003. Only after follow-up telephone calls did Sanofi assure FDA in an August 21, 2003 letter that it had discontinued use of this additional misleading piece.

144. FDA concluded on November 12, 2003 that these three ads likewise "misleadingly overstate[d] the survival benefits ... and impl[ied] that survival depends on treatment with Taxotere," while simultaneously "minimizing the serious and potentially life-threatening risks associated with the drug."

145. As late as January 2004, Sanofi distributed banned materials to physicians and other healthcare providers that promoted Taxotere, using materials with the same misleading slogans and substantially similar misleading information.

146. In addition, Sanofi's salespeople were directed to "cherry pick" positive clinical study results. For example, in the breast cancer setting, Sanofi trained its salespeople to downplay the results of clinical trial results and the NIH Guidelines for Adjuvant Breast Cancer, which showed that evidence of taxanes' role in the adjuvant treatment of node positive breast cancer was inconclusive. By contrast, to emphasize Taxotere's superiority over Taxol, they were also

instructed to highlight preliminary results and abstracts from weaker trials. Similarly, they were trained to emphasize the lower incidence of non-lethal side effects when compared with Taxol while omitting the lethal side effect of severe neutropenia that occurs more frequently when using Taxotere.

147. In doing so, Sanofi continued to make false and misleading statements promoting the "superior efficacy" of Taxotere over the competing product paclitaxel (Taxol). In June 2008, Sanofi utilized marketing and promotional materials for Taxotere at the annual meeting for the American Society of Clinical Oncology, comparing the efficacy of Taxotere versus paclitaxel (Taxol). Specifically, Sanofi utilized a "reprint carrier," citing a clinical study published in the August 2005 edition of the Journal of Clinical Oncology. The cover of the reprint carrier claimed, among other things:

- "Taxotere demonstrated efficacy benefits vs paclitaxel"
- "This phase III study demonstrated that docetaxel is superior to paclitaxel in TTP, response duration, and OS [overall survival]."
- "Phase III trial demonstrated improved survival for Taxotere vs paclitaxel in metastatic breast cancer"

148. Sanofi's statements in the "reprint carrier" marketing the conclusions of the 2005 Journal of Clinical Oncology study were false and/or misleading in light of the 2007 and 2008 studies finding that Taxotere was not more effective than paclitaxel (Taxol) in the treatment of breast cancer.

149. Specifically, in August 2007, Cancer Treatment Reviews published a study that found no significant differences in the efficacy and outcomes obtained with Taxotere or Taxol (paclitaxel) in breast cancer treatment. Likewise, a 2008 study in the New England Journal of Medicine concluded that Taxol (paclitaxel) was more effective than Taxotere for patients undergoing standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

150. As a result of these false and misleading statements, in 2009, the FDA issued a warning letter to Sanofi citing these unsubstantiated claims of superiority over paclitaxel stating:

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a professional reprint carrier [US.DOC.07.04.078] for Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion (Taxotere) submitted under cover of Form FDA 2253 by Sanofi-Aventis (SA) and obtained at the American Society of Clinical Oncology annual meeting in June 2008. The reprint carrier includes a reprint from the Journal of Clinical Oncology, which describes the TAX 311 study. This reprint carrier is false or misleading because it presents unsubstantiated superiority claims and overstates the efficacy of Taxotere. Therefore, this material misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a) and 321(n). *Cf.* 21 CFR 202.1(e)(6)(i), (ii) & (e)(7)(ii).
>
> …
>
> The reference cited in support of these claims … does not constitute substantial evidence or substantial clinical experience to support these claims and representations because, among other factors, the study failed to demonstrate statistical significance on the primary endpoint and has not been replicated.

151. In addition, Sanofi also began indirectly promoting Taxotere through a series of direct-to-consumer television commercials that began airing in 2007. One of these commercials showed breast cancer patients slowly removing their wigs as an omniscient voice stated: "Cancer is tough but so are you. Get the facts, share the feelings, look to the future—Sanofi Aventis—because health matters and so do you." These and other similar direct-to-consumer advertisements continued at least through 2010.

VI. Permanent Alopecia is Devastating for Plaintiff.

152. Research indicates that a majority of women consider alopecia the most traumatic side effect of cancer treatment. One study states that 58 percent of women preparing for chemotherapy describe alopecia as the most disturbing anticipated side effect, and that 8 percent of women may choose to forego treatment based on possible alopecia. Although baldness is the most commonly recognized form of alopecia, chemotherapy-related hair loss can extend to

eyebrows, eyelashes, arm and leg hair, pubic hair, etc.

153. Women with cancer who experience alopecia, as compared with women with cancer who do not, report lower self-esteem, poorer body image, and a lower quality of life. Alopecia can be stigmatizing and may result in anger, anxiety, embarrassment, sadness, depression, shame, helplessness, fear, and loss of sense of self. Women with alopecia may experience a loss of sense of femininity, sexuality, attractiveness, self-confidence, and womanhood. Even if hair does grow back, studies have found that these negative thoughts and feelings remain; body image tends not to return to pre-treatment levels.

154. Alopecia also alters how women interact with others and experience social situations. Alopecia symbolizes cancer identity and treatment, even when individuals wear wigs or garments to cover the hair loss. These symbols can heighten an individual's everyday awareness that she has or had cancer.

155. Hair loss alters how women recognize themselves and how others interact with them. Hair is a critical aspect of appearance that can facilitate recognition as female, young, and healthy. By contrast, loss of hair may cause others to categorize individuals as old and unhealthy. As a result, women who suffer from alopecia have a heightened awareness of their appearance during social interactions, and may be treated differently than they were before their hair loss.

156. To cope, many avoid social situations because they are nervous that others will treat them differently. These fears are not unfounded. In one study of cancer survivors, 75 percent of participants reported experiencing silent stares from others that they attributed to their "cancer appearance." Participants also reported that people they knew avoided public contact with them.

157. Hair loss can also increase risk of injury to the body. Nose hair, eyelashes, ear hair, etc. serve important bodily functions and are necessary for the protection against injury to organs

critical to human senses. Hair loss in these areas places women at risk of permanent injuries.

158. Even when, unlike here, patients were warned that cancer-related hair loss may occur, cancer patients have reported feeling that they were not given adequate information about how to manage cancer-related hair loss. This underscores the importance of healthcare providers appreciating the traumatic effect that cancer-related alopecia may have on their patients.

THE CAUSES OF ACTION
CLAIMS ASSERTED BY PLAINTIFF

159. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

160. Plaintiff was administered Taxotere (docetaxel) or was injured as a result of Taxotere (docetaxel) outside of the state of New Jersey. To the extent the court chooses to apply the law of a state other than New Jersey, Plaintiffs are placing Defendant on notice of all claims which may be asserted by the individual Plaintiffs from other states and jurisdictions in addition to New Jersey:

FIRST CAUSE OF ACTION
Strict Products Liability – Design, Manufacturing and Warning

161. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

162. At all relevant times, Defendant was in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate as hereinabove described that was used by Plaintiff, or have recently acquired the entities that did the same.

163. The Plaintiff brings this claim under the applicable state's common law, including

the Restatement of Torts (Second).

164. The Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendant failed to provide adequate warnings to users and their healthcare providers, including Plaintiff and Plaintiff's healthcare providers, of the risk of side effects associated with the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, particularly the risk of developing disfiguring, permanent alopecia.

165. The Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendant and ultimately administered to Plaintiff lacked such warnings when it left Defendant's control.

166. The risks of developing disfiguring, permanent alopecia were known to or reasonably scientifically knowable by Defendant at the time the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate left Defendant's control.

167. Any warnings actually provided by Defendant did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing disfiguring, permanent alopecia.

168. Without adequate warning of these side effects, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate are not reasonably fit, suitable, or safe for its reasonably anticipated or intended purposes.

169. Plaintiff was a reasonably foreseeable user of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate who used the drug in reasonably anticipated manners. Plaintiff did not misuse the product.

170. Plaintiff would not have used Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had she (and her Physicians) been provided an adequate warning by Defendant of the risk of these side effects.

171. Further, Defendant misrepresented facts as set forth herein concerning the character or quality of the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate that would be material to potential prescribers and purchasers or users of the product.

172. Defendant's misrepresentations were made to potential prescribers and/or purchasers or users as members of the public at large.

173. As a purchaser or user, Plaintiff and/or her healthcare providers reasonably relied on the misrepresentations.

174. Plaintiff was a person who would reasonably be expected to use, consume, or be affected by the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

175. As a result of the foregoing acts and omissions, Defendant caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counselling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful

fees, costs and such other relief as this Court deems just and proper.

SECOND CAUSE OF ACTION
Negligence

176. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

177. Defendant had a duty to exercise reasonable care in the design, research, formulation, manufacture, production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and dangerous side effects.

178. Defendant breached these duties when they put Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate into interstate commerce, unreasonably and without adequate and/or proper warning to Plaintiff and her healthcare providers, a product that Defendant knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

179. The negligence of Defendant, their agents, servants, and/or employees, included but was not limited to, the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate without thoroughly, adequately, and/or sufficiently testing it—including pre-clinical and clinical testing and post-marketing surveillance—for safety and fitness for use and/or its dangers and risks;

(b) Marketing Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate to Plaintiff, Plaintiff' healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent alopecia;

(c) Marketing Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate to Plaintiff, Plaintiff' healthcare providers, the public, and the medical

and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez;

(d) Advertising and recommending the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez; without sufficient knowledge of its safety profile;

(e) Representing to Plaintiff, Plaintiff's healthcare providers, the public, and the medical and healthcare professions that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were superior to other commercially available products designed to treat the same forms of cancer Taxotere was designed to treat, when in fact they were not;

(f) Designing, manufacturing, producing, and/or assembling Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in a manner that was dangerous to its users;

(g) Concealing information from Plaintiff, Plaintiff's healthcare providers, the public, other medical and healthcare professionals, and the FDA that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were unsafe, dangerous, and/or non-conforming with FDA regulations;

(h) Concealing from and/or misrepresenting information to Plaintiff, Plaintiff's healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, as compared to other forms of treatment for cancer.; and

(i) Encouraging the sale of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, either directly or indirectly, orally or in writing, to Plaintiff and Plaintiff's healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects.

180. Despite the fact that Defendant knew or should have known that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate caused unreasonably dangerous side effects, Defendant continued and continue to market, manufacture, distribute, and/or sell Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate to consumers, including Plaintiff.

181. Plaintiff and Plaintiff's healthcare providers were therefore forced to rely on safety

information that did not accurately represent the risks and benefits associated with the use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate as compared to other products already commercially available to treat the same types of cancer Taxotere was designed to treat.

182. Defendant knew or should have known that consumers such as Plaintiff would use their product and would foreseeably suffer injury as a result of Defendant' failure to exercise reasonable care, as set forth above.

183. Defendant's negligence was a proximate cause of Plaintiff's injuries, harms, damages, and losses, in connection with the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent and irreversible alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

THIRD CAUSE OF ACTION
Negligent Misrepresentation

184. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

185. Defendant had a duty to represent to Plaintiff, Plaintiff's healthcare providers, the medical and healthcare community, and the public in general that Taxotere, Docefrez, Docetaxel

Injection, and Docetaxel Injection Concentrate had been tested and found to be safe and effective for the treatment of various forms of cancer.

186. When warning of safety and risks of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, Defendant negligently represented to Plaintiff, Plaintiff's healthcare providers, the medical and healthcare community, and the public in general that they had been tested and was found to be safe and/or effective for its indicated use.

187. Defendant concealed their knowledge of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, defects from Plaintiff, Plaintiff's healthcare providers, and the public in general and/or the medical community specifically.

188. Defendant concealed their knowledge of the defects in their products from Plaintiff, Plaintiff's healthcare providers, and the public in general.

189. Defendant misrepresented the novel nature of their product in order to gain a market advantage resulting in billions of dollars in revenues at the expense of vulnerable cancer victims such as Plaintiff.

190. Defendant made these misrepresentations with the intent of defrauding and deceiving Plaintiff, Plaintiff's healthcare providers, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff, Plaintiff's healthcare providers, the public in general, and the medical community in particular, to recommend, dispense, and/or purchase Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for use in the treatments of various forms of cancer, including, but not limited to, breast cancer.

191. Defendant failed to exercise ordinary and reasonable care in their representations of Taxotere while involved in its manufacture, sale, testing, quality assurance, quality control,

and/or distribution into interstate commerce, and Defendant negligently misrepresented the high risks of unreasonable, dangerous side effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

192. Defendant breached their duty in misrepresenting Taxotere's, Docetaxel Injection's, Docetaxel Injection Concentrate's, and Docefrez's, serious side effects to Plaintiff, Plaintiff's healthcare providers, the medical and healthcare community, the FDA, and the public in general.

193. Plaintiff and Plaintiff's healthcare providers reasonably relied on Defendant to fulfil their obligations to disclose all facts within their knowledge regarding the serious side effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

194. As a result of the foregoing acts and omissions, Defendant caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counselling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

FOURTH CAUSE OF ACTION
Fraudulent Misrepresentation

195. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

196. Defendant represented to Plaintiff, Plaintiff's healthcare providers, the medical and healthcare community, and the public in general that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had been tested and was found to be safe and effective for the treatment of certain forms of cancer and was free of defects that could and would cause serious side effects, including permanent and irreversible hair loss.

197. Defendant fraudulently omitted from these representations information that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate could and did cause serious side effects, including permanent and irreversible hair loss.

198. These representations were material and false.

199. Defendant made these representations and omissions:

(a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or belief of falsity of the resulting statements;

(b) positively and recklessly without knowledge of their truth or falsity;

(c) with knowledge that they were made without any basis; and/or

(d) without confidence in the accuracy of the representations or statements resulting from the omissions.

200. Defendant made these false representations with the intention or expectation that Plaintiff, Plaintiff's healthcare providers, the public in general, and the medical community in particular, would recommend, dispense, and/or purchase Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for use in the treatments of various forms of cancer, including, but not limited to, breast cancer, all of which evidenced a callous, reckless, willful, wanton, and

depraved indifference to the health, safety, and welfare of Plaintiff.

201. At the time Defendant made the aforesaid representations, and, at the time Plaintiff used Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of Defendant's representations, statements and/or implications and justifiably and reasonably relied upon Defendant's representations, statements, and implications, believing them to be true.

202. In reliance upon Defendant's representations, Plaintiff and Plaintiff's healthcare providers were induced to and did use and prescribe Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, which caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

FIFTH CAUSE OF ACTION
Fraudulent Concealment

203. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

204. At all times during the course of dealing between Defendant and Plaintiff and

Plaintiff's healthcare providers, Defendant misrepresented the design characteristics and safety of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for their intended use.

205. Defendant knew or were reckless in not knowing that its representations were false.

206. In representations made to Plaintiff and Plaintiff's healthcare providers, Defendant fraudulently concealed and intentionally omitted the following material information:

(a) that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were not as safe as other forms of treatment for which they were marketed and sold to cancer patients;

(b) that the risks of adverse events with Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were higher than those with other forms of treatment for which they were marketed and sold to cancer patients;

(c) that the risks of adverse events with Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were not adequately tested and/or known by Defendant;

(d) that Defendant were aware of dangers in Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, in addition to and above and beyond those associated with other forms of treatment for cancer patients;

(e) that Taxotere, Docefrez, Docetaxel Injection, Docetaxel Injection Concentrate, and Docetaxel Injection Concentrate were defective in that it caused dangerous side effects as well as other severe and permanent health consequences in a much more and significant rate than other forms of treatment for cancer patients;

207. Defendant had a duty to disclose to Plaintiff and Plaintiff's healthcare providers the defective nature of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, including, but not limited to, the heightened risks of disfiguring, permanent alopecia.

208. Defendant had sole access to material facts concerning the defective nature of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate and their propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used the drugs at issue, including Plaintiff, in particular.

209. Defendant's concealment and omissions of material fact concerning the safety of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were made purposefully, wilfully, wantonly, and/or recklessly to mislead Plaintiff and Plaintiff's healthcare providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or dispense Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate and/or use them.

210. Defendant knew that Plaintiff and Plaintiff's healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, including the material omissions of fact surrounding Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate set forth herein.

211. Plaintiff and Plaintiff's healthcare providers reasonably relied on information revealed by Defendant that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

212. As a result of the foregoing acts and omissions, Defendant caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant, for

damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

SIXTH CAUSE OF ACTION
Fraud and Deceit

213. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

214. Defendant committed fraud by omission in applying for and gaining patent protection for Taxotere resulting in increased sales and market penetration. This increased market penetration was the proximate cause of Plaintiff's exposure to the side effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

215. Defendant fraudulently claimed superior efficacy over other products designed to treat the same conditions for which Taxotere was designed to treat. These fraudulent representations were the proximate cause of Plaintiff's exposure to the side effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

216. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally distributed false information, including, but not limited to, assuring Plaintiff, Plaintiff's healthcare providers and/or the public that Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate was safe and effective for use in the treatment of various forms of cancer, including breast cancer.

217. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and or research to Plaintiff, Plaintiff's healthcare providers, healthcare professionals, and/or the public.

218. Defendant had a duty when disseminating information to Plaintiff, Plaintiff's healthcare providers, and the public to disseminate truthful information.

219. Defendant had a duty when disseminating information to Plaintiff, Plaintiff's healthcare providers, and the public not to deceive Plaintiff, Plaintiff' healthcare providers, and/or the public.

220. The information Defendant distributed to Plaintiff, Plaintiff's healthcare providers, and the public, including, but not limited to, reports, press releases, advertising campaigns, and other forms of media contained material misrepresentations of fact and/or omissions.

221. The information Defendant distributed to Plaintiff, Plaintiff's healthcare providers, and the public intentionally included false representations that Defendant's drug Taxotere was safe and effective for the treatment of various forms of cancer, including breast cancer.

222. The information Defendant distributed to Plaintiff, Plaintiff's healthcare providers, and the public intentionally included false representations that Defendant's drug Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate carried the same risks, hazards, and/or dangers as other forms of treatment for the same conditions for which Taxotere was designed to treat.

223. The information Defendant distributed to Plaintiff, Plaintiff's healthcare providers, and the public intentionally included false representations that Taxotere was not injurious to the health and/or safety of its intended users.

224. The information Defendant distributed to Plaintiff, Plaintiff's healthcare providers, and the public intentionally included false representations that Taxotere was no more injurious to the health and/or safety of its intended users as other forms of cancer treatments for which Taxotere was designed to treat.

225. These representations by Defendant were all false and misleading.

226. Defendant intentionally suppressed, ignored, and disregarded test results not

favorable to Defendant and that demonstrated Taxotere was not safe as a means of treatment for certain types of cancer for which Taxotere was designed to treat.

227. Defendant intentionally made material misrepresentations to Plaintiff, Plaintiff's healthcare providers, and the public in general, including the medical profession, regarding the safety of Taxotere, specifically, but not limited to, Taxotere not having dangerous and serious health and/or safety concerns.

228. Defendant intentionally made material misrepresentations to Plaintiff, Plaintiff's healthcare providers, and the public in general, including the medical profession, regarding the safety of Taxotere, specifically, but not limited to, Taxotere being as safe as other products designed to treat the same conditions Taxotere was designed to treat.

229. It was Defendant's intent and purpose in making these false representations to deceive and defraud Plaintiff, Plaintiff's healthcare providers, and/or the public and to gain the confidence of Plaintiff , Plaintiff's healthcare providers, the public, and/or healthcare professionals to falsely ensure the quality and fitness for use of Taxotere and induce Plaintiff, Plaintiff's healthcare providers, and the public, including the medical profession, to purchase, request, dispense, prescribe, recommend, and/or continue to use Taxotere.

230. Defendant made the aforementioned false claims and false representations with the intent of convincing Plaintiff, Plaintiff's healthcare providers, the public, and/or healthcare professionals that Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate was fit and safe for use as treatment for certain types of cancer, including breast cancer.

231. Defendant made the aforementioned false claims and false representations with the intent of convincing Plaintiff, Plaintiff's healthcare providers, the public, and/or healthcare professionals that Taxotere was fit and safe for use as treatment for certain forms of cancer and

did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for which Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate was designed to treat.

232. Defendant made false claims and false representations in its documents submitted to Plaintiff , Plaintiff's healthcare providers, the public, and healthcare professionals that Taxotere did not present risks related to disfigurement secondary to permanent alopecia.

233. Defendant made false claims and false representations in its documents submitted to Plaintiff, Plaintiff's healthcare providers, the public, and healthcare professionals that Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate did not present health and/or safety risks greater than other forms of treatment for the same conditions Taxotere was designed to treat.

234. Defendant made these and other representations with a pretense of actual knowledge when Defendant had no knowledge of the truth or falsity of these representations, and Defendant made these representations recklessly and without regard to the actual facts.

235. Defendant made these and other representations with the intention of deceiving and defrauding Plaintiff and Plaintiff's healthcare providers.

236. Defendant made these and other representations in order to induce Plaintiff and Plaintiff's healthcare providers to rely upon the misrepresentations.

237. Defendant's false misrepresentations caused Plaintiffand/or Plaintiff's healthcare providers to purchase, use, rely on, request, dispense, recommend, and/or prescribe Taxotere.

238. Defendant recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Taxotere to the public at large, and Plaintiff and Plaintiff's healthcare providers in particular, for the purpose of influencing the marketing of a product

Defendant knew was dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for cancer.

239. Defendant wilfully and intentionally failed to disclose, concealed, and/or suppressed the material facts regarding the dangerous and serious health and/or safety concerns related to Taxotere.

240. Defendant wilfully and intentionally failed to disclose the truth and material facts related to Taxotere and made false representations with the purpose and design of deceiving and lulling Plaintiff and Plaintiff's healthcare providers into a sense of security so that Plaintiff and Plaintiff's healthcare providers would rely on Defendant's representations to purchase, use, dispense, prescribe, and/or recommend Taxotere.

241. Defendant, through their public relations efforts, which included, but were not limited to, public statements and press releases, knew or should have known that the public, including Plaintiff and Plaintiff's healthcare providers, would rely upon the information being disseminated.

242. Plaintiff and/or Plaintiff's healthcare providers did in fact rely on and believe Defendant's false representations to be true at the time they were made, and they relied upon Defendant's false representations and superior knowledge of how Taxotere would treat certain forms of cancer for which Taxotere was designed to treat.

243. At the time Defendant's false representations were made, Plaintiff and/or Plaintiff's healthcare providers did not know the truth and were not with reasonable diligence able to discover the truth with regard to the dangerous and serious health and/or safety concerns of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

244. Plaintiff and Plaintiff's healthcare providers did not discover the true facts with

respect to Defendant's false representations and the dangerous and serious health and/or safety concerns of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, and Plaintiff and Plaintiff's healthcare providers with reasonable diligence could not have discovered the true facts.

245. Had Plaintiff and Plaintiff's healthcare providers known the true facts with respect to the dangerous and serious health and/or safety concerns of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, Plaintiff would not have purchased, used, and/or relied on Defendant's drug Taxotere.

246. Defendant's aforementioned conduct constitutes fraud and deceit, and it was committed and/or perpetrated wilfully, wantonly, and/or purposefully on Plaintiff.

247. As a result of the foregoing acts and omissions, Defendant caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counselling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION
Violation of New Jersey Consumer Fraud Act

248. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further allege as follows.

249. Prescription drugs, such as Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, are "merchandise" as defined by N.J.S.A. 56:8-1(c).

250. Defendant is a manufacturer, promoter, marketer, developer, seller or distributor of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

251. Defendant knew or should have known that the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez causes serious side effects including compulsive behavior and compulsive gambling.

252. Defendant's practice of promoting Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez (a) created or reinforced a false impression as to the safety of taking the drug (b) places all consumers of Taxotere (docetaxel) products at risk for serious side effects including compulsive behavior and compulsive gambling.

253. Defendant's statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including Plaintiff, would rely on the Defendant's statements or omissions.

254. Plaintiff’s physician prescribed or otherwise provided Plaintiff with Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, and Plaintiff consumed the drug(s), primarily for personal and family reasons and suffered ascertainable losses of money as a result of the Defendant's use or employment of the methods, acts, or practices alleged herein.

255. The aforesaid promotion and release of the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products into the stream of commerce constitutes an

unconscionable commercial practice, deception, false pretense, misrepresentation or knowing concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Defendant, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

256. Defendant acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

257. As a proximate result of consumer fraud set forth above, Plaintiff has purchased an unsafe product and incurred economic loss that includes the purchase price of the Taxotere (docetaxel) product(s) and other out-of-pocket healthcare related costs, for which Defendant is liable to Plaintiffs for treble damages.

EIGHTH CAUSE OF ACTION
Violation of Consumer Protection Laws

258. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

259. Plaintiff was administered Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

260. Had Defendant not engaged in the deceptive conduct described herein, Plaintiff would not have purchased or paid for the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, and would not have incurred related medical costs and injury.

261. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiff for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

262. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services has characteristics, ingredients, uses, benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

263. Plaintiff was injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. Each aspect of Defendant's conduct combined to artificially create sales of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

264. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

265. Had Defendant not engaged in the deceptive conduct described above, Plaintiff would not have purchased or paid for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, and would not have incurred related medical costs.

266. Defendant's 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 applicable to this action.

267. Defendant's actions, as complained of herein, constitute unfair competition or

unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of applicable state consumer protection statutes.

268. Defendant has engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of applicable state laws.

269. Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendant is the supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

270. Defendant violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, were fit to be used for the purpose for which they were intended, when in fact the drugs were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

271. The actions and omissions of Defendant alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

272. Defendant had actual knowledge of the defective and dangerous condition of the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products and failed to take any action to cure such defective and dangerous conditions.

273. Plaintiff and the medical community relied upon Defendant's misrepresentations and omissions in determining which products to use and prescribe.

274. Defendant's deceptive, unconscionable or fraudulent representations and material

omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

275. By reason of the unlawful acts engaged in by Defendant, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

276. As a direct and proximate result of Defendant's violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

NINTH CAUSE OF ACTION
Punitive Damages

277. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

278. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendant's intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendant's reckless disregard for the public safety and welfare. Defendant intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiffs, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Taxotere (docetaxel) products. Defendant intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of the Taxotere (docetaxel) products, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting the Taxotere (docetaxel) products, despite Defendant's knowledge and awareness of the serious side effects and risks associated with these products.

279. Defendant had knowledge of, and were in possession of evidence demonstrating that the Taxotere (docetaxel) products caused serious side effects. Notwithstanding Defendant's knowledge of the serious side effects of the Taxotere (docetaxel) products, Defendant continued to market the drug products by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the Taxotere (docetaxel) products.

280. Although Defendant knew or recklessly disregarded the fact that the Taxotere (docetaxel) products cause debilitating and permanent side effects, Defendant continued to market, promote, and distribute the Taxotere (docetaxel) products to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating breast cancer.

281. Defendant failed to provide warnings that would have dissuaded physicians from administering the Taxotere (docetaxel) products and consumers from purchasing and absorbing the Taxotere (docetaxel) products, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing or consuming the Taxotere (docetaxel) products.

282. Defendant knew of the Taxotere (docetaxel) products' defective nature as set forth herein, but continued to design, manufacturer, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff in a conscious or negligent disregard of the foreseeable harm caused by the Taxotere (docetaxel) products.

283. The aforementioned conduct of Defendant was committed with knowing, conscious, and deliberate disregard of the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in the amount appropriate to punish Defendant and deter

them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

TENTH CAUSE OF ACTION
Negligent Infliction of Emotional Distress

284. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

285. Plaintiff was present during the injuries that are caused or associated with the Taxotere (docetaxel) product(s).

286. As a result, Plaintiff suffered shock and severe emotional distress.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

ELEVENTH CAUSE OF ACTION
Loss of Consortium

287. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

288. Tina J. Stewart and Michael Stewart are husband and wife.

289. Plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

290. As a further result of the tortious conduct of the Defendant named herein, Michael Stewart suffered, and will continue to suffer for an indefinite time in the future, loss of services,

security, companionship, and consortium of his wife.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendant for damages, interest, costs of suit, and all other damages permissible under New Jersey law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper as follows:

1. Awarding actual damages to Plaintiffs incidental to her administration of Taxotere (docetaxel) in an amount to be determined at trial;

2. Awarding the costs of treatment for Plaintiff's injuries caused by Taxotere (docetaxel);

3. Awarding damages for Plaintiff's mental, physical, and economic pain and suffering;

4. Awarding damages for Plaintiff's mental and emotional anguish;

5. Awarding damages for loss of consortium;

6. Awarding pre-judgment and post-judgment interest;

7. Awarding punitive damages;

8. Awarding the costs and expenses of this litigation;

9. Awarding reasonable attorneys' fees and costs as provided by law;

10. For such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

The Plaintiffs demand trial by jury on all of the triable issues of this Complaint, pursuant to New Jersey Court Rules 1:8-2(b) and 4:35-1(a).

Dated: August 10, 2018

Respectfully submitted,

ROBINS KAPLAN LLP

By: /s/ Rayna E. Kessler
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**Pro hac vice motions to be filed*

DESIGNATION OF TRIAL COUNSEL

Pursuant to Rule 4:25-4, Rayna E. Kessler, Esq., is hereby designated as trial counsel for Plaintiffs.

/s/ Rayna E. Kessler
Rayna E. Kessler, Esq.

CERTIFICATION PURSUANT TO RULE 4:5-1

I certify that the dispute about which I am suing is not the subject of any other action pending in any other court or a pending arbitration proceeding to the best of my knowledge and belief. Also, to the best of my knowledge and belief no other action or arbitration proceeding is contemplated. Further, other than the parties set forth in this complaint, I know of no other parties that should be made a part of this lawsuit. In addition, I recognize my continuing obligation to file and serve on all parties and the court an amended certification if there is a change in the facts stated in this original certification.

/s/ Rayna E. Kessler
Rayna E. Kessler, Esq.

Dated: August 10, 2018

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-004822-18

Case Caption: STEWART TINA VS SANDOZ, INC.
Case Initiation Date: 08/10/2018
Attorney Name: RAYNA ELIZABETH KESSLER
Firm Name: ROBINS KAPLAN LLP
Address: 399 PARK AVENUE STE 3600
NEW YORK NY 10022
Phone:
Name of Party: PLAINTIFF : Stewart, Tina, J
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? YES

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

08/10/2018
Dated

/s/ RAYNA ELIZABETH KESSLER
Signed