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IN RE TAXOTERE LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION - MIDDLESEX COUNTY CASE TYPE: MCL NO. 628 MASTER DOCKET NO. MID-L-4998-18-CM **CIVIL ACTION** **IN RE TAXOTERE LITIGATION** **THIRD AMENDED MASTER LONG FORM COMPLAINT & JURY DEMAND**

Plaintiffs, by and through their Liaison Counsel, bring this Third Amended Master Long Form Complaint as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. Pursuant to this Court's December 14, 2018 Order, all allegations pled herein are deemed pled in any previously filed Complaint and any Short-Form Complaint hereafter filed. Accordingly, Plaintiffs allege as follows:

1. This Third Amended Master Complaint sets forth common allegations of Plaintiffs (hereinafter "Plaintiffs" and "Plaintiff" refer to the plaintiffs who were prescribed and ingested the pharmaceutical at issue) who were injured as a direct and proximate result of 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 were approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA").

2. These brand-name drug sponsors, manufacturers, labelers, and distributors—Defendants SANOFI S.A.; AVENTIS PHARMA S.A.; SANOFI U.S. SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS U.S. LLC, separately and doing business as WINTHROP U.S.; SANDOZ, INC.; HOSPIRA, INC.; HOSPIRA WORLDWIDE, LLC formerly known as HOSPIRA WORLDWIDE, INC.; ACCORD HEALTHCARE, INC.; MCKESSON CORPORATION doing business as MCKESSON PACKAGING; SUN PHARMA GLOBAL FZE; SUN PHARMACEUTICAL INDUSTRIES, INC. formerly known as CARACO PHARMACEUTICAL LABORATORIES, LTD.; ACTAVIS PHARMA, INC.; ACTAVIS LLC formerly known as ACTAVIS INC.; PFIZER INC.; and SAGENT PHARMACEUTICALS, INC. (collectively "Defendants") — designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold Taxotere. Defendants are liable to Plaintiffs for their

wrongful conduct causing damages and such other relief deemed just and proper.

3. This Third Amended Master Complaint is intended to achieve efficiency and economy by presenting certain common allegations and common questions of fact and law that generally pertain to Plaintiffs adopting this Complaint. Plaintiffs plead all Counts of this Third Amended Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable law and pursuant to choice of law principles, including the law of each Plaintiff's home state.

4. This Third Amended Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court. It is anticipated that individual Plaintiffs will adopt this Third Amended Master Complaint and selected causes of action herein through the use of a separate Short Form Complaint. Any individual facts, jurisdictional allegations, additional legal claims and/or requests for relief of individual Plaintiffs may be set forth as necessary in the Short Form Complaint filed by the respective Plaintiffs. This Third Amended Master Complaint does not constitute a waiver or dismissal of any claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery and trials proceed.

INTRODUCTION

5. Taxotere (docetaxel) is a chemotherapy drug administered to many who suffer primarily from breast cancer. Defendants, 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 by preventing the regrowth of hair, 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, Defendants hid this devastating side effect.

6. Plaintiffs are men and women who were diagnosed with breast cancer, underwent chemotherapy using Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and/or Docefrez, and now suffer from permanent hair loss, a side effect for which they were not warned and were wholly unprepared. Had these men, 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)).

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

8. Defendants failed to adequately warn that permanent or irreversible hair loss is a common side effect of Taxotere (docetaxel). As such, Plaintiffs were unable to weigh the devastating possibility of permanent hair loss when deciding among a variety of treatment options. Plaintiffs seek recovery for her mental and physical suffering stemming from permanent and

irreversible hair loss.

THE PARTIES

A. Plaintiff.

9. This Third Amended Master Complaint is filed on behalf of all Individual Injured Plaintiffs ("Plaintiff" and "Plaintiffs") whose claims are subsumed within MCL No. 628. Plaintiffs in these individual actions have suffered personal injuries as a result of the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez. Plaintiffs include men and women residing within and outside of New Jersey who have suffered personal injuries as a direct and proximate result of Defendants' 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 Injection, Docetaxel Injection Concentrate, and Docefrez.

10. The Plaintiffs also include, where applicable in this Third Amended Master Complaint, the Plaintiffs' spouses, children, parents, decedents, wards and/or heirs, as well as others with standing to file claims arising from the use of Taxotere (docetaxel).

11. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labelling, warning and sale of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

12. Plaintiffs file these lawsuits within the applicable statute of limitations period. Plaintiffs could not, by the exercise of reasonable diligence, have discovered their usage of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez resulted in their injuries. In fact, Defendants have yet to acknowledge that these drugs permanently prevent hair

regrowth, and Plaintiffs did not suspect, nor did they have reason to suspect that these drugs prevented hair regrowth or the tortious nature of the conduct causing their injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit. Consequently, the discovery rule applies to toll the running of the statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence should have discovered, that Plaintiff may have a basis of an actionable claim.

13. Additionally, Plaintiffs were prevented from discovering this information at an earlier date because: (1) Defendants misrepresented to the public and the medical profession that Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, are free from the permanent side effect claimed herein; (2) Defendants failed to disclose to the public and the medical profession their knowledge of the risk of this permanent side effect; and (3) Defendants fraudulently concealed facts and information that could have led Plaintiffs to discover the liability of the Defendants.

14. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the truth, quality, and nature of Plaintiff's injuries and the connection between the injuries and Defendants' tortious conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with Taxotere (docetaxel).

15. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with use of Taxotere (docetaxel) as this was non-public information over which Defendants had and continue to have exclusive control and because Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers, and/or Plaintiff's healthcare facilities. In addition, Defendants are estopped from relying on any statute of limitations

defense because of their concealment of the facts.

16. Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

B. Sanofi-Related Entities & Taxotere (Docetaxel).

17. Defendant Sanofi S.A. f/k/a Sanofi Aventis S.A. is the owner and operator of a multinational vertically integrated pharmaceutical company organized and existing under the laws of France with a principal place of business at 54 Rue La Boétie, 75008 Paris, France. Sanofi S.A. formed in 2004 after Sanofi-Synthélabo acquired Aventis Group, including subsidiary Defendant Aventis Pharma, S.A. Sanofi S.A. is engaged in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere. American Depositary Receipts for Sanofi SA are traded on the New York Stock Exchange. It is the only publicly traded company among the various Sanofi entities named as defendants in the case.

18. Defendant Aventis Pharma S.A. is a corporation organized and existing under the laws of France with a principal place of business at 20 Avenue Raymond Aron, 92160 Antony, France. Aventis Pharma S.A. is a wholly owned subsidiary of Defendant Sanofi S.A. Defendant Aventis Pharma S.A. is the owner/holder of the patents for Taxotere. Aventis Pharma S.A. previously sought to protect Taxotere patents by filing an action for patent infringement in the United States District Court for the District of Delaware and availing itself of United States law.

19. Upon information and belief, at the direction of Sanofi S.A., Defendant Aventis Pharma S.A. licensed the patents for Taxotere to Defendants Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC.

20. Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation,

with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi US Services Inc. engages in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere (docetaxel).

21. The predecessor to Sanofi US Services Inc. was founded in 1950 and until 2006, was known as Sanofi-Aventis US Inc.

22. Sanofi US Services Inc. develops, manufactures, markets, and distributes pharmaceutical products across the United States, including throughout the State of New Jersey.

23. Sanofi US Services Inc. operates a pharmaceutical research site in Bridgewater, New Jersey where, upon information and belief, important and relevant decisions and actions concerning, *inter alia*, the design, marketing, promotion, labelling and regulatory approval of Taxotere occurred.

24. Sanofi US Services Inc. markets its parent's products in the United States through its substantial number of field sales professionals, including throughout the State of New Jersey.

25. Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a wholly owned subsidiary of Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's sole member. Sanofi-Aventis U.S. LLC engages in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere (docetaxel).

26. Sanofi U.S. LLC is a healthcare company that was founded in 1999 and discovers, develops, produces, and markets therapeutic solutions focused on patients' needs in the United States, including throughout the State of New Jersey.

27. Upon information and belief, Sanofi-Aventis U.S. LLC is one of the current holders of the approved New Drug Application ("NDA") and supplemental NDAs for Taxotere.

28. Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S. operates, promotes, markets, sells, also distributes 505(b)(2) pharmaceutical products, including Taxotere equivalent drugs, under the name of Winthrop U.S., which is a business unit and/or division operating within and part of Sanofi-Aventis U.S. LLC. Winthrop U.S. is the generic arm of Sanofi-Aventis U.S. LLC. Winthrop U.S. is headquartered at Sanofi-Aventis U.S. LLC's 55 Corporate Drive, Bridgewater, NJ 08807 location. At all pertinent times, Sanofi remained in control of the content of the warnings and labeling of Winthrop US products.

29. Since 2006, Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market. Prior to 2006, Aventis Pharmaceuticals Inc. served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market until Aventis Pharmaceuticals Inc. merged with Sanofi S.A.

30. 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.

31. 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.

32. Sanofi S.A. is the alter ego of wholly owned subsidiary Defendants Aventis Pharma S.A., Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC; Sanofi S.A. is using these named

subsidiary Defendants as its agents; and/or Sanofi S.A. and the named subsidiary Defendants are one single integrated enterprise.

33. Defendant Sanofi S.A.'s Executive Vice-President of Pharmaceutical Operations in 2004, Hanspeter Spek, publicly stated in Sanofi S.A.'s Annual Report that the company was committed to growing its international presence by focusing on the United States, noting that "no pharmaceutical firm can call itself international unless it has achieved success and made its mark [in the United States]."

34. According to Mr. Spek, Defendant Sanofi S.A. was well-suited to handle the complexities of the U.S. pharmaceutical market, explaining:

> When you look at current trends in the U.S., you see a form of regionalization between different states beginning to emerge. That's a sign that the U.S. market is also becoming more complex in response to the country's economic constraints, pressure on prices, and so on. These are factors that we know and are used to dealing with; we have the experience and the knowhow to cope with them in all serenity.

35. In fact, Defendant Sanofi S.A. has provided the financial resources and human capital, installing "a management team made up of a perfect mix of U.S. and European talents" and controlling the operations of subsidiary Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. by providing financing, Sanofi S.A.'s unique manufacturing "know-how," direction of sales force, and management of operational risks to subsidiary Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc.

36. Defendant Sanofi S.A. represents itself as a global company with over 110,000 employees in more than 100 countries, including approximately 17,000 employees in the United States. Sanofi S.A. touts a global sales force of tens of thousands of representatives, noting that these sales representatives, including those in the United States, "embody the [Sanofi] Group's

values on a day-to-day basis."

37. In addition, Defendant Sanofi S.A. manages the cash surpluses of subsidiary Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., including controlling and transferring equity holdings among Sanofi S.A.'s subsidiaries. Sanofi S.A. includes the earnings of its subsidiaries in its annual reports, noting that 36.2% of its annual sales come from the United States.

38. Sanofi S.A. also represents that it has 17 manufacturing sites, 2 development centers, and 8 distribution hubs in the United States, including at least one in the State of New Jersey.

39. Furthermore, Defendant Sanofi S.A. formulates and coordinates the global strategy for Sanofi business and maintains central corporate policies regarding Sanofi subsidiaries, including subsidiary Defendants named herein, under the general guidance of the Sanofi group control. For example, Sanofi S.A. has a corporate tax policy overseen by Sanofi S.A.'s Tax Department.

40. Employees of Sanofi S.A. and its subsidiaries maintain reporting relationships that are not defined by legal, corporate relationships, but in fact cross corporate lines. For example, the U.S. heads of Human Resources, Communications, and Public Affairs are not affiliated with any specific U.S. subsidiary but serve as heads of Sanofi's North American organizations, overseeing strategies and activities for the entire North American region. For Human Resources specifically, Defendant Sanofi S.A. has adopted the "One Sanofi, One HR" concept to harmonize and align human resources practices across of Sanofi S.A.'s business activities, blurring corporate lines. In 2013, Sanofi S.A. launched the Short-Term Work Assignment Program ("SWAP"), an employee exchange program that features six-month job exchanges between Sanofi employees in mature and

emerging markets.

41. Defendant Sanofi S.A. has a number of policies for employee benefits and salaries that cross corporate lines. In 2001, Sanofi launched the "essential protection" project. This project provided all employees, across corporate lines, with coverage against unexpected events: illness, death benefit, and short and long-term disability. This project also provided for compulsory pensions for all employees. Sanofi S.A. also has a compensation policy that all Sanofi subsidiaries have to follow. This policy aims to offer all employees in all subsidiaries compensation that is superior to the average salary for the pharmaceutical market. Each subsidiary's employee benefits and salary program are subject to a preliminary approval procedure by Sanofi S.A. This means that Sanofi S.A. dictates the salary levels and benefits that must be paid to employees of its subsidiaries. Defendant Sanofi S.A. also controls research and development activities for Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. by defining priorities, coordinating work, and obtaining the industrial property rights under Sanofi S.A.'s name and at Sanofi S.A.'s own expense. As mentioned above, Sanofi has a global Research & Development organization that works closely with Sanofi's Senior Leadership Team.

42. On November 6, 2015, Sanofi S.A. CEO Oliver Brandicourt presented a "strategic roadmap," a plan to restructure the company and simplify the organizational structure. Before the restructuring, Research & Development, Industrial Affairs, Finance, Human Resources, Business Development & Strategy, External Affairs, Information Systems, Medical, Legal, Compliance, & Procurement were globalized functions. After the restructuring, Sanofi S.A. introduced plans to move further to a Global Business Unit organization and divide its products into five globalized units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Specialty Care, Vaccines, and Animal Health. The restructuring additionally included plans to reshape Sanofi's

global network of manufacturing plants. As a result of the restructuring Sanofi S.A. announced it would be cutting about 20 percent of its U.S. staff from its diabetes and cardiovascular unit alone with more U.S. staff cuts likely to come in the future.

43. Defendants 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, including in the State of New Jersey, by providing marketing information regarding Taxotere to health care providers and similarly soliciting purchases for the drug.

44. Defendants Sanofi S.A. and Aventis Pharma S.A. expected that Taxotere would be sold, purchased, and used throughout the United States, including in the State of New Jersey. In fact, Defendants Sanofi S.A. and Aventis Pharma S.A., through Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., distributed and sold Taxotere to healthcare providers and patients throughout the United States, including in the State of New Jersey.

45. At all times relevant hereto, Defendants Sanofi S.A., Aventis Pharma S.A., and/or Sanofi-Aventis U.S. LLC were engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Sanofi S.A., Aventis Pharma S.A., and/or Sanofi-Aventis U.S. LLC were involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians and healthcare providers.

C. Other Brand Name Drug Sponsors, Manufacturers, Labelers, and Distributors.

46. 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).

47. 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.

48. 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.

49. 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.

50. 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).

1. Sandoz

51. 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.

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

53. 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.

54. 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.

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

56. Defendant Sandoz expected that Docetaxel Injection would be sold, purchased, and used throughout the United States, including in the State of New Jersey.

57. 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.

58. 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.

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

60. 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.

61. 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.

62. 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."

63. 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."

64. There is no mention of the risk of permanent or irreversible hair loss, however, in the Warnings and Precautions or Adverse Reactions portions of Sandoz's labeling of its docetaxel products.

65. At all times relevant hereto, Defendants Sandoz was engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally

disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Sandoz was involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians and healthcare providers.

2. Hospira Entities

66. Defendant Hospira, Inc. is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

67. Defendant Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc. is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

68. Defendants Hospira, Inc. and Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc. (collectively "Hospira") have transacted and conducted business throughout the United States, including the State of New Jersey.

69. Hospira 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.

70. At all relevant times, Hospira has been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #022234. Hospira expected that Docetaxel Injection would be sold, purchased, and used throughout the United States, including the State of Colorado.

71. Hospira filed NDA #022234 on July 11, 2007 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.

72. Hospira's formulation, however, is different from Taxotere's formulation in several ways. First, upon the filing of its NDA in 2007, its pre-mixed, one-vial solution differed from Taxotere's original two-vial formulation, which required initial dilution. (Taxotere's one-vial, "ready-to-use" formulation was not FDA approved until 2010.) Second, it is packaged at a concentration of 10 mg / mL, which is one-fourth of the strength of two-vial Taxotere and one-half the strength of one-vial Taxotere. Third, Hospira's 10 mg / mL formulation was marketed in a 160 mg vial, in addition to 20 mg and 80 mg vials. Fourth, whereas Taxotere labels all its dosage forms as "single-use," Hospira's 80 mg and 160 mg formulations are marketed as "multi-use." Fifth, unlike Taxotere, Hospira's Docetaxel Injection contains both citric acid and polyethylene glycol 300.

73. Hospira received FDA approval for NDA #022234 on March 8, 2011 and began marketing the drug in the United States on March 17, 2011.

74. 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.

75. On September 11, 2013, Hospira submitted a "Prior Approval" sNDA (S-003) adding certain indications consistent with Taxotere's package insert at the time. Hospira also included in this sNDA new safety information concerning ethanol intoxication, which the FDA had requested Hospira add by letter of April 21, 2014. The FDA approved this sNDA on July 10, 2014. This update did not concern hair loss.

76. There is no mention of the risk of permanent or irreversible hair loss in Hospira's labeling of its docetaxel products.

77. At all times relevant hereto, Defendant Hospira was engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Hospira was involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians and healthcare providers.

3. Accord Healthcare & McKesson

78. Defendant Accord Healthcare, Inc. ("Accord") is a pharmaceutical company organized and existing under the laws of the State of North Carolina with a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

79. Defendant McKesson Corporation d/b/a McKesson Packaging ("McKesson") is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at One Post Street, San Francisco, California 94104.

80. Defendants Accord and McKesson have transacted and conducted business throughout the United States, including in the State of New Jersey.

81. Accord and McKesson have derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States as well as the State of New Jersey.

82. At all relevant times, Accord has been in the business of designing, testing,

manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #201195. Accord expected that Docetaxel Injection would be sold, purchased, and used throughout the United States, including in the State of New Jersey.

83. At all relevant times, McKesson has been in the business of packaging and distributing Docetaxel Injection approved by the FDA under NDA #201195. McKesson expected that Docetaxel Injection would be sold, purchased, and used throughout the United States, including in the State of New Jersey.

84. Accord filed NDA #201195 on December 7, 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.

85. Accord's two-vial formulation, however, was different from Taxotere's two-vial formulation in that it added new excipients citric acid (as a pH adjusting agent) and polyethylene glycol (PEG 400) (added to the diluent vial at 13 percent w/v). A one-vial formulation by Accord was later added in the same concentration and doses as the one-vial Taxotere, with the addition of a 160 mg / 8 mL "multiple dose" form.

86. Accord received FDA approval for NDA #201195 on June 8, 2011 and began marketing the drug in the United States on August 15, 2011.

87. 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 statement refers to permanent hair loss.

88. On November 14, 2013, Accord submitted a CBE sNDA (S-006) that was unrelated

to hair loss. It was approved on July 3, 2014. Prior to that, Accord had also submitted a Manufacturing sNDA (S-004) that, upon information and belief, resulted in various labeling changes on or before April 5, 2013, which did not relate to hair loss.

89. Accord submitted a CBE sNDA (S-009) that was approved on July 26, 2016. As a result, the current label states that "[c]ases of permanent alopecia have been reported." Patient Counseling Information directs: "Explain to patients that side effects such as [...] hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." The Patient Information section now reads, in part: "The most common side effects of Docetaxel Injection include [...] hair loss, in most cases normal hair growth should return. In some cases (frequency not known), permanent hair loss has been observed."

90. There is no mention of the risk of permanent or irreversible hair loss, however, in the Warnings and Precautions or Adverse Reactions portions of Accord's and McKesson's labeling of their docetaxel products.

91. At all times relevant hereto, Defendants Accord and McKesson were engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Accord and McKesson were involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians and healthcare providers.

4. Sun Pharma Entities

92. Sun Pharma Global FZE ("Sun Pharma Global") is a pharmaceutical company

organized and existing under the laws of the Emirate of Sharjah with a principal place of business at Executive Suite #43, Block &, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

93. Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. ("Sun Pharma") is a pharmaceutical company organized and existing under the laws of New Jersey with a principal mailing address of 270 Prospect Plains Road Cranbury, NJ 08512 United States.

94. Sun Pharma Global has transacted and conducted business throughout the United States, on its own behalf and through its agent and distributor Sun Pharma.

95. Sun Pharma Global and Sun Pharma have derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States, including in the State of New Jersey.

96. At all relevant times, Sun Pharma Global and Sun Pharma have been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docefrez, approved by the FDA under NDA #022534. Sun Pharma Global and Sun Pharma expected that Docefrez would be sold, purchased, and used throughout the United States, including in the State of New Jersey.

97. Sun Pharma Global filed NDA #022534 on April 23, 2009 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.

98. Sun Pharma Global's two-vial docetaxel formulation, however, is different from Taxotere's two-vial formulation for several reasons. First, as opposed to Taxotere's active ingredient vial, which solution is viscous, Sun Pharma Global's active ingredient vial contains a powder. Second, and relatedly, Sun Pharma Global's polysorbate 80 is found in the diluent vial. Third, Sun Pharma Global's diluent vial contains a higher percentage of ethanol (35.4 percent)

than Taxotere's (13 percent). Fourth, Sun Pharma Global's concentration is two times that of the two-vial Taxotere.

99. Sun Pharma Global received FDA approval for NDA #022534 on May 3, 2011 and began marketing the drug in the United States in May 2011.

100. 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" the drug is "hair loss." Neither of these statements refer to permanent hair loss.

101. Sun Pharma Global submitted, through its agent Sun Pharma, a CBE sNDA (S-002) to the FDA on July 28, 2011, for a label change that was approved on July 13, 2012. It also submitted a "Prior Approval" sNDA (S-004) for a label change through its agent Sun Pharma on May 22, 2014, which was approved on October 30, 2014. Neither change related to hair loss.

102. Sun Pharma Global and Sun Pharma ceased marketing Docefrez in November 2015, and at no time has the labeling for Docefrez referred to permanent or irreversible hair loss.

103. There is no mention of the risk of permanent or irreversible hair loss in the Sun Pharma Entities' labeling of their docetaxel products.

104. At all times relevant hereto, Defendants Sun Pharma Entities were engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Sun Pharma Entities were involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription

drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians and healthcare providers.

5. Pfizer

105. Pfizer Inc. ("Pfizer") is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 235 E 42nd Street, New York, New York 10017.

106. Pfizer has transacted and conducted business throughout the United States, including in the State of New Jersey.

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

108. At all relevant times, Pfizer has been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #202356. Pfizer expected that its Docetaxel Injection would be sold, purchased, and used throughout the United States, including in the State of New Jersey.

109. Pfizer filed NDA #202356 on September 13, 2013, 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.

110. Pfizer's one-vial formulation, however, was different from Taxotere's one-vial formulation in that it added 130 mg / 13 mL and 200 mg / 20 mL dosage forms. Further, ethanol and propylene glycol were added as excipients in amounts greater than in Taxotere.

111. Pfizer received FDA approval for NDA #202356 on March 13, 2014 and began marketing the drug in the United States on June 23, 2014.

112. 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" the drug is "hair loss." Neither of these statements refer to permanent hair loss.

113. Pfizer stopped marketing the 200 mg / 20 mL dosing of its Docetaxel Injection on October 31, 2016. In addition, Pfizer stopped marketing the 20 mg / 2 mL dosing and the 80 mg / 8 L dosing of its Docetaxel Injection on December 31, 2016.

114. Upon information and belief, Pfizer continues to market the 130 mg / 13 mL dosing of its Docetaxel Injection.

115. There is no mention of the risk of permanent or irreversible hair loss in Pfizer's labeling of its docetaxel products.

116. At all times relevant hereto, Defendant Pfizer was engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Pfizer was involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians and healthcare providers.

6. Actavis Entities

117. Actavis Inc., now known as Actavis LLC, is a pharmaceutical limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960 and 400 Interpace

Parkway, Parsippany, New Jersey 07054.

118. Defendant Actavis Pharma Inc. is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. In 2016, Teva Pharmaceutical Industries, Ltd. acquired Defendant Actavis Pharma Inc. Prior to 2016, Actavis Pharma Inc. was a wholly owned subsidiary of Defendant Actavis LLC f/k/a Actavis Inc.

119. Defendant Sagent Pharmaceuticals, Inc. ("Sagent") is incorporated under the laws of Delaware and maintains a principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, IL 60195.

120. Defendants Actavis LLC f/k/a Actavis Inc. and Actavis Pharma Inc. (collectively "Actavis") and Sagent transacted and conducted business throughout the United States, including in the State of New Jersey.

121. Actavis and Sagent derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States, including in the State of New Jersey.

122. At all relevant times, Actavis and Sagent were in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection Concentrate approved by the FDA under NDA #203551. Actavis and Sagent expected that Docetaxel Injection Concentrate would be sold, purchased, and used throughout the United States, including in the State of New Jersey.

123. Actavis filed NDA #203551 on March 14, 2012 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.

124. Actavis and Sagent's one-vial formulation, however, was different from Taxotere's one-vial formulation because it is offered at an additional 140 mg dosage form, contains excipients citric acid and Kollidor 12 PF (Povidone k12), and uses reduced levels of polysorbate 80. After Actavis' initial docetaxel approval, a 160 mg dosage form was also introduced.

125. Actavis received FDA approval for NDA #203551 on April 12, 2013 and began marketing these dosage forms on July 1, 2013.

126. 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" the drug is "hair loss." Neither of these statements refer to permanent hair loss.

127. Actavis submitted a CBE sNDA (S-001) on May 14, 2013, which was approved on November 4, 2013. Actavis also submitted a "Prior Approval" sNDA (S-002) on March 21, 2014, which was approved on September 17, 2014. Neither resulting label change related to hair loss.

128. There is no mention of the risk of permanent or irreversible hair loss in the Actavis Entities' and Sagent's labeling of their docetaxel products.

129. At all times relevant hereto, Defendants Actavis Entities and Sagent were engaged in, and intentionally and deliberately conducted, substantial transactions and business within the State of New Jersey and have derived substantial revenue from goods and products knowingly and intentionally disseminated and used in the State of New Jersey. At all times relevant hereto, as part of its business, Activis Entities and Sagent were involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiffs and Plaintiffs' physicians

and healthcare providers.

D. John Doe Defendants #1-10.

130. On information and belief, John Doe Drug Company Defendants #1-10, whose specific identities are currently unknown to Plaintiffs, are the individuals, business entities, and corporations within the chain of commerce, that manufactured the Taxotere (docetaxel) products for marketing, sale and distribution to Plaintiffs and other members of the American consuming public. The pseudonymous designations are being used to preserve claims against these parties who will be named more fully if and when their identities are uncovered.

E. All Defendants.

131. The term "Defendants" is used hereafter to refer to all the entities named above.

132. Defendants are corporations organized under the laws of various states of the United States of America that were or are doing business within the State of New Jersey. The aforementioned Defendants designed, marketed, sold, distributed, packaged, promoted, labeled, researched, tested or manufactured the Taxotere (docetaxel) product(s) which were administered to Plaintiffs.

133. At all times relevant to this action, all Defendants and each of them were in the capacity of the principal or agent of all of the other Defendants, and each of them, and acted within the scope of their principal and agent relationships in undertaking their actions, conduct, and omissions alleged in this Complaint. All Defendants, and each of them, acted together in concert or aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of reaping substantial monetary profits from the sale of the Taxotere (docetaxel) products and for the purpose of enriching themselves financially to the serious detriment of Plaintiff's health and well-being. At all times alleged herein, Defendants include and

included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

134. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

135. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

136. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, which necessarily includes New Jersey, directly or indirectly through partners, servants, subsidiaries or related entities acting in concert, the drug Taxotere.

JURISDICTION AND VENUE

137. At all times relevant to this action, the Defendants have 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.

138. At all times relevant to this action, the Defendants have 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.

139. At all times relevant to this action, the Defendants have 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.

140. At all times relevant to this action, the Defendants were 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.

141. Defendant Sanofi US Services Inc. is a resident of New Jersey because its principal place of business is in the state.

142. Defendant Sanofi-Aventis U.S. LLC is a resident of New Jersey because its principal place of business is in the state.

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

144. Defendant Actavis LLC f/k/a Actavis, Inc. is a resident of New Jersey because its principal place of business is in the state.

145. Defendant Actavis Pharma, Inc. is a resident of New Jersey because its principal place of business is in the state.

146. Venue is proper in the State of New Jersey pursuant to Rule 4:3-2 because the Defendants are regularly conducting and doing substantial business throughout the State of New Jersey, including the sale, marketing, promotion and distribution of the Taxotere (docetaxel) products relevant to this action.

147. Venue is proper in Middlesex County as on July 17, 2018 this matter was designated as multicounty litigation ("MCL") for centralized management purposes pursuant to R. 4:38A.

148. Filing any individual matter in Middlesex County does not constitute a waiver of plaintiffs' rights to return such cases to the original county of venue for disposition, pursuant to the July 17, 2018 New Jersey Supreme Court Order.

FACTUAL BACKGROUND

149. Plaintiffs were administered Taxotere (docetaxel) that had been designed, developed, manufactured, sold, distributed, labelled, packaged, promoted, advertised, marketed, tested, and otherwise produced by Defendants.

150. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' 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).

151. Plaintiffs file this lawsuit within the applicable statute of limitations period of first suspecting that these drugs made by these particular Defendants caused the appreciable harm s/he 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 s/he have reason to suspect that she had been injured, the cause of his/her

injuries, or the tortious nature of the conduct causing his/her injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

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

153. Defendants failed to warn Plaintiffs of these injuries. Neither Defendants nor the healthcare providers who administered Taxotere (docetaxel) to Plaintiffs had informed him/her that hair loss would be permanent. To the contrary, Defendants had made representations, assertions, suggestions, and/or warnings that any hair loss suffered would be temporary in nature.

154. Plaintiffs believed Defendants' representations that the hair loss, if any, was temporary.

155. Plaintiffs would not have used Taxotere (docetaxel) had the Defendants properly disclosed the risks associated with its use.

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

156. 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.

157. 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.

158. 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).

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

160. 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.

161. 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.

162. 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.

163. 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.

164. 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.

165. 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.

166. 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.

167. 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.

168. The label approved for Taxotere for this indication reflected the medical community's understanding that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent alopecia.

169. In fact, the clinical trial sponsored by Sanofi to support initial approval did not evaluate alopecia as a long-term side-effect of Taxotere.

170. 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.

171. 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."

172. 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."

173. 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.

174. 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."

175. 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."

176. 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."

177. 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."

178. 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.

179. 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." Additional changes to this label included a number of edits described by Sanofi as "housekeeping" that, among other things, deleted the phrase "hair generally grows back" and added "most common side effects of TAXOTERE include: [...] hair loss" to the "Patient Information" section of the label. As with previous labels, the May 2010 label provides no information about irreversible or permanent hair loss.

180. On March 5, 2015, Sanofi conducted an audit of its U.S. product labels, finding that the U.S. label for Taxotere did not include the required safety information, including information about persisting alopecia. Sanofi determined this information should have been added to the U.S. label in 2011.

181. Shortly thereafter, on March 23, 2015, FDA requested information from Sanofi regarding instances of permanent alopecia. On April 8, 2015, Sanofi issued its response to FDA identifying that out of 2118 cases of reported alopecia from Taxotere patients, 89 (4.2%) appeared to be permanent.

182. In response, FDA requested on October 5, 2015 that Sanofi provide any additional information on permanent or irreversible alopecia and amend the Taxotere label to identify permanent alopecia in the "Adverse Reactions" section of the label.

183. On November 11, 2015, Sanofi issued a Final Clinical Overview of Permanent Alopecia, finding a causal association between Taxotere and permanent alopecia. Sanofi then submitted a CBE sNDA on November 24, 2015 adding the language "cases of permanent alopecia have been reported" to the "Adverse Reactions" and "Patient Counseling Information" sections of the label. Sanofi also made changes to the "Patient Information" section of the label adding 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 FDA approved Sanofi's sNDA on December 11, 2015.

184. On April 11, 2018, Sanofi submitted a Prior Approval sNDA, request that that the Taxotere label be updated to identify adverse events occurring at the conclusion of the follow-up period in TAX 316 in 2010. Among the adverse events identified by Sanofi included 29 patients who had alopecia ongoing at a median follow-up of 10-years. FDA approved Sanofi's proposed label change on October 5, 2018.[1]

II. Defendants' Duties Under the FDCA and State Law.

185. 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.

186. 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.

187. 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

[1] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/020449Orig1s079ltr.pdf

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.

188. 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.

189. 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).

190. 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).

191. 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).

192. 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.

193. 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.

194. 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.

III. Defendants Knew That Taxotere (docetaxel) May Cause Permanent Alopecia.

195. In 1997, Sanofi initiated TAX 316, a self-sponsored clinical trial comparing the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC") with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC") in patients with operable node-positive breast cancer. A total of 1040 patients from 112 centers participated in TAX 316 with 744 patients receiving TAC and 736 receiving FAC. In 2004, an interim analysis of TAX 316's 55-month median follow-up data demonstrated that 3.2% of patients who took Taxotere had persistent alopecia.

196. 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.

197. In March 2006, Sanofi's pharmacovigilance department received an inquiry from a physician about the reversibility of alopecia following Taxotere treatment, noting that a patient had been experiencing alopecia since 2004. In response, Sanofi's Global Safety Officer for

Taxotere internally acknowledged that cases of irreversible alopecia had occurred during Sanofi's clinical trials for Taxotere and that the medical literature might contain additional reports of irreversible alopecia. Despite this, Sanofi's Global Safety Officer advised against doing a literature search on the topic of irreversible alopecia and Taxotere. In addition, Sanofi withheld this information from the Taxotere label and concealed it from the medical community and consumers, including Plaintiffs.

198. 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."

199. 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."

200. 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."

201. By early 2010, Sanofi had received reports from hundreds of women describing their permanent hair loss following treatment with Taxotere. Despite this fact, Sanofi withheld this information from the label and concealed it from the medical community and consumers, including Plaintiffs.

202. On March 5, 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."

203. 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."

204. 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."

205. 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."

206. 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."

207. Later in 2010, Sanofi completed its analysis of the ten-year follow-up results for TAX 316, the clinical trial used to support the adjuvant breast cancer indication. This analysis

found that the number of women reporting persisting hair loss had increased from the 22 patients reported in 2004 to 29 patients out of the 687 patients tracked into follow-up. This represented an increase in the incidence of persistent alopecia from approximately 3% to 4.2%. Sanofi had previously decided in 2009 not to update the U.S. label with the follow-up data from TAX 316. Instead, Sanofi submitted to the FDA only the Final Clinical Study Report for TAX 316, which is over a thousand pages long, without submitting a labeling change. In addition, Sanofi continued to conceal this information from the medical community and consumers, including Plaintiffs.

208. In March of 2011, the French Health Authorities responded to Sanofi's overview of persisting alopecia, concluding that patients and healthcare providers should be provided information about the risk of permanent alopecia given the serious psychological consequences of this adverse effect.

209. The following month, Sanofi's Compliance Department issued an internal audit of drug labeling for various drug products, including Taxotere, to evaluate the accuracy and completeness of the safety data presented in the drug labeling For Taxotere, the audit revealed that the labeling failed to include the incidence rate of persistent alopecia from TAX 316. Sanofi did not add this information to the label until 2018.

210. In June of 2011, the European Medicines Agency adopted the consensus of the French Health Authorities regarding persistent alopecia, informing Sanofi that the label for Taxotere needed to be updated to inform patients of the risk of irreversible alopecia. Sanofi updated the Taxotere label distributed in the European Union but did not update the label in the United States. Instead, Sanofi continued to conceal this information from the medical community and consumers in the United States, including Plaintiffs.

211. Also 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 ... ."

212. 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."

213. 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."

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

Symposium.

215. 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.

216. 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.

217. 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.

218. Likewise, in a self-sponsored clinical trial, the informed consent form provided by Sanofi to Canadian patients disclosed irreversible alopecia as a possible side effect but a similar

informed consent form provided to United States patients in 2006 and 2007 did not. Again, Sanofi concealed this information from patients in the United States.

219. 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.

220. 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.

221. 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)."

222. 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."

223. 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."

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

225. On December 11, 2015, FDA approved the CBE. Under the "Adverse Reactions"

and "Patient Counseling Information" sections of the label, Sanofi added the language that "cases of permanent hair loss have been reported." In the "Patient Information" section, Sanofi added 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."

226. On April 11, 2018, Sanofi submitted a Prior Approval sNDA, request that the Taxotere label be updated to identify adverse events occurring at the conclusion of the follow-up period in TAX 316 in 2010. Among the adverse events identified by Sanofi included alopecia still ongoing at median follow-up of 8-years. FDA approved Sanofi's proposed label change on October 5, 2018.

227. Upon information and belief, Defendants failed to comply with the FDA post marketing 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 Defendants, failing to promptly investigate all adverse drug experiences concerning these drug products that are the subject of these post marketing 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.

228. Also, consistent with the Changes Being Effected regulations, Defendants had and continue 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, Defendants have 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.

229. 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.

230. 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.

231. 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.

232. 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.

233. 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.

234. 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.

235. 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.

236. Unlike the temporary and reversible alopecia that ordinarily results from chemotherapy, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate cause Permanent Chemotherapy Induced Alopecia

237. There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed "persistent" six months beyond the completion of chemotherapy.

238. Sanofi has stated in court filings that "persistent" alopecia generally describes hair loss for some duration of time following chemotherapy (e.g., 3 days, 30 days, 3 months, 6 months, etc.) and carries with it the potential for hair regrowth to occur.

239. Sanofi has also stated in court filings that "irreversible" or "permanent" alopecia, at a basic level means that an individual's hair will never regrow.

240. Before this litigation and after, Sanofi has described Permanent Chemotherapy Induced Alopecia in a number of different ways. Employees of Sanofi have testified that permanent hair loss does not necessarily mean hair loss of six months. In 2010, Sanofi's Global Safety Officer concluded it was reasonable to assume that chemotherapy induced alopecia is "permanent" if alopecia persists for longer than four years following chemotherapy treatment. Consistent with that conclusion, in August of 2018, Sanofi's Global Safety Officer stated that it is reasonable to consider alopecia to be permanent if hair has not regrown for four years after chemotherapy. Nevertheless, in 2015, Sanofi's Global Safety Officer utilized a two-year cut off for deciding that chemotherapy induced alopecia is "permanent." Internal email correspondence indicates that the company chose a two-year cut off in order to underreport to the FDA the incidence of permanent hair loss.

241. Upon information and belief, the varying definitions of Permanent Chemotherapy Induced Alopecia, as described above, were not reasonably knowable to prescribers or consumers of Taxotere, including Plaintiffs.

242. 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.

243. 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.

244. 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.

245. 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 patients, 6.3 percent suffered permanent alopecia with hair regrowth of less than 50 percent of the amount before chemotherapy.

246. 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.

247. 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.

248. 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.

249. 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."

250. 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."

251. Because NDA holders and their assigns or agents are held to the knowledge of an expert in the field concerning the products they sell, Defendants 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.

252. 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**

253. 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.

254. 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.

255. 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.

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

257. 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.

258. 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.

259. 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.

260. 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."

261. 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."

262. 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.

263. 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.

264. 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.

265. 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.

266. 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.

267. 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."

268. 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.

269. 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.

270. 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"

271. 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.

272. 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.

273. 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.

274. 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.

275. The Defendants chose to withhold the risk of permanent alopecia information from the U.S. market despite informing physicians, patients, and regulatory agencies in other countries, including, but not limited to, the European Union and Canada, that Taxotere caused an increased risk of permanent and disfiguring alopecia.

276. Defendants' fraudulent conduct caused thousands of individuals to be exposed to more frequent and/or more severe side effects, including but not limited to disfiguring and permanent alopecia (hair loss).

277. Taxotere consumers were not given the opportunity to make an informed decision because they were unable to perform a risk benefit analysis due to the systematic and continuous deception perpetrated by the Defendants by overstating and/or misrepresenting the benefits and failing to warn of the true risks of permanent and disfiguring alopecia while other less potent but equally effective alternatives were available.

278. It is notable that the Defendants published information in other countries to individual patients, as well as regulatory agencies, informing patients of a risk of permanent alopecia relating to Taxotere use, however despite the numerous U.S. label changes and safety warnings issued by the Defendants during the nearly two decades Taxotere has been on the U.S. market, the words "permanent alopecia" or "permanent hair loss" did not appear in any published information from the Defendants.

279. As a direct result of Defendants' surreptitious acts and deceptive marketing, thousands of women were exposed to the risk of and sustained disfiguring and permanent alopecia without any warning, and without any additional benefit.

280. The Defendants' failure to warn patients healthcare providers, physicians, and

patients, including Plaintiff, of the true risk of disfiguring and permanent alopecia in the U.S. deprived them of the chance to make an informed decision as to exposing oneself to Taxotere (docetaxel) when other comparably effective and less toxic products were available.

281. Defendants took advantage of vulnerable groups of individuals during one of the most difficult times of their lives and made billions of dollars in increased revenues at the expense of unwary cancer victims who wanted a chance at a normal life again.

VI. Sanofi Actively Sought to Hide that Taxotere Could Cause Permanent Hair Loss.

282. Sanofi's marketing efforts also affirmatively sought to minimize any association between Taxotere and permanent alopecia.

283. According to Sanofi's Global Safety Officer for Taxotere, Sanofi knew that Taxotere could cause permanent hair loss in 2006. Despite this, Sanofi created and published in 2006 an information brochure for oncology nurses that described alopecia as "a common, yet temporary, side effect of some cancer medicines" and provided no information regarding the risk of permanent alopecia associated with Taxotere.

284. In addition, in 2010, Sanofi began proactively removing any comments about permanent alopecia from its Facebook page titled "Voices," which Sanofi sponsored for the alleged purpose of "mak[ing] Voices heard throughout the community on issues of importance to patients..."

285. Sanofi began this practice after it observed posts from women about permanent alopecia following a March 5, 2010 article in the Globe and Mail, which described instances of permanent hair loss among Taxotere patients. In response, Sanofi's communications department formed a Rapid Response Team, and among its responsibilities included monitoring Sanofi's Voices Facebook page at all times to remove any posts about Taxotere and permanent hair loss.

286. Sanofi shortly thereafter hired an outside company, InTouch Solutions, to conduct this around-the-clock monitoring of its Facebook page. At Sanofi's direction, InTouch logged and removed posts about permanent hair loss, blocked the user posting about it, and reported the user to Facebook to have her banned from the platform.

287. For example, one Facebook user posted on Sanofi's page the following: "When will you inform oncologists that there is a problem with your chemo drug, Taxotere? Why don't you want women to know they could be left permanently disfigured? Because they will choose a different drug not made by you. The net is closing in on you, Sanofi." At Sanofi's direction, InTouch Solutions removed the post within an hour, blocked the user from posting on the page, and reported the user to Facebook.

288. Another user posted, "My medical team have spoken to you, and therefore I have been informed that YOUR DRUG Taxotere has done this to me. Why do you ignore me and REFUSE to contact me? Why don't you explain to me why your drug Taxotere has permanently disfigured me and hundreds of others?" InTouch Solutions removed the post within an hour and reported the user to Facebook. The same user posted 28 more times, and at Sanofi's direction, InTouch Solutions removed the post from Facebook and had the woman permanently banned from the page.

289. A different user posted "I did say I wouldn't stop until there was global publicity. You can't shut up women that you disfigure." Her post was removed by InTouch Solutions within an hour.

290. After successfully scrubbing mention of permanent hair loss from Sanofi's Voices Facebook page, InTouch Solutions created a presentation to market its services to other drug companies, and it used the "crisis management" services it provided to Sanofi as a case study of

what it could accomplish for its clients.

291. As a result of Sanofi's fraudulent concealment of the association between Taxotere and Permanent Chemotherapy Induced Alopecia, the medical community and patients, including Plaintiffs, were deprived of adequate information about the drug. Consequently, Plaintiffs were unaware of the connection between their use of Taxotere and their injury of permanent hair loss.

VII. Permanent Alopecia is Devastating for Plaintiff.

292. 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.

293. 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.

294. 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.

295. 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.

296. 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.

297. 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.

298. 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

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

300. The Plaintiffs were administered Taxotere (docetaxel) or were injured as a result of Taxotere (docetaxel). To the extent the Court chooses to apply the law of a state other than New Jersey, Plaintiffs are placing Defendants on notice of all claims which may be asserted by the

individual Plaintiff from other states and jurisdictions in addition to New Jersey as set forth in their Short Form Complaint.

FIRST CAUSE OF ACTION

Strict Products Liability – Failure to Warn Under New Jersey Products Liability Act

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

302. At all relevant times, Defendants were 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.

303. At all times relevant herein, Defendants placed the Product at Issue (Taxotere/docetaxel) into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for their intended purpose. Insofar as Taxotere could not be used safely without the unreasonable risk of harm, Taxotere was ineffective for the purpose for which its use was promoted.

304. The Plaintiffs bring this claim under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq.

305. 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 Defendants failed to provide adequate warnings to users and their healthcare providers, including Plaintiffs and Plaintiffs' 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.

306. As the holder of the Referenced Listed Drug ("RLD") for Taxotere, Sanofi supplied the labeling for Winthrop US's version of Taxotere.

307. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

308. 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 Defendants and ultimately administered to Plaintiffs lacked such warnings when it left Defendants' control.

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

310. Defendants were aware that consumers, including Plaintiffs or Plaintiffs' physicians, would use the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products in the manner directed by the package insert; which is to say that Plaintiffs or Plaintiffs' Decedents were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

311. Plaintiffs and/or their physicians were at all relevant times in privity with Defendants.

312. The Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products was expected to reach and did in fact reach consumers, including Plaintiffs

or Plaintiffs' physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

313. Defendants' products are designed in such a way that, when used as intended, the defective product causes serious, permanent, and devastating damage to patients in whom the product is used. Defendants acted unreasonably in its design of the product in that Defendants failed to adopt a safer design for the product that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

314. Defendants' products do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

315. The risks of Defendants' products outweigh the benefits of using the products.

316. There were numerous safer alternative designs to the products which in reasonable probability would have prevented or significantly reduced the risk of the personal injuries suffered by Plaintiffs herein without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the products left the control of Defendants by the application of existing or reasonably-achievable scientific knowledge. Any warnings actually provided by Defendants 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.

317. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the risks and benefits of the Defendants' Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate, given the Plaintiffs' conditions and need for information.

318. 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.

319. The Defendants intentionally, recklessly, and/or maliciously misrepresented the safety, risks and benefits of the Defendants' Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

320. Plaintiffs were reasonably foreseeable users of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate who used the drug in reasonably anticipated manners. Plaintiffs did not misuse the product.

321. Plaintiffs would not have used Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had s/he (and the treating Physicians) been provided an adequate warning by Defendants of the risk of these side effects.

322. Further, Defendants 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.

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

324. As a purchaser or user, Plaintiffs and/or the healthcare providers reasonably relied on the misrepresentations.

325. Plaintiffs were persons who would reasonably be expected to use, consume, or be affected by the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

326. Defendants improperly, negligently, falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Taxotere to and/or from the FDA, that had the FDA known of such facts, Taxotere would have never been approved with the warnings and instructions for use that accompanied it and/or were provided to prescribing physicians and the public, so that Taxotere would not have been prescribed to nor used by Plaintiff.

327. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, that these decisions were economically driven manipulation of the postmarket regulatory process, and that the Defendants knew or should have known in the postmarketing phase that their products' labels were inadequate based on the label warning updating requirements of the FDA, no statutory presumptions in favor of Defendants are warranted.

328. In reliance upon Defendants' implied warranty, Plaintiffs used the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

329. As a direct and proximate result of the foregoing acts and omissions, Defendants caused Plaintiffs 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 Defendants, jointly and severally, 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

Strict Products Liability – Design and Manufacturing Under New Jersey Products Liability Act

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

331. At all relevant times, Defendants were 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.

332. At all times relevant herein, Defendants placed the Product at Issue (Taxotere/docetaxel) into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for their intended purpose. Insofar as Taxotere could not be used safely without the unreasonable risk of harm, Taxotere was ineffective for the purpose for which its use was promoted.

333. The Plaintiffs bring this claim under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq.

334. At the time the Taxotere was used, the drug was defectively designed. As described

above, there was an unreasonable risk that the drug would not perform safely and effectively for the purposes for which it was intended.

335. The Taxotere contained a manufacturing defect when it left the possession, custody and control of Defendants. The Taxotere differs from their intended result and/or from other safer alternatives for treating cancer. Defendants knew or should have known that the Taxotere could cause permanent hair loss, thereby giving rise to pain and suffering, debilitation and yet, Defendants continued to market Taxotere as a safe and effective medication.

336. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

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

338. Defendants were aware that consumers, including Plaintiffs or Plaintiffs' physicians, would use the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products in the manner directed by the package insert; which is to say that Plaintiffs or Plaintiffs' Decedents were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

339. Plaintiffs and/or their physicians were at all relevant times in privity with Defendants.

340. The Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products was expected to reach and did in fact reach consumers, including Plaintiffs or Plaintiffs' physicians, without substantial change in the condition in which they were

manufactured and sold by Defendants.

341. Defendants' products are designed in such a way that, when used as intended, the defective product causes serious, permanent, and devastating damage to patients in whom the product is used. Defendants acted unreasonably in its design of the product in that Defendants failed to adopt a safer design for the product that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

342. Defendants' products do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

343. The risks of Defendants' products outweigh the benefits of using the products.

344. Defendants failed to design against the dangers outlined herein, and failed to provide adequate warnings and instructions concerning these risks.

345. There were numerous safer alternative designs to the products which in reasonable probability would have prevented or significantly reduced the risk of the personal injuries suffered by Plaintiffs herein without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the products left the control of Defendants by the application of existing or reasonably-achievable scientific knowledge. Any warnings actually provided by Defendants 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.

346. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the risks and benefits of the Defendants' Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate, given the Plaintiffs' conditions and need

for information.

347. 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.

348. The Defendants intentionally, recklessly, and/or maliciously misrepresented the safety, risks and benefits of the Defendants' Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

349. Plaintiffs were reasonably foreseeable users of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate who used the drug in reasonably anticipated manners. Plaintiffs did not misuse the product.

350. Plaintiffs would not have used Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had s/he (and the treating Physicians) been provided an adequate warning by Defendants of the risk of these side effects.

351. Further, Defendants 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.

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

353. As a purchaser or user, Plaintiffs and/or the healthcare providers reasonably relied on the misrepresentations.

354. Plaintiffs were persons who would reasonably be expected to use, consume, or be

affected by the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

355. Defendants improperly, negligently, falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Taxotere to and/or from the FDA, that had the FDA known of such facts, Taxotere would have never been approved with the warnings and instructions for use that accompanied it and/or were provided to prescribing physicians and the public, so that Taxotere would not have been prescribed to nor used by Plaintiff.

356. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, that these decisions were economically driven manipulation of the postmarket regulatory process, and that the Defendants knew or should have known in the postmarketing phase that their products' labels were inadequate based on the label warning updating requirements of the FDA, no statutory presumptions in favor of Defendants are warranted.

357. In reliance upon Defendants' implied warranty, Plaintiffs used the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

358. The design and manufacturing defects in the Taxotere were a producing cause of Plaintiff's injuries and damages.

359. As a direct and proximate result of the foregoing acts and omissions, Defendants caused Plaintiffs 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 Defendants, jointly and severally, 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

Breach of Express Warranty - Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.

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

361. At all relevant and material times, Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

362. At all relevant Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by

consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately tested and fit for its intended use.

363. At all relevant times, Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

364. Plaintiffs and/ or their prescribing/administering physicians were at all relevant times in privity with Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.

365. The Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

366. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit

for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

367. These express warranties became part of the basis of the bargain Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. made with Plaintiffs.

368. Plaintiffs and their healthcare providers relied on Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.'s express warranties in electing to purchase and use their product.

369. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.'s express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

370. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly

known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. represented that their drug was free from permanent side effects;

b. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent hair loss associated with their drug;

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

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information

about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy and risks of the products.

371. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending, prescribing, and/or dispensing the drugs at issue.

372. In reliance upon Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.'s express warranty, Plaintiffs were administered

the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

373. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

374. At the time of making such express warranties, Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. knew or should have known that the Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

375. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. in connection with the use recommendation, description, and/or dispensing of the Defendants'

Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

376. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. breached their express warranties to Plaintiffs in that the Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

377. As a result of the foregoing acts and omissions, Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. caused Plaintiffs 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 Defendants, jointly and severally, 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

Breach of Express Warranty - Sandoz, Inc.

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

379. At all relevant and material times, Defendants Sandoz, Inc. manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

380. At all relevant Defendants Sandoz, Inc. intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately tested and fit for its intended use.

381. At all relevant times, Defendants Sandoz, Inc. were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

382. Plaintiffs and/ or their prescribing/administering physicians were at all relevant times in privity with Defendants Sandoz, Inc.

383. The Defendants Sandoz, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

384. Defendants Sandoz, Inc. expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

385. These express warranties became part of the basis of the bargain Defendants Sandoz, Inc. made with Plaintiffs.

386. Plaintiffs and their healthcare providers relied on Defendants Sandoz, Inc.'s express warranties in electing to purchase and use their product.

387. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Sandoz, Inc.'s express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

388. Defendants Sandoz, Inc. breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Sandoz, Inc. represented that their drug was free from permanent side effects;

b. Defendants Sandoz, Inc. warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Sandoz, Inc. warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent

hair loss associated with their drug;

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

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection

Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy and risks of the products.

389. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Sandoz, Inc. for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending, prescribing, and/or dispensing the drugs at issue.

390. In reliance upon Defendants Sandoz, Inc.'s express warranty, Plaintiffs were administered the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

391. Defendants Sandoz, Inc. knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

392. At the time of making such express warranties, Defendants Sandoz, Inc. knew or should have known that the Defendants Sandoz, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

393. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of

Defendants Sandoz, Inc. in connection with the use recommendation, description, and/or dispensing of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

394. Defendants Sandoz, Inc. breached their express warranties to Plaintiffs in that the Defendants Sandoz, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

395. As a result of the foregoing acts and omissions, Defendants Sandoz, Inc. caused Plaintiffs 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 Defendants, jointly and severally, 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

Breach of Express Warranty - Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.

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

397. At all relevant and material times, Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

398. At all relevant Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately tested and fit for its intended use.

399. At all relevant times, Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

400. Plaintiffs and/ or their prescribing/administering physicians were at all relevant times in privity with Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.

401. The Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in

which it was manufactured and sold by Defendants.

402. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

403. These express warranties became part of the basis of the bargain Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. made with Plaintiffs.

404. Plaintiffs and their healthcare providers relied on Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.'s express warranties in electing to purchase and use their product.

405. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.'s express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

406. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira

Worldwide, Inc. represented that their drug was free from permanent side effects;

b. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent hair loss associated with their drug;

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

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers

that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy and risks of the products.

407. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending, prescribing, and/or dispensing the drugs at issue.

408. In reliance upon Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.'s express warranty, Plaintiffs were administered the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

409. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

410. At the time of making such express warranties, Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. knew or should have known that the Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

411. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. in connection with the use recommendation, description, and/or dispensing of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

412. Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. breached their express warranties to Plaintiffs in that the Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

413. As a result of the foregoing acts and omissions, Defendants Hospira, Inc. and Hospira Worldwide, LLC formerly known as Hospira Worldwide, Inc. caused Plaintiffs 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 Defendants, jointly and severally, 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

Breach of Express Warranty - Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging

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

415. At all relevant and material times, Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

416. At all relevant Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately

tested and fit for its intended use.

417. At all relevant times, Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

418. Plaintiffs and/ or their prescribing/administering physicians were at all relevant times in privity with Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging

419. The Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging's Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

420. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

421. These express warranties became part of the basis of the bargain Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging made with Plaintiffs.

422. Plaintiffs and their healthcare providers relied on Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging's express warranties in electing to purchase and use their product.

423. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging's express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

424. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging represented that their drug was free from permanent side effects;

b. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent hair loss associated with their drug;

d. Representing that goods or services has characteristics, ingredients, uses, benefits

or quantities that they do not have;

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy

and risks of the products.

425. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending, prescribing, and/or dispensing the drugs at issue.

426. In reliance upon Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging's express warranty, Plaintiffs were administered the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

427. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

428. At the time of making such express warranties, Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging knew or should have known that the Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging's Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

429. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging in connection with the use recommendation, description, and/or dispensing of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

430. Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging breached their express warranties to Plaintiffs in that the Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging's Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

431. As a result of the foregoing acts and omissions, Defendants Accord Healthcare, Inc. and McKesson Corporation doing business as McKesson Packaging caused Plaintiffs 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 Defendants, jointly and severally, 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

Breach of Express Warranty - Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd.

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

433. At all relevant and material times, Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

434. At all relevant Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately tested and fit for its intended use.

435. At all relevant times, Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

436. Plaintiffs and/ or their prescribing/administering physicians were at all relevant

times in privity with Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd

437. The Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd's Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

438. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

439. These express warranties became part of the basis of the bargain Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd made with Plaintiffs.

440. Plaintiffs and their healthcare providers relied on Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd's express warranties in electing to purchase and use their product.

441. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd's express warranties, because is the

drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

442. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd represented that their drug was free from permanent side effects;

b. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent hair loss associated with their drug;

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

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy and risks of the products.

443. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in

recommending, prescribing, and/or dispensing the drugs at issue.

444. In reliance upon Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd's express warranty, Plaintiffs were administered the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

445. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

446. At the time of making such express warranties, Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd knew or should have known that the Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd's Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

447. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd in connection with the use recommendation, description,

and/or dispensing of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

448. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd breached their express warranties to Plaintiffs in that the Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd's Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

449. As a result of the foregoing acts and omissions, Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. formerly known as Caraco Pharmaceutical Laboratories, Ltd caused Plaintiffs 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 Defendants, jointly and severally, 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.

EIGHTH CAUSE OF ACTION

Breach of Express Warranty - Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.

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

451. At all relevant and material times, Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

452. At all relevant Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately tested and fit for its intended use.

453. At all relevant times, Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

454. Plaintiffs and/ or their prescribing/administering physicians were at all relevant times in privity with Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.

455. The Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

456. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

457. These express warranties became part of the basis of the bargain Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. made with Plaintiffs.

458. Plaintiffs and their healthcare providers relied on Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.'s express warranties in electing to purchase and use their product.

459. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.'s express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

460. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. represented that their drug was free from permanent side effects;

b. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent hair loss associated with their drug;

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

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the

Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy and risks of the products.

461. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending, prescribing, and/or dispensing the drugs at issue.

462. In reliance upon Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.'s express warranty, Plaintiffs were administered

the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

463. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

464. At the time of making such express warranties, Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. knew or should have known that the Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

465. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. in connection with the use recommendation, description, and/or dispensing of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

466. Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. breached their express warranties to Plaintiffs in that the

Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

467. As a result of the foregoing acts and omissions, Defendants Actavis Pharma, Inc.; Actavis LLC formerly known as Actavis Inc.; and Sagent Pharmaceuticals, Inc. caused Plaintiffs 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 Defendants, jointly and severally, 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

Breach of Express Warranty - Pfizer, Inc.

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

469. At all relevant and material times, Defendants Pfizer, Inc. manufactured, distributed, advertised, promoted, and sold the Defendants' Taxotere, Docetaxel Injection,

Docetaxel Injection Concentrate, or Docefrez products.

470. At all relevant Defendants Pfizer, Inc. intended that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other chemotherapy agents used to treat breast cancer, and that it was adequately tested and fit for its intended use.

471. At all relevant times, Defendants Pfizer, Inc. were aware that consumers, including Plaintiffs, would use the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products; which is to say that Plaintiffs were foreseeable users of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

472. Plaintiffs and/ or their prescribing/administering physicians were at all relevant times in privity with Defendants Pfizer, Inc.

473. The Defendants Pfizer, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were expected to reach and did in fact reach consumers, including Plaintiffs and their prescribing/administering physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

474. Defendants Pfizer, Inc. expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

475. These express warranties became part of the basis of the bargain Defendants Pfizer,

Inc. made with Plaintiffs.

476. Plaintiffs and their healthcare providers relied on Defendants Pfizer, Inc.'s express warranties in electing to purchase and use their product.

477. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants Pfizer, Inc.'s express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

478. Defendants Pfizer, Inc. breached various express warranties with respect to the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products including the following particulars:

a. Defendants Pfizer, Inc. represented that their drug was free from permanent side effects;

b. Defendants Pfizer, Inc. warranted that the hair loss would not be a permanent and long-lasting side effect of their drug;

c. Defendants Pfizer, Inc. warranted that temporary hair loss is commonly associated with chemotherapy drugs and provided no information about the risk of permanent hair loss associated with their drug;

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

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

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding; and

g. Failing to advise the incidence and risk of permanent alopecia.

h. Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or permanent alopecia associated with using the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products;

i. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were as safe, and/or safer than other alternative procedures and medications, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

j. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy and risks of the products.

479. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants Pfizer, Inc. for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending,

prescribing, and/or dispensing the drugs at issue.

480. In reliance upon Defendants Pfizer, Inc.'s express warranty, Plaintiffs were administered the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

481. Defendants Pfizer, Inc. knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

482. At the time of making such express warranties, Defendants Pfizer, Inc. knew or should have known that the Defendants Pfizer, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products do not conform to these express representations because the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products unreasonably unsafe for their intended purpose.

483. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants Pfizer, Inc. in connection with the use recommendation, description, and/or dispensing of the Defendants' Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products.

484. Defendants Pfizer, Inc. breached their express warranties to Plaintiffs in that the Defendants Pfizer, Inc.'s Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products were not of merchantable quality, safe and fit for their intended uses, nor were

they adequately tested.

485. As a result of the foregoing acts and omissions, Defendants Pfizer, Inc. caused Plaintiffs 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 Defendants, jointly and severally, 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

Loss of Consortium

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

487. At all relevant times hereto, the Plaintiffs had spouses (hereinafter referred to as "Spouse Plaintiffs") and/or family members (hereinafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez products and Plaintiffs' injuries.

488. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring,

medications and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

489. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

490. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

491. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

492. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs and/or intimate partners of the aforesaid Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs and intimate partners jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

WHEREFORE, Plaintiffs demand judgment against the above-named Defendants 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 Defendants, jointly and severally, 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 his/her administration of Taxotere (docetaxel) in an amount to be determined at trial;

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

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

4. Awarding damages for Plaintiffs' mental and emotional anguish;

5. Awarding damages for loss of consortium;

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

7. Awarding the costs and expenses of this litigation;

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

9. 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: December 19, 2019

Respectfully submitted,

ROBINS KAPLAN LLP

By: _____

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BURNETT LAW FIRM

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