

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: TAXOTERE (DOCETAXEL))	MDL No. 2740
PRODUCTS LIABILITY LITIGATION)	
)	Section: "N" (5)
)	
THIS DOCUMENT RELATES TO:)	
ALL CASES)	

**SANDOZ INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO
PLAINTIFFS' FIRST AMENDED MASTER LONG FORM COMPLAINT**

Defendant Sandoz Inc. ("Sandoz"), by and through its undersigned counsel of record, submits its Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint ("FAC"). Sandoz denies each and every allegation of the FAC except as expressly admitted or otherwise responded to herein, and in response to each of the numbered paragraphs of Plaintiffs' FAC, states as follows:

1. Sandoz admits that it is a manufacturer of a docetaxel product approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act. Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 1 directed to it. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1 directed to other named Defendants, and therefore denies the same.

2. Sandoz avers that Paragraph 2 does not contain a factual allegation directed toward Sandoz, and thus no further response is required. To the extent a response is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and therefore denies the same.

3. Sandoz avers that Paragraph 3 does not contain a factual allegation directed toward Sandoz, and thus no further response is required. To the extent a response is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies the same. Sandoz denies any allegations with respect to waiver and/or claims not asserted.

INTRODUCTION¹

4. Sandoz admits that Taxotere is a chemotherapy drug administered to many who suffer primarily from breast cancer. Except as thus stated, Sandoz denies the remaining allegations of Paragraph 4 directed to it. Sandoz specifically denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4 directed to other named Defendants, and on that basis denies the same.

5. Sandoz denies the allegations contained in Paragraph 5 directed to it. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 directed to other named Defendants, and therefore denies the same.

6. Sandoz denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6 relating to Plaintiffs, and on that basis denies the same.

¹ Headings and subheadings throughout this Answer are taken directly from the FAC and are included solely for ease of reference. They do not constitute admissions by Sandoz, and any portion of a heading or subheading that may be construed as a factual allegation is specifically denied.

7. Sandoz denies the allegations contained in Paragraph 7 directed to Sandoz. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 pertaining to other parties, and therefore denies the same.

THE PARTIES

A. Plaintiffs

8. Sandoz denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs or their spouses, children, parents, decedents, wards, or heirs. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 8, and on that basis denies the same.

9. Sandoz denies the allegations contained in Paragraph 9 directed to it. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 9 directed at other parties, and on that basis denies the same.

10. The allegations in Paragraph 10 call for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 10, and therefore denies the same.

11. Sandoz denies the allegations contained in Paragraph 11 directed to it. Sandoz specifically denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 11 directed to other Defendants, and therefore denies the same.

B. Sanofi-Related Entities

12. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth Paragraph 12, and therefore denies the same.

13. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 13, and therefore denies the same.

14. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 14, and therefore denies the same.

15. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 15, and therefore denies the same.

16. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 16, and therefore denies the same.

17. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 17, and therefore denies the same.

18. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 18, and therefore denies the same.

19. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 19, and therefore denies the same.

20. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 20, and therefore denies the same.

21. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 21, and therefore denies the same.

22. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 22, and therefore denies the same.

23. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 23, and therefore denies the same.

24. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 24, and therefore denies the same.

25. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 25, and therefore denies the same.

26. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 26, and therefore denies the same.

27. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 27, and therefore denies the same.

28. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 28, and therefore denies the same.

29. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 29, and therefore denies the same.

30. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 30, and therefore denies the same.

31. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 31, and therefore denies the same.

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

32. Sandoz admits that it obtained approval to market Docetaxel Injection. Sandoz further admits that its new drug application for Docetaxel Injection was approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 355(b)(2). Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 32 directed to other parties, and therefore denies the same.

33. The allegations in Paragraph 33 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 33 and states that federal statutes and regulations speak for themselves.

34. The allegations in Paragraph 34 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 34 and states that federal statutes and regulations speak for themselves.

35. The allegations in Paragraph 35 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 35 and states that federal statutes and regulations speak for themselves.

36. The allegations in Paragraph 36 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 36 and states that federal statutes and regulations speak for themselves.

1. Sandoz

37. Sandoz admits the allegations contained in Paragraph 37.

38. Sandoz admits that it has transacted and conducted business in the United States. Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 38.

39. Sandoz admits that it designs, manufactures, sells, and distributes generic drugs in certain markets in the United States. Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 39. Sandoz specifically denies the characterization of its revenue in Paragraph 39.

40. Sandoz admits that it designed, tested, manufactured, labeled, sold, and/or distributed its FDA-approved Docetaxel Injection. Sandoz states that FDA approved Sandoz' New Drug Application for Docetaxel Injection on June 29, 2011 and Sandoz began selling

Docetaxel Injection on or around August 15, 2011. Sandoz further admits that Docetaxel Injection was approved by FDA under New Drug Application number 201525. Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 40.

41. Sandoz admits that the name of its drug is Docetaxel Injection. Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 41.

42. Sandoz admits that Docetaxel Injection is sold, purchased, and used in the United States. Sandoz further admits that its New Drug Application for Docetaxel Injection, which was approved by FDA, provided for the sale of docetaxel throughout the United States. Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 42.

43. Sandoz admits the allegations contained in Paragraph 43.

44. Sandoz admits that its formulation of Docetaxel Injection contains less polysorbate 80 and more ethanol 96% than Taxotere, as well as polyethylene glycol 300 as a solubizer, and anhydrous citric acid for pH adjustment.

45. Sandoz admits the allegations contained in Paragraph 45.

46. Sandoz admits that when Docetaxel Injection was approved, a portion of the FDA-approved Patient Counseling Information read as follows: “Explain to patients that side effects such as ... hair loss are associated with docetaxel administration.” Sandoz also admits that the FDA-approved Docetaxel Labeling also stated that one of the “most common side effects of Docetaxel Injection” is “hair loss,” but denies that such language appeared in the Patient Counseling Information. Except as thus stated, Sandoz avers that the remaining allegations in Paragraph 46 seek to characterize the Docetaxel Injection labeling. Sandoz denies the remaining allegations of Paragraph 46 and states that the Docetaxel Injection labeling speaks for itself.

47. Sandoz admits that it submitted a Changes Being Effectuated (“CBE”) Supplemental New Drug Application (“sNDA”) (S-002) on July 29, 2011, that was approved on March 5, 2012, and a CBE sNDA (S-003) on August 15, 2013, that was approved on April 23, 2014. Except as thus stated, Sandoz avers that the remaining allegations in Paragraph 47 seek to characterize the labeling changes submitted in CBE sNDA S-002 and S-003. Sandoz denies the remaining allegations of Paragraph 47 and states that the labeling submissions speak for themselves.

48. Sandoz admits the allegations contained in Paragraph 48.

49. Sandoz admits that the December 2015 version of the labeling for Sandoz’s Docetaxel Injection product states under “Post-Marketing Experiences” that “[c]ases of permanent alopecia have been reported.” Sandoz admits that this version of the Docetaxel Injection labeling states in the Patient Counseling Information that “side effects such as . . . hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration,” and that the Patient Information in this labeling version states, with respect to “most common side effects,” the following: “hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed.” Except as thus stated, Sandoz denies the remaining allegations contained in Paragraph 49.

50. Sandoz avers that the allegations in Paragraph 50 seek to characterize the Docetaxel Injection labeling. Sandoz denies the allegations in Paragraph 50 and states that the Docetaxel Injection labeling speaks for itself.

2. *Accord Healthcare & McKesson*

51. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 51, and therefore denies the same.

52. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 52, and therefore denies the same.

53. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 53, and therefore denies the same.

54. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 54, and therefore denies the same.

55. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 55, and therefore denies the same.

56. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 56, and therefore denies the same.

57. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 57, and therefore denies the same.

58. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 58, and therefore denies the same.

59. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 59, and therefore denies the same.

60. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 60, and therefore denies the same.

61. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 61, and therefore denies the same.

62. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 62, and therefore denies the same.

63. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 63, and therefore denies the same.

4. *Hospira Entities*²

² The numbering of the Subsections in Plaintiffs' FAC erroneously skips to number 4 here instead of continuing at number 3. For consistency, Sandoz's Answer contains the same numbering as Plaintiffs' FAC.

64. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 64, and therefore denies the same.

65. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 65, and therefore denies the same.

66. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 66, and therefore denies the same.

67. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 67, and therefore denies the same.

68. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 68, and therefore denies the same.

69. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 69, and therefore denies the same.

70. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 70, and therefore denies the same.

71. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 71, and therefore denies the same.

72. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 72, and therefore denies the same.

73. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 73, and therefore denies the same.

74. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 74, and therefore denies the same.

5. *Sun Pharma Entities*

75. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 75, and therefore denies the same.

76. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 76, and therefore denies the same.

77. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 77, and therefore denies the same.

78. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 78, and therefore denies the same.

79. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 79, and therefore denies the same.

80. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 80, and therefore denies the same.

81. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 81, and therefore denies the same.

82. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 82, and therefore denies the same.

83. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 83, and therefore denies the same.

84. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 84, and therefore denies the same.

85. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 85, and therefore denies the same.

6. Pfizer

86. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 86, and therefore denies the same.

87. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 87, and therefore denies the same.

88. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 88, and therefore denies the same.

89. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 89, and therefore denies the same.

90. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 90, and therefore denies the same.

91. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 91, and therefore denies the same.

92. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 92, and therefore denies the same.

93. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 93, and therefore denies the same.

94. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 94, and therefore denies the same.

95. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 95, and therefore denies the same.

96. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 96, and therefore denies the same.

7. *Actavis Entities*

97. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 97, and therefore denies the same.

98. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 98, and therefore denies the same.

99. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 99, and therefore denies the same.

100. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 100, and therefore denies the same.

101. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 101, and therefore denies the same.

102. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 102, and therefore denies the same.

103. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 103, and therefore denies the same.

104. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 104, and therefore denies the same.

105. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 105, and therefore denies the same.

106. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 106, and therefore denies the

same.

107. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations directed at other parties set forth in Paragraph 107, and therefore denies the same.

JURISDICTION & VENUE

108. The allegations in Paragraph 108 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 108 relating to the citizenship of other parties, and therefore denies the same. Sandoz denies the remaining allegations in Paragraph 108.

109. The allegations in Paragraph 109 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 109, and therefore denies the same.

110. The allegations in Paragraph 110 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz admits only that paragraph 110 purports to refer to and characterize Transfer Orders of the Judicial Panel on Multidistrict Litigation, which speak for themselves.

111. The allegations in Paragraph 111 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations in Paragraph 111 directed to it. Sandoz states that it lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 111 directed to other Defendants, and therefore denies the same.

FACTUAL ALLEGATIONS

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

112. Sandoz admits the allegations in Paragraph 112.

113. Sandoz admits that taxanes were originally derived from the Yew tree and inhibit the multiplication of cancer cells and are widely used as chemotherapy agents.

114. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 114, and therefore denies the same.

115. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 115, and therefore denies the same.

116. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 116, and therefore denies the same.

117. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 117, and therefore denies the same.

118. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 118, and therefore denies the same.

119. Sandoz avers that Paragraph 119 seeks to characterize the use and administration of Docetaxel Injection. Sandoz denies the characterization of the use and administration of Docetaxel Injection in Paragraph 119 and states that the medical literature and labeling discussing the use and administration of Docetaxel Injection speak for themselves. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 119, and therefore denies the same.

120. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 120 directed to other parties, and therefore denies the same.

121. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 121 directed to another Defendant, and therefore denies the same.

122. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 122 directed to another Defendant, and therefore denies the same.

123. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 123 directed to another Defendant, and therefore denies the same.

124. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 124 directed to another Defendant, and therefore denies the same.

125. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 125 directed to another Defendant, and therefore denies the same.

126. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 126 directed to another Defendant, and therefore denies the same.

127. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 127 directed to another Defendant, and therefore denies the same.

128. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 128 directed to another Defendant, and therefore denies the same.

129. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 129 directed to another Defendant, and therefore denies the same.

130. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 130 directed to another Defendant, and therefore denies the same.

131. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 131 directed to another Defendant, and therefore denies the same.

132. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 132 directed to another Defendant, and therefore denies the same.

133. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 133 directed to another Defendant, and therefore denies the same.

134. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 134 directed to another Defendant, and therefore denies

the same.

135. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 135 directed to another Defendant, and therefore denies the same.

136. Sandoz admits the allegations in Paragraph 136.

137. Sandoz admits the FDA approved an sNDA on December 11, 2015. Sandoz avers that the remaining allegations in Paragraph 137 seek to characterize Taxotere labeling. To the extent a response is deemed necessary, Sandoz denies the characterization and states that the labeling speaks for itself.

II. Defendants' Duties under the FDCA and State Law

138. Allegations contained in Paragraph 138 state a legal conclusion, to which no response is required. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

139. Allegations contained in Paragraph 139 state a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the same. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

140. Allegations contained in Paragraph 140 state a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the same. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

141. Allegations contained in Paragraph 141 state a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the same. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

142. Paragraph 142 seeks to characterize federal statutes and regulations. Sandoz denies the characterization of the cited federal statutes and regulations in Paragraph 142, and states that the federal statutes and regulations speak for themselves. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

143. Paragraph 143 seeks to characterize federal regulations. Sandoz denies the characterization of the cited federal regulations in Paragraph 143, and states that the federal regulations speak for themselves. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

144. Paragraph 144 seeks to characterize federal regulations. Sandoz denies the characterization of the cited federal regulations in Paragraph 144, and states that the federal regulations speak for themselves. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

145. Paragraph 145 seeks to characterize federal regulations. Sandoz denies the characterization of the cited federal regulations in Paragraph 145, and states that the federal regulations speak for themselves. To the extent a response is required, Sandoz affirmatively

states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

146. Paragraph 146 seeks to characterize federal regulations. Sandoz denies the characterization of the cited federal regulations in Paragraph 146, and states that the federal regulations speak for themselves. Sandoz denies the remaining allegations in Paragraph 146. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

147. Sandoz denies the allegations in Paragraph 147.

III. Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia.

148. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 148 directed to another Defendant, and therefore denies the same. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 148 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 148.

149. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 149 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 149.

150. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 150 directed to another Defendant, and therefore denies the same. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 150 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 150.

151. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the publications referenced in Paragraph 151 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 151.

152. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 152 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 152.

153. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 153 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 153.

154. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 154 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 154.

155. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 155 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 155.

156. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 156 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 156.

157. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 157 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 157.

158. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 158 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 158.

159. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies, presentations, and publications referenced in Paragraph 159 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 159.

160. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the publications referenced in Paragraph 160 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 160.

161. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 161 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 161.

162. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 162 directed to another Defendant, and therefore denies the same.

163. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 163 directed to another Defendant, and therefore denies the same.

164. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 164 directed to another Defendant, and therefore denies the same.

165. Sandoz admits the allegations in Paragraph 165.

166. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 166 directed to another Defendant, and therefore denies the same.

167. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 167 directed to another Defendant, and therefore denies the same.

168. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 168 directed to another Defendant, and therefore denies the same.

169. Sandoz admits the allegations in Paragraph 169.

170. Sandoz admits the allegations in Paragraph 170.

171. Sandoz denies the allegations contained in Paragraph 171 directed to it. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 171 directed at other parties, and on that basis denies the same.

172. Sandoz denies the allegations contained in Paragraph 172 directed to it. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 172 directed at other parties, and on that basis denies the same.

IV. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate Caused Permanent Alopecia in Many Breast Cancer Patients.

173. Sandoz admits that chemotherapy can cause hair loss, which in some cases is temporary. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 173, and therefore denies the same.

174. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 174, and therefore denies the same.

175. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 175, and therefore denies the same.

176. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 176, and therefore denies the same.

177. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 177, and therefore denies the same.

178. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 178, and therefore denies the same.

179. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the publications referenced in Paragraph 179 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 179.

180. Sandoz avers that Paragraph 180 attempts to characterize the side effects associated with Docetaxel Injection. Sandoz denies the characterization of the side effects of Docetaxel Injection in Paragraph 180, and states that the medical literature and Docetaxel Injection labeling discussing the side effects of this drug speak for themselves. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 180 directed to other Defendants, and therefore denies the same. Sandoz denies the remaining allegations in Paragraph 180.

181. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 181 directed to another Defendant, and therefore denies the same.

182. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 182 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 182 directed to another Defendant, and therefore denies the same. Sandoz denies the remaining allegations in Paragraph 182.

183. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 183 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 183.

184. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 184 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 184.

185. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 185 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 185.

186. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the presentations and publications referenced in Paragraph 186 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 186.

187. Sandoz denies the allegations contained in Paragraph 187 directed to it. Sandoz specifically denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge

or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 187 directed to other Defendants, and therefore denies the same.

188. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 188 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 188.

189. Sandoz denies the allegations contained in Paragraph 189 directed to it. Sandoz specifically denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 189 directed to other Defendants, and therefore denies the same.

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

190. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 190 directed to another Defendant and nonparties, and therefore denies the same.

191. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 191 directed to another Defendant, and therefore denies the same.

192. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 192 directed to another Defendant, and therefore denies the same.

193. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 193 directed to another Defendant, and therefore denies the same.

194. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 194 directed to another Defendant, and therefore denies the same.

195. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 195 directed to another Defendant, and therefore denies the same.

196. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 196 directed to another Defendant, and therefore denies the same.

197. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 197 directed to another Defendant, and therefore denies the same.

198. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 192 directed to another Defendant, and therefore denies the same.

199. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 199 directed to another Defendant, and therefore denies the same.

200. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 200 directed to another Defendant, and therefore denies the same.

201. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 201 directed to another Defendant, and therefore denies the same.

202. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 202 directed to another Defendant, and therefore denies the same.

203. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 203 directed to another Defendant, and therefore denies the same.

204. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 204 directed to another Defendant, and therefore denies the same.

205. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 205 directed to another Defendant, and therefore denies the same.

206. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 206 directed to another Defendant, and therefore denies the same.

207. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 207 directed to another Defendant, and therefore denies the same.

208. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 208 directed to another Defendant, and therefore denies the same.

209. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 209 directed to another Defendant, and therefore denies the same.

210. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 210, and therefore denies the same.

211. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 211 directed to another Defendant, and therefore denies the same.

212. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 212 directed to another Defendant, and therefore denies the same.

VI. Permanent Alopecia is Devastating for Plaintiffs.

213. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 213 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 213.

214. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 214 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 214.

215. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 215, and therefore denies the same.

216. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 216, and therefore denies the same.

217. Sandoz states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 217 are erroneous and/or taken out of context, and the same are therefore denied. Sandoz denies the remaining allegations in Paragraph 217.

218. Sandoz denies the allegations set forth in Paragraph 218.

219. Sandoz denies the allegations set forth in Paragraph 219. Sandoz specifically denies any wrongdoing or liability to Plaintiffs whatsoever.

FIRST CLAIM FOR RELIEF
(Strict Products Liability – Failure to Warn – Against All Defendants)

220. Sandoz restates and incorporates by reference its answers to all prior paragraphs of the FAC, as if fully set forth herein.

221. Sandoz admits that it developed, manufactured, tested, distributed and sold its FDA-approved docetaxel product in compliance with all applicable legal duties, laws, and regulations. Except as thus stated, Sandoz denies the remaining allegations in Paragraph 221 directed to Sandoz. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 221 directed to other Defendants, and therefore denies the same.

222. Sandoz denies the allegations contained in Paragraph 222. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 222 directed to other Defendants, and therefore denies the same.

223. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 223 directed to another Defendant and nonparty, and therefore denies the same.

224. Sandoz denies the allegations contained in Paragraph 224. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 224 directed to other Defendants, and therefore denies the same.

225. Sandoz denies the allegations contained in Paragraph 225. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 225 directed to other Defendants, and therefore denies the same.

226. Sandoz denies the allegations contained in Paragraph 226. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 226 directed to other Defendants, and therefore denies the same.

227. Paragraph 227 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 227. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 227 directed to other Defendants, and therefore denies the same.

228. Paragraph 228 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 228.

229. Sandoz denies the allegations contained in Paragraph 229. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 229 directed to other Defendants, and therefore denies the same.

230. Sandoz denies the allegations contained in Paragraph 230. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 230 directed to other Defendants, and therefore denies the same.

SECOND CLAIM FOR RELIEF
(Strict Products Liability for Misrepresentation – Against All Defendants)

Sandoz states that Count 2 of Plaintiffs' FAC was dismissed by the Court in Pretrial Order No. 61, dated September 27, 2017, and therefore no answer is required. To the extent an answer is required, Sandoz denies the allegations contained in Paragraphs 231 – 238 of Plaintiffs' FAC.

THIRD CLAIM FOR RELIEF
(Negligence – Against All Defendants)

239. Sandoz restates and incorporates by reference its answers to all prior paragraphs of the FAC, as if fully set forth herein.

240. Paragraph 240 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

241. Sandoz denies the allegations in Paragraph 241. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 241 directed to other Defendants, and therefore denies the same.

242. Sandoz denies the allegations contained in Paragraph 242 and all subparts thereof. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 242 directed to other Defendants, and therefore denies the same.

243. Sandoz denies the allegations contained in Paragraph 243. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 243 directed to other Defendants, and therefore denies the same.

244. Sandoz denies the allegations contained in Paragraph 244. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 245 directed to other Defendants, and therefore denies the same.

245. Sandoz denies the allegations in Paragraph 245. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 245 directed to other Defendants, and therefore denies the same.

246. Sandoz denies the allegations contained in Paragraph 246. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 246 directed to other Defendants, and therefore denies the same.

FOURTH CLAIM FOR RELIEF
(Negligent Misrepresentation – Against All Defendants)

247. Sandoz restates and incorporates by reference its answers to all prior paragraphs of the FAC, as if fully set forth herein.

248. Paragraph 248 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

249. Paragraph 249 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz denies the allegations in Paragraph 249. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 249 directed to other Defendants, and therefore denies the same.

250. Sandoz denies the allegations contained in Paragraph 250. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 250 directed to other Defendants, and therefore denies the same.

251. Sandoz denies the allegations contained in Paragraph 251. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 251 directed to other Defendants, and therefore denies the same.

252. Sandoz denies the allegations contained in Paragraph 252. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 252 directed to other Defendants, and therefore denies the same.

253. Sandoz denies the allegations in Paragraph 253. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 253 directed to other Defendants, and therefore denies the same.

254. Sandoz denies the allegations in Paragraph 254. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 254 directed to other Defendants, and therefore denies the same.

255. Sandoz denies the allegations in Paragraph 255. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 255 directed to other Defendants, and therefore denies the same.

256. Sandoz denies the allegations in Paragraph 256. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 256 directed to other Defendants, and therefore denies the same.

257. Sandoz denies the allegations in Paragraph 257. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 257 directed to other Defendants, and therefore denies the same.

FIFTH CLAIM FOR RELIEF
(Fraudulent Misrepresentation – Against All Defendants)

258. Sandoz restates and incorporates by reference its answers to all prior paragraphs of the FAC, as if fully set forth herein.

259. Sandoz admits that it sold docetaxel injection, which was accompanied by its FDA-Approved labeling, which discussed the risks and benefits of the medication. Except as thus stated, Sandoz denies the allegations contained in Paragraph 259.

260. Sandoz denies the allegations in Paragraph 260. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 260 directed to other Defendants, and therefore denies the same.

261. Sandoz denies the allegations in Paragraph 261. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 261 directed to other Defendants, and therefore denies the same.

262. Sandoz denies the allegations contained in Paragraph 262 and all subparts therein. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 262 directed to other Defendants, and therefore denies the same.

263. Sandoz denies the allegations contained in Paragraph 263. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 263 directed to other Defendants, and therefore denies the same.

264. Sandoz denies the allegations contained in Paragraph 264. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 264 directed to other Defendants, and therefore denies the same.

265. Sandoz denies the allegations contained in Paragraph 265. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 265 directed to other Defendants, and therefore denies the same.

SIXTH CLAIM FOR RELIEF
(Fraudulent Concealment – Against All Defendants)

266. Sandoz restates and incorporates by reference its answers to all prior paragraphs of the FAC, as if fully set forth herein.

267. Sandoz denies the allegations contained in Paragraph 267. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 267 directed to other Defendants, and therefore denies the same.

268. Sandoz denies the allegations contained in Paragraph 268. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 268 directed to other Defendants, and therefore denies the same.

269. To the extent a response is required, Sandoz denies the allegations contained in Paragraph 269 and all subparts therein. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 269 directed to other Defendants, and therefore denies the same.

270. Sandoz denies the allegations contained in Paragraph 270. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 270 directed to other Defendants, and therefore denies the same.

271. Sandoz denies the allegations contained in Paragraph 271. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 271 directed to other Defendants, and therefore denies the same.

272. Sandoz denies the allegations contained in Paragraph 272. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 268 directed to other Defendants, and therefore denies the same.

273. Sandoz denies the allegations contained in Paragraph 273. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 273 directed to other Defendants, and therefore denies the same.

274. Sandoz denies the allegations contained in Paragraph 274. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 274 directed to other Defendants, and therefore denies the same.

275. Sandoz denies the allegations contained in Paragraph 275. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 275 directed to other Defendants, and therefore denies the same.

SEVENTH CLAIM FOR RELIEF
(Fraud and Deceit Against All Defendants)

276. Sandoz restates and incorporates by reference its answers to all prior paragraphs of the FAC, as if fully set forth herein.

277. Sandoz denies the allegations contained in Paragraph 277. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in Paragraph 277 directed to other Defendants, and therefore denies the same.

278. Sandoz denies the allegations contained in Paragraph 278. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 278 directed to other Defendants, and therefore denies the same.

279. Sandoz denies the allegations contained in Paragraph 279. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 279 directed to other Defendants, and therefore denies the same.

280. Sandoz denies the allegations contained in Paragraph 280. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 280 directed to other Defendants, and therefore denies the same.

281. Paragraph 281 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

282. Paragraph 282 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sandoz affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

283. Sandoz denies the allegations contained in Paragraph 283. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in Paragraph 283 directed to other Defendants, and therefore denies the same.

284. Sandoz denies the allegations contained in Paragraph 284. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 284 directed to other Defendants, and therefore denies the same.

285. Sandoz denies the allegations contained in Paragraph 285. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 285 directed to other Defendants, and therefore denies the same.

286. Sandoz denies the allegations contained in Paragraph 286. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 286 directed to other Defendants, and therefore denies the same.

287. Sandoz denies the allegations contained in Paragraph 287. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 287 directed to other Defendants, and therefore denies the same.

288. Sandoz denies the allegations contained in Paragraph 288. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 288 directed to other Defendants, and therefore denies the same.

289. Sandoz denies the allegations contained in Paragraph 289. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 289 directed to other Defendants, and therefore denies the same.

290. Sandoz denies the allegations contained in Paragraph 290. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 290 directed to other Defendants, and therefore denies the same.

291. Sandoz denies the allegations contained in Paragraph 291. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 291 directed to other Defendants, and therefore denies the same.

292. Sandoz denies the allegations contained in Paragraph 292. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 292 directed to other Defendants, and therefore denies the same.

293. Sandoz denies the allegations contained in Paragraph 293. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 293 directed to other Defendants, and therefore denies the same.

294. Sandoz denies the allegations contained in Paragraph 294. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in Paragraph 294 directed to other Defendants, and therefore denies the same.

295. Sandoz denies the allegations contained in Paragraph 295. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 295 directed to other Defendants, and therefore denies the same.

296. Sandoz denies the allegations contained in Paragraph 296. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 296 directed to other Defendants, and therefore denies the same.

297. Sandoz denies the allegations contained in Paragraph 297. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 297 directed to other Defendants, and therefore denies the same.

298. Sandoz denies the allegations contained in Paragraph 298. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 298 directed to other Defendants, and therefore denies the same.

299. Sandoz denies the allegations contained in Paragraph 299. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 299 directed to other Defendants, and therefore denies the same.

300. Sandoz denies the allegations contained in Paragraph 300. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 300 directed to other Defendants, and therefore denies the same.

301. Sandoz denies the allegations contained in Paragraph 301. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 301 directed to other Defendants, and therefore denies the same.

302. Sandoz denies the allegations contained in Paragraph 302. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 302 directed to other Defendants, and therefore denies the same.

303. Sandoz denies the allegations contained in Paragraph 303. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 303 directed to other Defendants, and therefore denies the same.

304. Sandoz denies the allegations contained in Paragraph 304. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 304 directed to other Defendants, and therefore denies the same.

305. Sandoz denies the allegations contained in Paragraph 305. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in Paragraph 305 directed to other Defendants, and therefore denies the same.

306. Sandoz denies the allegations contained in Paragraph 306. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 306 directed to other Defendants, and therefore denies the same.

307. Sandoz denies the allegations contained in Paragraph 307. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 307 directed to other Defendants, and therefore denies the same.

308. Sandoz denies the allegations contained in Paragraph 308. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 308 directed to other Defendants, and therefore denies the same.

309. Sandoz denies the allegations contained in Paragraph 309. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 309 directed to other Defendants, and therefore denies the same.

310. Sandoz denies the allegations contained in Paragraph 310. Sandoz specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 310 directed to other Defendants, and therefore denies the same.

EIGHTH CLAIM FOR RELIEF
(Breach of Express Warranty –Against Sanofi Related Entities Only)

Sandoz states that Count 8 of Plaintiffs' FAC was dismissed by the Court in Pretrial Order No. 61, dated September 27, 2017, and therefore no answer is required. Sandoz further states that Count 8 sets forth claims directed to other Defendants, to which no answer is required. To the extent an answer is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraphs 311 – 318 of Plaintiffs' FAC directed to other Defendants, and therefore denies the same.

PRAYER FOR RELIEF

319. Sandoz denies that it is liable to Plaintiffs in any manner whatsoever, and denies each and every allegation of the Paragraph to the extent said allegations imply any wrongdoing by Sandoz. Sandoz further denies Plaintiffs are entitled to any of the relief requested.

JURY DEMAND

320. Sandoz avers that Paragraph 320 does not contain any factual allegations directed toward Sandoz, and thus no further response is required.

DEMAND FOR JURY TRIAL

Now comes Sandoz Inc. and files this JURY DEMAND and requests that this case be set for trial before a jury of twelve persons.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following defenses and/or affirmative defenses will be available to Sandoz. Sandoz thus gives notice it intends to rely upon any other defense or defenses that may become available. Sandoz further reserves the right to amend its Answer to assert any additional defenses, whether specifically identified herein or otherwise, as further information becomes available.

Sandoz only undertakes the burden of proof as to those defenses deemed affirmative defenses by law regardless of how such defenses are denominated herein. Subject to the foregoing, and without assuming any burden it would not otherwise bear, Sandoz asserts the following defenses to preserve its rights:

FIRST AFFIRMATIVE DEFENSE:

The FAC and each cause of action contained therein fail to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE:

The FAC and each and every cause of action asserted therein may be, as a matter of law, preempted in whole or in part by federal law, pursuant to *Mutual Pharmaceuticals Co. v. Bartlett*, 133 S. Ct. 2466 (2013), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

THIRD AFFIRMATIVE DEFENSE:

Plaintiffs' claims may be barred, in whole in part, by *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), and its progeny.

FOURTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims may be preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription medications.

FIFTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims may be preempted, in whole or in part, by the deference the common law gives in discretionary actions by the FDA under the Food, Drug, and Cosmetic Act.

SIXTH AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by intervening or superseding events, factors, occurrences, or conditions, which were in no way caused by Sandoz and for which Sandoz cannot be held liable.

SEVENTH AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by misuses, abuse, modification, alteration, acts, or omissions of Plaintiffs or third parties over whom Sandoz had no control or authority, and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

EIGHTH AFFIRMATIVE DEFENSE:

The alleged injuries and damages of which Plaintiffs complain were not caused by any Docetaxel Injection product manufactured, sold, or distributed by Sandoz or any actions of Sandoz of any kind, but were caused by some other product, process, occurrence, event, service, and/or person over which Sandoz exercised no control or right of control.

NINTH AFFIRMATIVE DEFENSE:

Some or all of the injuries alleged in the FAC were caused or aggravated by Plaintiffs' preexisting medical conditions, idiosyncratic reactions, or exposure to other substances utilized throughout their lifetimes.

TENTH AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are barred, in whole or in part, because Plaintiffs may have failed to exercise ordinary care on their own behalves for their own safety, thereby causing the alleged injuries or damages.

ELEVENTH AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are or may be barred, in whole or in part, by lack of standing.

TWELFTH AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are, or may be, barred by the applicable statute of limitations, statute of prescription, or statute of repose and/or by the equitable doctrines of waiver, estoppel, and/or laches and/or statutory and regulatory compliance.

THIRTEENTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims may be barred, in whole or in part, to the extent that Plaintiffs have released, settled, entered into an accord and satisfaction, or otherwise compromised those causes of action.

FOURTEENTH AFFIRMATIVE DEFENSE:

All or some of Plaintiffs' claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

FIFTEENTH AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are barred or reduced, in whole or in part, to the extent discovery or investigation reveals Plaintiffs failed to mitigate the alleged damages.

SIXTEENTH AFFIRMATIVE DEFENSE:

Sandoz pleads that it is liable only for damages found by the trier of fact equal to their percentage of responsibility, if any. Pursuant to Louisiana Civil Code article 2323, and any

similar provisions under any applicable state law deemed to apply to the individual Plaintiffs' claims, if a person suffers injury, death, or loss as the result partly of her own negligence and partly as a result of the fault of another person or persons, the amount of damages recoverable shall be reduced in proportion to the degree or percentage of negligence attributable to the person suffering the injury, death, or loss. Furthermore, liability for damages caused by two or more persons shall be a joint and divisible obligation. *See, e.g.*, La. C.C. art. 2324. Furthermore, Sandoz contends that it shall not be solely liable with any other person for damages attributable to the fault of such other person, including the person suffering injury, death, or loss, regardless of such other person's insolvency, ability to pay, degree of fault, immunity by statute, or otherwise. *See, e.g., id.*

SEVENTEENTH AFFIRMATIVE DEFENSE:

Any verdict or judgment rendered against Sandoz must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiffs in whole or in part, for any past or future claimed economic loss from any collateral source such as insurance, social security, worker's compensation, or employee benefit programs.

EIGHTEENTH AFFIRMATIVE DEFENSE:

Sandoz further asserts that any finding against it may not be based solely on evidence of a bad result to Plaintiffs, and asserts its right to instructions to the fact finder in this regard.

NINETEENTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims are or may be barred, in whole or in part, by the learned intermediary doctrine. Upon information and belief, Plaintiffs were at all relevant times under the care and treatment of licensed physicians who prescribed the medication at issue. Plaintiffs readily admit that the drugs at issue are not purchased by patients at a pharmacy, but rather administered via

injection and/or intravenously at a physician's office or medical treatment facility. If Plaintiffs were injured by the medication manufactured by Sandoz, which Sandoz denies, Sandoz fully informed and disclosed to the physician(s) caring for Plaintiffs all relevant information necessary to warn Plaintiffs of any risks associated with using the product. The physicians caring for Plaintiffs had a duty to warn them of the risks associated with using the medication at issue. As such, Plaintiffs' claims are barred, in whole or in part, by the learned intermediary doctrine, because if the Plaintiffs were injured by any medication manufactured by Sandoz, which Sandoz denies, the learned intermediary doctrine provides that Sandoz's sole duty to warn of the risks and hazards associated with any medication it manufactured was fulfilled when Sandoz provided adequate warnings about such risks and hazards to prescribing healthcare providers.

TWENTIETH AFFIRMATIVE DEFENSE:

Any dangers associated with the use of the Sandoz's Docetaxel Injection product, if any, were open and obvious, and Plaintiffs are therefore barred from recovery.

TWENTY-FIRST AFFIRMATIVE DEFENSE:

Upon information and belief, Plaintiffs were fully aware of and informed of the nature of the risks of the product that is the subject of Plaintiffs' claims against Sandoz, and Plaintiffs accepted and assumed all of those risks. Plaintiffs' causes of action are therefore barred, in whole or in part, by the principles of assumption of risk and informed consent.

TWENTY-SECOND AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are barred because Plaintiffs' medical providers owed a nondelegable duty to obtain their informed consent for all medical procedures and treatment, and Sandoz could not assume or comply with this duty because it is not a medical provider.

TWENTY-THIRD AFFIRMATIVE DEFENSE:

Plaintiffs' causes of action are or may be barred, in whole or in part, because the benefits of Docetaxel Injection exceed any risks, and the product conformed to the state-of-the-art for the design, manufacturing, labeling, and packaging of such or similar products and complied and was in conformity with all industry and FDA standards and regulations applicable to the product at the time it was manufactured and distributed.

TWENTY-FOURTH AFFIRMATIVE DEFENSE:

Any Docetaxel Injection product manufactured, sold, or distributed by Sandoz that was or may have been furnished to Plaintiffs was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and appropriate warnings.

TWENTY-FIFTH AFFIRMATIVE DEFENSE:

Any and all warnings and information pertaining to the Docetaxel Injection product manufactured, distributed, or sold by Sandoz were, at all times relevant to the FAC, in conformity with governmental requirements.

TWENTY-SIXTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims are barred, in whole or in part, because Sandoz made no false or misleading representations or omissions of any nature whatsoever to Plaintiffs.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE:

Plaintiffs' negligence claims are barred, in whole or in part, because Sandoz did not owe or assume any duty to Plaintiffs, and Sandoz has no legal relationship, special relationship, and/or privity with Plaintiffs by which liability can be attributed to it.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE:

To the extent any duty is found to exist, Sandoz denies that it breached any duty to Plaintiffs.

TWENTY-NINTH AFFIRMATIVE DEFENSE:

Plaintiffs' negligence claims are barred, in whole or in part, to the extent that Sandoz shows that, at all times relevant to the FAC, Sandoz met or exceeded the requisite standard of care.

THIRTIETH AFFIRMATIVE DEFENSE:

Plaintiffs' claims are barred, in whole or in part, because Sandoz acted reasonably and in good faith.

THIRTY-FIRST AFFIRMATIVE DEFENSE:

Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs did not reasonably rely on any act, representation, or omission by Sandoz.

THIRTY-SECOND AFFIRMATIVE DEFENSE:

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co.*, 531 U.S. at 341.

THIRTY-THIRD AFFIRMATIVE DEFENSE:

Plaintiffs received detailed disclosures regarding all material facts and risks associated with the product at issue.

THIRTY-FOURTH AFFIRMATIVE DEFENSE:

Liability may not be imposed as to a properly manufactured prescription drug distributed with information regarding the risks of which the manufacturer knew at the time of the manufacture, and liability may not be imposed for untold risks not known at the time of such design, manufacture, and sale of the subject prescription drug.

THIRTY-FIFTH AFFIRMATIVE DEFENSE:

No act or omission of Sandoz was due to malice, oppression, or fraud or due to an evil motive or a reckless indifference to the rights of others; therefore, any award of punitive damages is barred. *Molzof v. United States*, 502 U.S. 301 (1992); *Smith v. Wade*, 461 U.S. 30 (1983).

THIRTY-SIXTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims are barred, reduced, and/or limited pursuant to applicable statutory and common laws regarding limitation of awards, caps on recovery, and setoffs. Further, Plaintiffs are not entitled to collect an award of punitive damages because such an award would violate the due process, equal protection, and excessive fines clauses of the Louisiana and United States Constitutions and any similar provisions under any other state's law deemed to apply to the individual Plaintiffs' claims.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE:

Plaintiffs' claim for punitive damages cannot be sustained if punitive damages are awarded absent evidence that Sandoz has engaged in intentionally malicious conduct and had actual knowledge of malicious conduct. Absent such evidence, an award of punitive damages would violate Sandoz's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and Article I, Section 2 of the Constitution of the State of Louisiana,

or any similar provision under any other state's law deemed to apply to the individual Plaintiffs' claims. Plaintiffs' claim for punitive damage cannot be sustained if there is an award of punitive damages by a jury that (1) is not provided standards of sufficient clarity determining the appropriateness and the appropriate size of the punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by applicable standards of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Sandoz; (4) is permitted to award punitive damages under the standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; or (5) is not subject to trial-court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards. Accordingly, each of the aforementioned conditions would violate Sandoz's due process and equal protection rights guaranteed by the Fourteenth Amendment to the United States Constitution and the due process and equal protection provisions of the Constitution of the State of Louisiana, or any similar provisions under any other state's law deemed to apply to the individual Plaintiffs' claims, and would be improper under applicable common law and public policies.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE:

No punitive damages are recoverable under Louisiana law for any claims asserted herein.

THIRTY-NINTH AFFIRMATIVE DEFENSE:

While denying at all times that Plaintiffs have stated a valid claim under the Louisiana Products Liability Act (“LPLA”), La. Rev. Stat. § 9:2800.51, et seq., to the extent such a claim is found to exist, Sandoz pleads all the limitations and defenses set forth in the provisions of the LPLA, including the sections which provide that the LPLA provides an exclusive remedy.

FORTIETH AFFIRMATIVE DEFENSE:

The claims asserted in the Complaint are barred, in whole or in part, by Restatement (Second) of Torts § 402A, Comment k, and Restatement (Third) of Torts: Products Liability § 6.

FORTY-FIRST AFFIRMATIVE DEFENSE:

To the extent that Plaintiffs’ claims relate to Sandoz’s advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Louisiana or that of any other state whose laws may apply, such claims are barred.

FORTY-SECOND AFFIRMATIVE DEFENSE:

Plaintiffs’ warranty-based claims are barred by Plaintiffs’ failure to give proper or timely notice of any alleged defect or breach of warranty.

FORTY-THIRD AFFIRMATIVE DEFENSE:

Plaintiffs’ warranty-based claims are barred because Plaintiffs were not in privity with Sandoz, and are further barred and/or limited by any and all express conditions or disclaimers given by Sandoz, and by Plaintiffs’ lack of reliance upon such warranties.

FORTY-FOURTH AFFIRMATIVE DEFENSE:

Sandoz made no express or implied representations or warranties of any kind to Plaintiffs, nor did Plaintiffs rely on any representations or warranties made by Sandoz to others. To the extent Plaintiffs relied on any representations or warranties, such reliance was unjustified.

FORTY-FIFTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims are barred in whole or in part because the drug at issue was consistent with and/or exceeded consumer expectations.

FORTY-SIXTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims for fraud, fraudulent concealment, and/or fraudulent misrepresentation are not pled with the requisite specificity.

FORTY-SEVENTH AFFIRMATIVE DEFENSE:

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

FORTY-EIGHTH AFFIRMATIVE DEFENSE:

Plaintiffs' claims may be subject to dismissal due to lack of personal jurisdiction under the Due Process clause and any potentially applicable state law.

FORTY-NINTH AFFIRMATIVE DEFENSE:

Venue may be improper or inconvenient in this action.

FIFTIETH AFFIRMATIVE DEFENSE:

Plaintiffs' product liability cause of action is barred because, at the time any Docetaxel Injection product left Sandoz's control, a practical and technically feasible alternative design or formulation was not available that would have prevented Plaintiffs' alleged injuries and/or damages without substantially impairing the usefulness or intended purpose of the Docetaxel Injection product.

FIFTY-FIRST AFFIRMATIVE DEFENSE:

Plaintiffs' claims are barred by the doctrine of immunity for prescription drugs, by the Commerce Clause, Article 1, Section 8 of the United States Constitution as an undue burden upon interstate commerce in that Plaintiffs have asserted claims for relief which, if granted, would constitute an impermissible burden on federal laws, regulations and policy relating to the development and marketing of prescription drugs in violation of the Supremacy Clause, Article VI, Clause 2 of the United States Constitution.

To the extent not incorporated above, Sandoz raises all affirmative defenses applicable under Louisiana law and any other state law deemed to apply to the individual Plaintiffs' claims. Sandoz hereby gives notice that it intends to rely on any additional affirmative defenses that become available or apparent during discovery, and thus reserves the right to amend this Answer to assert such defenses in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR RELIEF

WHEREFORE, Defendant Sandoz Inc. requests the following relief:

1. That Plaintiffs' FAC be dismissed in its entirety, with prejudice and on the merits, as to all claims against Sandoz;

2. That Sandoz be awarded the attorneys' fees and costs incurred in connection with this action; and

3. For such other and further relief as the Court deems just and proper.

Dated this 16th day of October, 2017.

Respectfully submitted,

/s/ Lori G. Cohen

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Counsel for Defendant Sandoz Inc.

CERTIFICATE OF SERVICE

I hereby certify that Defendant Sandoz Inc.'s Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint was electronically filed with the Court, and that counsel of record, who are deemed to have consented to electronic service in the above-referenced case, are being served this 16th day of October, 2017, with a copy of the above-document via the Court's CM/ECF System.

/s/ Lori G. Cohen _____

Lori G. Cohen