UNITED STATES DISTRICT COURT EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	MDL NO. 2740
	SECTION "N" (5)
THIS DOCUMENT RELATES TO:	
ALL CASES	HON. KURT D. ENGELHARDT

ANSWER OF MCKESSON PACKAGING SERVICES, A DIVISION OF MCKESSON CORPORATION, TO FIRST AMENDED MASTER LONG FORM COMPLAINT AND DEMAND FOR JURY TRIAL

McKesson Packaging Services, a division of McKesson Corporation ("McKesson") hereby files its answer to Plaintiffs' First Amended Master Long Form Complaint and Demand for Jury Trial ("FAMLFC").

- 1. To the extent the allegations in paragraph 1 contain conclusions of law or are directed toward other defendants, no response is required. McKesson expressly denies liability and denies that Plaintiffs are entitled to relief. McKesson denies that it holds the New Drug Application ("NDA") for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1 and therefore denies them.
- 2. To the extent the allegations in paragraph 2 are directed toward other defendants or contain conclusions of law, no response is required. To the extent a response is required, McKesson does not have knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore denies them.

3. To the extent the allegations in paragraph 3 are directed toward other defendants or contain conclusions of law, no response is required. To the extent a response is required, McKesson does not have knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies them.

INTRODUCTION

- 4. To the extent the allegations in paragraph 4 are directed toward other defendants or contain conclusions of law, no response is required. McKesson admits that Taxotere is an FDA-approved chemotherapy drug indicated for the treatment of breast cancer. Because McKesson does not hold an NDA or Abbreviated New Drug Application ("ANDA") for any docetaxel or Taxotere product, McKesson has never had the ability to independently update the label for any docetaxel or Taxotere product. McKesson therefore denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 4 and therefore denies them.
- 5. To the extent the allegations in paragraph 5 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 5 and therefore denies them.
- 6. To the extent the allegations in paragraph 6 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 6 and therefore denies them.

7. To the extent the allegations in paragraph 7 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson denies any liability related to any Plaintiff's alleged injuries. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 and therefore denies them.

THE PARTIES

A. Plaintiffs

- 8. To the extent the allegations in paragraph 8 are directed towards other defendants or contain conclusions of law, no response is required. McKesson admits that the FAMLFC purports to be filed on behalf of all Plaintiffs whose claims are subsumed within MDL No. 2740. McKesson admits that the FAMLFC purports to be filed on behalf of Plaintiffs' spouses, children, parents, decedents, wards and/or heirs, all represented by Plaintiffs' counsel. McKesson denies that Plaintiffs suffered any injuries as a result of any use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez distributed or sold by McKesson. McKesson denies any liability related to any Plaintiff's alleged injuries. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8 and therefore denies them.
- 9. To the extent the allegations in paragraph 9 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 9.
- 10. To the extent the allegations in paragraph 10 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations

with respect to each and every Plaintiff in paragraph 10 and therefore denies them.

11. To the extent the allegations in paragraph 11 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 11.

B. Sanofi-Related Entities

- 12. The allegations in paragraph 12 are directed towards other defendants, therefore no response is required.
- 13. The allegations in paragraph 13 are directed towards other defendants, therefore no response is required.
- 14. The allegations in paragraph 14 are directed towards other defendants, therefore no response is required.
- 15. The allegations in paragraph 15 are directed towards other defendants, therefore no response is required.
- 16. The allegations in paragraph 16 are directed towards other defendants, therefore no response is required.
- 17. The allegations in paragraph 17 are directed towards other defendants, therefore no response is required.
- 18. The allegations in paragraph 18 are directed towards other defendants, therefore no response is required.
- 19. The allegations in paragraph 19 are directed towards other defendants, therefore no response is required.
- 20. The allegations in paragraph 20 are directed towards other defendants, therefore no response is required.
 - 21. The allegations in paragraph 21 are directed towards other defendants, therefore

no response is required.

- 22. The allegations in paragraph 22 are directed towards other defendants, therefore no response is required.
- 23. The allegations in paragraph 23 are directed towards other defendants, therefore no response is required.
- 24. The allegations in paragraph 24 are directed towards other defendants, therefore no response is required.
- 25. The allegations in paragraph 25 are directed towards other defendants, therefore no response is required.
- 26. The allegations in paragraph 26 are directed towards other defendants, therefore no response is required.
- 27. The allegations in paragraph 27 are directed towards other defendants, therefore no response is required.
- 28. The allegations in paragraph 28 are directed towards other defendants, therefore no response is required.
- 29. The allegations in paragraph 29 are directed towards other defendants, therefore no response is required.
- 30. The allegations in paragraph 30 are directed towards other defendants, therefore no response is required.
- 31. The allegations in paragraph 31 are directed towards other defendants, therefore no response is required.
 - C. Other Brand Name Drug Sponsors, Manufacturers, Labelers, and Distributors
 - 32. The allegations in paragraph 32 are directed towards other defendants or contain

legal conclusions, therefore no response is required. To the extent a response is required, McKesson denies that it submitted a New Drug Application ("NDA") under the FDCA to market Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 32 and therefore denies them.

- 33. The allegations in paragraph 33 are directed towards other defendants or contain legal conclusions, therefore no response is required. To the extent a response is required, McKesson does not have knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 and therefore denies them.
- 34. The allegations in paragraph 34 are directed towards other defendants or contain legal conclusions, therefore no response is required. To the extent a response is required, McKesson does not have knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34 and therefore denies them.
- 35. The allegations in paragraph 35 are directed towards other defendants or contain legal conclusions, therefore no response is required. To the extent a response is required, McKesson does not have knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35 and therefore denies them.
- 36. The allegations in paragraph 36 are directed towards other defendants or contain legal conclusions, therefore no response is required. To the extent a response is required, McKesson does not have knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 and therefore denies them.

1. Sandoz

37. The allegations in paragraph 37 are directed towards other defendants, therefore no response is required.

- 38. The allegations in paragraph 38 are directed towards other defendants, therefore no response is required.
- 39. The allegations in paragraph 39 are directed towards other defendants, therefore no response is required.
- 40. The allegations in paragraph 40 are directed towards other defendants, therefore no response is required.
- 41. The allegations in paragraph 41 are directed towards other defendants, therefore no response is required.
- 42. The allegations in paragraph 42 are directed towards other defendants, therefore no response is required.
- 43. The allegations in paragraph 43 are directed towards other defendants, therefore no response is required.
- 44. The allegations in paragraph 44 are directed towards other defendants, therefore no response is required.
- 45. The allegations in paragraph 45 are directed towards other defendants, therefore no response is required.
- The allegations in paragraph 46 are directed towards other defendants, therefore no response is required.
- 47. The allegations in paragraph 47 are directed towards other defendants, therefore no response is required.
- 48. The allegations in paragraph 48 are directed towards other defendants, therefore no response is required.
 - 49. The allegations in paragraph 49 are directed towards other defendants, therefore

no response is required.

50. The allegations in paragraph 50 are directed towards other defendants, therefore no response is required.

2. Accord Healthcare & McKesson

- 51. The allegations in paragraph 51 are directed towards other defendants, therefore no response is required.
- 52. McKesson admits that it is a Delaware corporation with its principal place of business at One Post Street, San Francisco, California 94104. McKesson admits that it is a pharmaceutical distributor. McKesson denies the remaining allegations in paragraph 52.
- 53. To the extent the allegations in paragraph 53 are directed towards other defendants, no response is required. McKesson admits that it has transacted and conducted business in the United States.
- 54. To the extent the allegations in paragraph 54 are directed towards other defendants, no response is required. McKesson admits that its annual revenues are disclosed in in annual reports as submitted to the Security Exchange Commission. McKesson does not have knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 54 and therefore denies them.
- 55. The allegations in paragraph 55 are directed towards other defendants, therefore no response is required.
- 56. McKesson denies that it submitted NDA # 201195 to the FDA. McKesson admits that it packaged and distributed two docetaxel products with NDC Codes 63739-971-17 and 63739-932-11 under NDA #201195 beginning March 26, 2015 and ending January 7, 2016 and April 20, 2016, respectively. McKesson also admits that it expected that docetaxel products with NDC Codes 63739-971-17 and 63739-932-11 would be sold throughout the United States.

McKesson denies the remaining allegations in paragraph 56.

- 57. The allegations in paragraph 57 are directed towards other defendants, therefore no response is required.
- 58. The allegations in paragraph 58 are directed towards other defendants, therefore no response is required.
- 59. The allegations in paragraph 59 are directed towards other defendants, therefore no response is required.
- 60. To the extent the allegations in paragraph 60 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 60 and therefore denies them.
- 61. The allegations in paragraph 61 are directed towards other defendants, therefore no response is required.
- 62. To the extent the allegations in paragraph 62 are directed towards other defendants or contain conclusions of law, no response is required. McKesson admits that the quoted language is consistent with the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 62 and therefore denies them.
- 63. To the extent the allegations in paragraph 63 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the allegations in paragraph 63 to the extent that they are inconsistent with the language in the FDA-approved label, which states in part:
 - "Explain to patients that side effects such as . . . hair loss (cases of permanent hair

loss have been reported) are associated with docetaxel administration."

• "In some cases (frequency not known) permanent hair loss has been observed."

McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 63 and therefore denies them.

3. Hospira Entities

- 64. The allegations in paragraph 64 are directed towards other defendants, therefore no response is required.
- 65. The allegations in paragraph 65 are directed towards other defendants, therefore no response is required.
- 66. The allegations in paragraph 66 are directed towards other defendants, therefore no response is required.
- 67. The allegations in paragraph 67 are directed towards other defendants, therefore no response is required.
- 68. The allegations in paragraph 68 are directed towards other defendants, therefore no response is required.
- 69. The allegations in paragraph 69 are directed towards other defendants, therefore no response is required.
- 70. The allegations in paragraph 70 are directed towards other defendants, therefore no response is required.
- 71. The allegations in paragraph 71 are directed towards other defendants, therefore no response is required.
- 72. The allegations in paragraph 72 are directed towards other defendants, therefore no response is required.
 - 73. The allegations in paragraph 73 are directed towards other defendants, therefore

no response is required.

74. The allegations in paragraph 74 are directed towards other defendants, therefore no response is required.

4. Sun Pharma Entities

- 75. The allegations in paragraph 75 are directed towards other defendants, therefore no response is required.
- 76. The allegations in paragraph 76 are directed towards other defendants, therefore no response is required.
- 77. The allegations in paragraph 77 are directed towards other defendants, therefore no response is required.
- 78. The allegations in paragraph 78 are directed towards other defendants, therefore no response is required.
- 79. The allegations in paragraph 79 are directed towards other defendants, therefore no response is required.
- 80. The allegations in paragraph 80 are directed towards other defendants, therefore no response is required.
- 81. The allegations in paragraph 81 are directed towards other defendants, therefore no response is required.
- 82. The allegations in paragraph 82 are directed towards other defendants, therefore no response is required.
- 83. The allegations in paragraph 83 are directed towards other defendants, therefore no response is required.
- 84. The allegations in paragraph 84 are directed towards other defendants, therefore no response is required.

85. The allegations in paragraph 85 are directed towards other defendants, therefore no response is required.

5. Pfizer

- 86. The allegations in paragraph 86 are directed towards other defendants, therefore no response is required.
- 87. The allegations in paragraph 87 are directed towards other defendants, therefore no response is required.
- 88. The allegations in paragraph 88 are directed towards other defendants, therefore no response is required.
- 89. The allegations in paragraph 89 are directed towards other defendants, therefore no response is required.
- 90. The allegations in paragraph 90 are directed towards other defendants, therefore no response is required.
- 91. The allegations in paragraph 91 are directed towards other defendants, therefore no response is required.
- 92. The allegations in paragraph 92 are directed towards other defendants, therefore no response is required.
- 93. The allegations in paragraph 93 are directed towards other defendants, therefore no response is required.
- 94. The allegations in paragraph 94 are directed towards other defendants, therefore no response is required.
- 95. The allegations in paragraph 95 are directed towards other defendants, therefore no response is required.

96. The allegations in paragraph 96 are directed towards other defendants, therefore no response is required.

6. Actavis Entities

- 97. The allegations in paragraph 97 are directed towards other defendants, therefore no response is required.
- 98. The allegations in paragraph 98 are directed towards other defendants, therefore no response is required.
- 99. The allegations in paragraph 99 are directed towards other defendants, therefore no response is required.
- 100. The allegations in paragraph 100 are directed towards other defendants, therefore no response is required.
- 101. The allegations in paragraph 101 are directed towards other defendants, therefore no response is required.
- 102. The allegations in paragraph 102 are directed towards other defendants, therefore no response is required.
- 103. The allegations in paragraph 103 are directed towards other defendants, therefore no response is required.
- 104. The allegations in paragraph 104 are directed towards other defendants, therefore no response is required.
- 105. The allegations in paragraph 105 are directed towards other defendants, therefore no response is required.
- 106. The allegations in paragraph 106 are directed towards other defendants, therefore no response is required.
 - 107. The allegations in paragraph 107 are directed towards other defendants, therefore

no response is required.

JURISDICTION AND VENUE

- 108. To the extent the allegations in paragraph 108 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 108 and therefore denies them.
- 109. To the extent the allegations in paragraph 109 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 109 and therefore denies them.
- 110. The allegations in paragraph 110 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson admits that the JPML found that cases transferred to the MDL "involve[] common questions of fact with the actions transferred to MDL No. 2740, and that transfer under 28 U.S.C. § 1407 will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 110 and therefore denies them.
- 111. To the extent the allegations in paragraph 111 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 111 and therefore denies them.

FACTUAL ALLEGATIONS

- I. DEVELOPMENT, APPROVAL, AND LABELING CHANGES FOR TAXOTERE, DOCETAXEL INJECTION, DOCETAXEL INJECTION CONCENTRATE, AND DOCEFREZ
- 112. McKesson admits that Taxotere is an FDA-approved chemotherapy drug indicated for the treatment of breast cancer. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 112 and therefore denies them.
- 113. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 113 and therefore denies them.
- 114. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 114 and therefore denies them.
- 115. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 115 and therefore denies them.
- 116. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 116 and therefore denies them.
- 117. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 117 and therefore denies them.
- 118. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 118 and therefore denies them.
- 119. To the extent the allegations in paragraph 119 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 119 and therefore denies them.
 - 120. The allegations in paragraph 120 are directed towards other defendants, therefore

no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 120 and therefore denies them.

- 121. The allegations in paragraph 121 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 121 and therefore denies them.
- 122. The allegations in paragraph 122 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 122 and therefore denies them.
- 123. The allegations in paragraph 123 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 123 and therefore denies them.
- 124. The allegations in paragraph 124 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 124 and therefore denies them.
- 125. The allegations in paragraph 125 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 125 and therefore denies them.

- 126. The allegations in paragraph 126 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 126 and therefore denies them.
- 127. The allegations in paragraph 127 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 127 and therefore denies them.
- 128. The allegations in paragraph 128 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 128 and therefore denies them.
- 129. The allegations in paragraph 129 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 129 and therefore denies them.
- 130. The allegations in paragraph 130 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 130 and therefore denies them.
- 131. The allegations in paragraph 131 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 131 and

therefore denies them.

- 132. The allegations in paragraph 132 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 132 and therefore denies them.
- 133. The allegations in paragraph 133 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 133 and therefore denies them.
- 134. The allegations in paragraph 134 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 134 and therefore denies them.
- 135. The allegations in paragraph 135 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 135 and therefore denies them.
- 136. The allegations in paragraph 136 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 136 and therefore denies them.
- 137. The allegations in paragraph 137 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have

information or knowledge sufficient to form a belief as to the allegations in paragraph 137 and therefore denies them.

II. DEFENDANTS' DUTIES UNDER THE FDCA AND STATE LAW

- 138. The allegations in paragraph 138 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 138 and therefore denies them.
- 139. The allegations in paragraph 139 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 139 and therefore denies them.
- 140. The allegations in paragraph 140 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it is an NDA holder of any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 140 and therefore denies them.
- 141. The allegations in paragraph 141 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel

Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 141 and therefore denies them.

- 142. The allegations in paragraph 142 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 142 and therefore denies them.
- 143. The allegations in paragraph 143 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson admits that federal law sets forth post-market surveillance requirements and that the statutes and regulations speak for themselves. McKesson denies that it is an NDA holder of any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 143 and therefore denies them.
- 144. The allegations in paragraph 144 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson admits that federal law sets forth labeling requirements and that the statutes and regulations speak for themselves. McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 144 and therefore denies them.

- 145. The allegations in paragraph 145 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson admits that federal law sets forth labeling requirements and that the statutes and regulations speak for themselves. McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 145 and therefore denies them.
- 146. The allegations in paragraph 146 are directed towards other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson admits that federal law sets forth labeling requirements and that the statutes and regulations speak for themselves. McKesson denies that it holds the NDA for any docetaxel product, including Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez. McKesson denies that it has the ability to use the CBE mechanism, as federal law prohibits McKesson from unilaterally changing the label for a drug when it is not the NDA holder. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 146 and therefore denies them.
- 147. To the extent the allegations in paragraph 147 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 147 and therefore denies them.
- III. DEFENDANTS KNEW THAT TAXOTERE, DOCEFREZ, DOCETAXEL INJECTION, AND DOCETAXEL INJECTION CONCENTRATE MAY CAUSE PERMANENT ALOPECIA.
 - 148. The allegations in paragraph 148 are directed towards other defendants, therefore

no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 148 and therefore denies them.

- 149. The allegations in paragraph 149 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 149 and therefore denies them.
- 150. The allegations in paragraph 150 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 150 and therefore denies them.
- 151. To the extent the allegations in paragraph 151 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 151 and therefore denies them.
- 152. To the extent the allegations in paragraph 152 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 152 and therefore denies them.
- 153. To the extent the allegations in paragraph 153 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 153 and therefore denies them.

- 154. To the extent the allegations in paragraph 154 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 154 and therefore denies them.
- 155. To the extent the allegations in paragraph 155 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 155 and therefore denies them.
- 156. To the extent the allegations in paragraph 156 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 156 and therefore denies them.
- 157. To the extent the allegations in paragraph 157 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 157 and therefore denies them.
- 158. To the extent the allegations in paragraph 158 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 158 and therefore denies them.
- 159. To the extent the allegations in paragraph 159 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 159 and therefore denies

them.

- 160. To the extent the allegations in paragraph 160 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 160 and therefore denies them.
- 161. To the extent the allegations in paragraph 161 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 161 and therefore denies them.
- 162. To the extent the allegations in paragraph 162 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 162 and therefore denies them.
- 163. To the extent the allegations in paragraph 163 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 163 and therefore denies them.
- 164. To the extent the allegations in paragraph 164 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 164 and therefore denies them.
- 165. To the extent the allegations in paragraph 165 are directed towards other defendants, no response is required. McKesson does not have information or knowledge

sufficient to form a belief as to the remaining allegations in paragraph 165 and therefore denies them.

- 166. The allegations in paragraph 166 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 166 and therefore denies them.
- 167. The allegations in paragraph 167 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 167 and therefore denies them.
- 168. The allegations in paragraph 168 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 168 and therefore denies them.
- 169. The allegations in paragraph 169 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 169 and therefore denies them.
- 170. To the extent the allegations in paragraph 170 are directed towards other defendants, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 170 and therefore denies them.
 - 171. To the extent the allegations in paragraph 171 are directed towards other

defendants and contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 171.

172. To the extent the allegations in paragraph 172 are directed towards other defendants and contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 172.

IV. TAXOTERE, DOCEFREZ, DOCETAXEL INJECTION, AND DOCETAXEL INJECTION CONCENTRATE CAUSED PERMANENT ALOPECIA IN MANY BREAST CANCER PATIENTS.

- 173. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 173 and therefore denies them.
- 174. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 174 and therefore denies them.
- 175. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 175 and therefore denies them.
- 176. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 176 and therefore denies them.
- 177. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 177 and therefore denies them.
- 178. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 178 and therefore denies them.
- 179. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 179 and therefore denies them.
- 180. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 180 and therefore denies them.
 - 181. McKesson does not have information or knowledge sufficient to form a belief as

to the allegations in paragraph 181 and therefore denies them.

- 182. The allegations in paragraph 182 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 182 and therefore denies them.
- 183. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 183 and therefore denies them.
- 184. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 184 and therefore denies them.
- 185. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 185 and therefore denies them.
- 186. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 186 and therefore denies them.
- 187. The allegations in paragraph 187 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson denies the allegations in paragraph 187.
- 188. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 188 and therefore denies them.
- 189. The allegations in paragraph 189 contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies the allegations in paragraph 189.

V. SANOFI MARKETED & PROMOTED TAXOTERE DESPITE KNOWING IT CAUSED PERMANENT ALOPECIA

190. The allegations in paragraph 190 are directed towards other defendants, therefore

no response is required.

- 191. The allegations in paragraph 191 are directed towards other defendants, therefore no response is required.
- 192. The allegations in paragraph 192 are directed towards other defendants, therefore no response is required.
- 193. The allegations in paragraph 193 are directed towards other defendants, therefore no response is required.
- 194. The allegations in paragraph 194 are directed towards other defendants, therefore no response is required.
- 195. The allegations in paragraph 195 are directed towards other defendants, therefore no response is required.
- 196. The allegations in paragraph 196 are directed towards other defendants, therefore no response is required.
- 197. The allegations in paragraph 197 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 197 and therefore denies them.
- 198. The allegations in paragraph 198 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 198 and therefore denies them.
- 199. The allegations in paragraph 199 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have

information or knowledge sufficient to form a belief as to the allegations in paragraph 199 and therefore denies them.

- 200. The allegations in paragraph 200 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 200 and therefore denies them.
- 201. The allegations in paragraph 201 are directed towards other defendants, therefore no response is required.
- 202. The allegations in paragraph 202 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 202 and therefore denies them.
- 203. The allegations in paragraph 203 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 203 and therefore denies them.
- 204. The allegations in paragraph 204 are directed towards other defendants, therefore no response is required.
- 205. The allegations in paragraph 205 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 205 and therefore denies them.
 - 206. The allegations in paragraph 206 are directed towards other defendants, therefore

no response is required.

- 207. The allegations in paragraph 207 are directed towards other defendants, therefore no response is required.
- 208. The allegations in paragraph 208 are directed towards other defendants, therefore no response is required.
- 209. The allegations in paragraph 209 are directed towards other defendants, therefore no response is required.
- 210. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 210 and therefore denies them.
- 211. The allegations in paragraph 211 are directed towards other defendants, therefore no response is required. To the extent a response is required, McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 211 and therefore denies them.
- 212. The allegations in paragraph 212 are directed towards other defendants, therefore no response is required.

VI. PERMANENT ALOPECIA IS DEVASTATING FOR PLAINTIFFS.

- 213. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 213 and therefore denies them.
- 214. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 214 and therefore denies them.
- 215. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 215 and therefore denies them.
- 216. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 216 and therefore denies them.

- 217. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 217 and therefore denies them.
- 218. McKesson does not have information or knowledge sufficient to form a belief as to the allegations in paragraph 218 and therefore denies them.
- 219. To the extent the allegations in paragraph 219 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 219 and therefore denies them.

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

- 220. McKesson incorporates by reference its responses to paragraphs 1-219 of the FAMLFC.
- 221. To the extent the allegations in paragraph 221 are directed towards other defendants, no response is required. McKesson admits that it sold and distributed two docetaxel products with NDC Codes 63739-971-17 and 63739-932-11 beginning March 26, 2015 and ending January 7, 2016 and April 20, 2016, respectively. McKesson denies that it designed, researched, manufactured, tested, promoted, or marketed Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 221 and therefore denies them.
- 222. To the extent the allegations in paragraph 222 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 222.

- 223. The allegations in paragraph 223 are directed towards other defendants, therefore no response is required.
- 224. To the extent the allegations in paragraph 224 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 224.
- 225. To the extent the allegations in paragraph 225 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 225.
- 226. To the extent the allegations in paragraph 226 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 226.
- 227. To the extent the allegations in paragraph 227 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 227.
- 228. To the extent the allegations in paragraph 228 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 228.
- 229. To the extent the allegations in paragraph 229 are directed toward other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 229.
- 230. To the extent the allegations in paragraph 230 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 230.

SECOND CLAIM FOR RELIEF

(Strict Products Liability for Misrepresentation – Against All Defendants)

231. The Court dismissed this claim (Dkt. No. 877), therefore no response is required to paragraphs 231-238.

THIRD CLAIM FOR RELIEF

(Negligence – Against All Defendants)

- 239. McKesson incorporates its responses to paragraphs 1-238 of the FAMLFC.
- 240. The allegations in paragraph 240 are directed toward other defendants or contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies the allegations in paragraph 240.
- 241. To the extent the allegations in paragraph 241 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 241.
- 242. To the extent the allegations in paragraph 242 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 242.
- 243. To the extent the allegations in paragraph 243 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 243.
- 244. To the extent the allegations in paragraph 244 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 244.
- 245. To the extent the allegations in paragraph 245 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the

remaining allegations in paragraph 245.

246. To the extent the allegations in paragraph 246 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 246.

FOURTH CLAIM FOR RELIEF

(Negligent Misrepresentation – Against All Defendants)

- 247. McKesson incorporates by reference its responses to paragraphs 1-246 of the FAMLFC.
- 248. The allegations in paragraph 248 are directed toward other defendants or contain conclusions of law, therefore no response is required.
- 249. To the extent the allegations in paragraph 249 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 249.
- 250. To the extent the allegations in paragraph 250 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 250.
- 251. To the extent the allegations in paragraph 251 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 251.
- 252. To the extent the allegations in paragraph 252 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 252.
- 253. To the extent the allegations in paragraph 253 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the

remaining allegations in paragraph 253.

- 254. To the extent the allegations in paragraph 254 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 254.
- 255. To the extent the allegations in paragraph 255 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 255.
- 256. To the extent the allegations in paragraph 256 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 256 and therefore denies them.
- 257. To the extent the allegations in paragraph 257 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 257.

FIFTH CLAIM FOR RELIEF

(Fraudulent Misrepresentation – Against All Defendants)

- 258. McKesson incorporates by reference its responses to paragraphs 1-257 of the FAMLFC.
- 259. To the extent the allegations in paragraph 259 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 259 and therefore denies them.
 - 260. To the extent the allegations in paragraph 260 are directed towards other

defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 260.

- 261. To the extent the allegations in paragraph 261 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 261.
- 262. To the extent the allegations in paragraph 262 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 262.
- 263. To the extent the allegations in paragraph 263 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 263.
- 264. To the extent the allegations in paragraph 264 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 264.
- 265. To the extent the allegations in paragraph 265 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 265.

SIXTH CLAIM FOR RELIEF

(Fraudulent Concealment – Against All Defendants)

- 266. McKesson incorporates by reference its responses to paragraphs 1-265 of the FAMLFC.
- 267. To the extent the allegations in paragraph 267 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 267.

- 268. To the extent the allegations in paragraph 268 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 268.
- 269. To the extent the allegations in paragraph 269 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 269.
- 270. The allegations in paragraph 270 contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 270 and therefore denies them.
- 271. To the extent the allegations in paragraph 271 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 271.
- 272. To the extent the allegations in paragraph 272 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 272.
- 273. To the extent the allegations in paragraph 273 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 273.
- 274. To the extent the allegations in paragraph 274 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 274.

275. To the extent the allegations in paragraph 275 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 275.

SEVENTH CLAIM FOR RELIEF

(Fraud and Deceit – Against All Defendants)

- 276. McKesson incorporates by reference its responses to paragraphs 1-275 of the FAMLFC.
- 277. To the extent the allegations in paragraph 277 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 277.
- 278. To the extent the allegations in paragraph 278 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 278.
- 279. To the extent the allegations in paragraph 279 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 279.
- 280. To the extent the allegations in paragraph 280 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 280.
- 281. The allegations in paragraph 281 contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 281 and therefore denies them.

- 282. The allegations in paragraph 282 contain conclusions of law, therefore no response is required. To the extent a response is required, McKesson denies that it had any obligation to warn that extended beyond the disclosures on the FDA-approved label. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 282 and therefore denies them.
- 283. To the extent the allegations in paragraph 283 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 283.
- 284. To the extent the allegations in paragraph 284 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 284.
- 285. To the extent the allegations in paragraph 285 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 285.
- 286. To the extent the allegations in paragraph 286 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 286.
- 287. To the extent the allegations in paragraph 287 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 287.
- 288. To the extent the allegations in paragraph 288 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 288.

- 289. To the extent the allegations in paragraph 289 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 289.
- 290. To the extent the allegations in paragraph 290 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 290.
- 291. To the extent the allegations in paragraph 291 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 291.
- 292. To the extent the allegations in paragraph 292 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 292.
- 293. To the extent the allegations in paragraph 293 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 293.
- 294. To the extent the allegations in paragraph 294 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 294.
- 295. To the extent the allegations in paragraph 295 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 295.
- 296. To the extent the allegations in paragraph 296 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the

remaining allegations in paragraph 296.

- 297. To the extent the allegations in paragraph 297 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 297.
- 298. To the extent the allegations in paragraph 298 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 298.
- 299. To the extent the allegations in paragraph 299 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 299.
- 300. To the extent the allegations in paragraph 300 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 300.
- 301. To the extent the allegations in paragraph 301 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 301.
- 302. To the extent the allegations in paragraph 302 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 302.
- 303. To the extent the allegations in paragraph 303 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 303.
 - 304. To the extent the allegations in paragraph 304 are directed towards other

defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 304.

- 305. To the extent the allegations in paragraph 305 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 305.
- 306. To the extent the allegations in paragraph 306 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 306.
- 307. To the extent the allegations in paragraph 307 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 307.
- 308. To the extent the allegations in paragraph 308 are directed towards other defendants or contain conclusions of law, no response is required. McKesson does not have information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 308 and therefore denies them.
- 309. To the extent the allegations in paragraph 309 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 309.
- 310. To the extent the allegations in paragraph 310 are directed towards other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 310.

EIGHTH CLAIM FOR RELIEF

(Breach of Express Warranty – Against Sanofi-Related Entities Only)

 877), therefore no response is required to paragraphs 311-318.

PLAINTIFFS' PRAYER FOR RELIEF

319. To the extent the allegations in paragraph 319 are directed toward other defendants or contain conclusions of law, no response is required. McKesson denies the remaining allegations in paragraph 319.

JURY DEMAND

320. McKesson admits that Plaintiffs request a jury demand. McKesson also respectfully demands a jury for trial of this matter.

SEPARATE AFFIRMATIVE DEFENSES

Without admitting any of the allegations in the FAMLFC and without admitting or acknowledging that McKesson has any burden to prove any of the following allegations,

McKesson alleges the following as separate and independent affirmative defenses:

FIRST DEFENSE (Failure to State a Claim)

The FAMLFC, and each of the alleged causes of action, fails to state a claim against McKesson upon which relief can be granted.

SECOND DEFENSE (Failure to Join Necessary or Indispensable Parties)

Plaintiffs have failed to join necessary or indispensable parties.

THIRD DEFENSE (Statute of Limitations or Repose)

The FAMLFC, and each cause of action stated therein, may be barred, in whole or in part, by applicable statutes of limitation or repose.

FOURTH DEFENSE (Proximate/Intervening/Superseding Cause)

Plaintiffs' alleged injuries or damages were caused in whole or in part by the acts or omissions of other persons over whom McKesson had no supervision or control, those acts or omissions being the sole proximate cause or an intervening or superseding cause of any injuries or damages sustained by Plaintiffs.

FIFTH DEFENSE (Claims are Barred/Need to Apportion Fault)

Plaintiffs' claims fail, in whole or in part, to the extent Plaintiffs' injuries and damages, if any, were caused by the acts or omissions of others, whether individual, corporate or otherwise, whether named or unnamed, for whom McKesson is not responsible. Judgment against McKesson, if any, should be reduced in proportion to each person's negligence, fault, or responsibility.

SIXTH DEFENSE (Product Modification)

If Plaintiffs were injured or damaged by a product distributed by McKesson, which McKesson denies, that product was altered, modified, or misused by persons over whom McKesson had no control or right of control, without McKesson's knowledge, consent, or advice, following the date of distribution of the product, and such alteration, modification, or misuse caused or contributed to the events alleged in the FAMLFC.

SEVENTH DEFENSE (Preemption)

Plaintiffs' claims are preempted by federal law in that the products at issue in this action were researched, tested, developed, manufactured, labeled, marketed, and sold in a manner consistent with the state of the art at the pertinent time and approved by the Food and Drug

Administration of the United States Department of Health and Human Services ("FDA"). Plaintiffs' claims against McKesson are also preempted as McKesson had no ability to alter the labels on the docetaxel products it sold without violating federal drug labeling laws. *PLIVA*, *Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

EIGHTH DEFENSE (State of Art)

Based on the state of scientific, medical, and technological knowledge existing at the time the products at issue in this action were allegedly administered to Plaintiffs, they were reasonably safe for their normal and foreseeable use at all relevant times, or in light of existing reasonably available medical, scientific, and technological knowledge.

NINTH DEFENSE (Collateral Source Rule)

Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources. Any verdict or judgment rendered against McKesson must be reduced by those amounts that have been, 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, workers' compensation, or employee benefit programs.

TENTH DEFENSE (Punitive Damages Barred or Limited)

Plaintiffs' punitive damages claims are barred or limited by provisions of the United States Constitution, state constitutions, or other applicable law including, without limitation, proscriptions against double jeopardy and excessive fines and provisions assuring due process of law and equal protection of the laws.

With respect to Plaintiffs' demands for punitive or exemplary damages, McKesson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

ELEVENTH DEFENSE (Claims Barred by *Buckman*)

To the extent Plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

TWELFTH DEFENSE (Compliance with Federal and State Statutes and Regulations/FDA Approval)

Plaintiffs' claims are barred and/or limited because McKesson complied with all applicable federal and state statutes and regulations in distributing its products, and/or because the drug was subject to premarket approval or licensure by the federal FDA under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq.

THIRTEENTH DEFENSE (Laches, Waiver and Estoppel)

Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver and/or estoppel.

FOURTEENTH DEFENSE (Pre-Existing Medical Condition)

Plaintiffs' claims are barred because the injuries, if any, were the result of pre-existing

medical conditions and were independent of, or far removed from, McKesson's conduct.

FIFTEENTH DEFENSE (Settlement Credit)

McKesson is entitled to a credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other defendant or other person or entity. If any codefendant, person or entity settles prior to verdict, McKesson will seek an allocation of the percentage of responsibility against the settling co-defendant, person or entity, whether or not there is an existing cross-claim against the settling co-defendant, person or entity at the time. McKesson reserves the right to obtain contribution and/or indemnity from such other codefendant, person or entity.

SIXTEENTH DEFENSE (Misuse of Product)

Plaintiffs' alleged injuries and damages, if any, may have been directly or proximately caused by misuse of a product distributed by McKesson, said misuse not being foreseeable to McKesson. Such misuse would bar any recovery against McKesson.

SEVENTEENTH DEFENSE (Assumption of Risk)

The FAMLFC, and each cause of action stated therein, may be barred, in whole or in part, by Plaintiffs' voluntary and knowing assumption of an unreasonable risk of injury and/or damage.

EIGHTEENTH DEFENSE (Learned Intermediary and/or Sophisticated User Doctrines)

Some or all of Plaintiffs' claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, Plaintiffs' prescribing physicians were

in the position of learned intermediaries, fully knowledgeable and informed with respect to the risks and benefits of the products at issue in this action.

NINETEENTH DEFENSE (Doctrine Concerning Unavoidably Unsafe Products)

Some or all of Plaintiffs' claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the Restatement (Second) of Torts and/or barred by the Restatement (Third) of Torts.

TWENTIETH DEFENSE (Informed Consent)

Plaintiffs were fully informed of the risks of the use of the product made the subject of this action by the treating physicians, and the informed consents and/or releases by Plaintiffs are pleaded as an affirmative defense.

TWENTY-FIRST DEFENSE (Bulk and/or Component Part Supplier)

Plaintiffs' claims are barred, in whole or in part, by the bulk and/or component part supplier doctrines. The raw materials which have allegedly caused injury to Plaintiffs (which causal connection McKesson denies), were supplied, if at all, by a bulk or component supplier, and therefore, McKesson cannot be held legally responsible for any lack of information or misinformation provided to Plaintiffs by others.

TWENTY-SECOND DEFENSE (Idiosyncratic Reaction)

Any damages sustained by Plaintiffs were caused by an idiosyncratic reaction to the products on which Plaintiffs base their alleged claims.

TWENTY-THIRD DEFENSE (Contributory/Comparative Negligence)

If Plaintiffs sustained any injury or incurred any loss or damage as alleged in the FAMLFC, the same was caused by Plaintiffs' own negligence or others in failing to exercise due and proper care under the existing circumstances and conditions, and damages against McKesson are barred or reduced by the doctrines of contributory or comparative negligence.

TWENTY-FOURTH DEFENSE (Reservation/Incorporation of Additional Defenses)

McKesson reserves the right to assert any additional defenses that might come to its attention or might be developed during the pendency of this action, and incorporates any and all other defenses raised by any other defendant in this litigation to the extent that said defenses are consistent with McKesson's assertion that it is not liable to any party for any amount whatsoever, and do not conflict with McKesson's affirmative defenses.

MCKESSON'S PRAYER FOR RELIEF

WHEREFORE, McKesson prays for judgment against Plaintiffs as follows:

- A. That the claims of Plaintiffs be dismissed, that Plaintiffs take nothing by this action, and that judgment on the FAMLFC be entered for McKesson;
- B. That McKesson be awarded the costs of defending this suit and attorneys' fees; and
 - C. That the Court grant such other relief as the Court may deem proper.

Dated: October 16, 2017 By: /s/ Erin M. Bosman

Erin M. Bosman (CA Bar No. 204987) Julie Y. Park (CA Bar No. 259929) MORRISON & FOERSTER LLP

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Attorneys for Defendant

MCKESSON PACKAGING SERVICES, a division of MCKESSON CORPORATION

CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2017, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

/s/ Erin M. Bosman

Erin M. Bosman (CA Bar No. 204987)