

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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

**DEFENDANT ACCORD HEALTHCARE, INC.’S ANSWER
TO PLAINTIFFS’ FIRST AMENDED MASTER LONG FORM COMPLAINT AND
DEMAND FOR JURY TRIAL**

Defendant Accord Healthcare, Inc., by and through counsel, responds to Plaintiffs’ First Amended Master Long Form Complaint and Demand for Jury Trial (the “Complaint”) as follows:

1. Paragraph 1 of the Complaint asserts a prefatory statement to which no response is required. To the extent a response is deemed required, Accord denies any allegations stated.
2. Paragraph 2 of the Complaint asserts a prefatory statement to which no response is required. To the extent a response is deemed required, Accord denies any allegations stated.
3. Paragraph 3 of the Complaint contains a statement about Plaintiffs to which no response is required; however, Accord denies any allegations with respect to waiver and/or claims not asserted.

INTRODUCTION

4. Paragraph 4 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

5. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore denies them.

6. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of the Complaint and therefore denies them.

7. Accord denies the allegations in the first sentence of Paragraph 7 of the Complaint regarding its alleged failure to warn. Accord lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 of the Complaint and therefore denies them and controverts any stated claim for relief.

THE PARTIES

A. Plaintiffs

8. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and therefore denies them.

9. Accord denies each and every allegation set forth in Paragraph 9 of the Complaint to the extent they refer to this answering Defendant.

10. The allegations in Paragraph 10 of the Complaint state legal conclusions to which no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

11. Accord denies each and every allegation set forth in Paragraph 11 of the Complaint, subparts (1)-(3) to the extent they refer to this answering Defendant.

B. Sanofi-Related Entities

12. The allegations set forth in Paragraph 12 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

13. The allegations set forth in Paragraph 13 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

14. The allegations set forth in Paragraph 14 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

15. The allegations set forth in Paragraph 15 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

16. The allegations set forth in Paragraph 16 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

17. The allegations set forth in Paragraph 17 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

18. The allegations set forth in Paragraph 18 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

19. The allegations set forth in Paragraph 19 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

20. The allegations set forth in Paragraph 20 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

21. The allegations set forth in Paragraph 21 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

22. The allegations set forth in Paragraph 22 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

23. The allegations set forth in Paragraph 23 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

24. The allegations set forth in Paragraph 24 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

25. The allegations set forth in Paragraph 25 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

26. The allegations set forth in Paragraph 26 of the Complaint of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

27. The allegations set forth in Paragraph 27 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

28. The allegations set forth in Paragraph 28 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

29. The allegations set forth in Paragraph 29 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

30. The allegations set forth in Paragraph 30 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

31. The allegations set forth in Paragraph 31 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

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

32. In response to Paragraph 32 of the Complaint, Accord admits only that it obtained approval to market Docetaxel/Docetaxel Injection pursuant to applicable Food and Drug

Administration (“FDA”) law and regulations. The remaining allegations are definitional and speak for themselves and therefore no response is required.

33. The applicable sections of the FDA speak for themselves and therefore no response is required to Paragraph 33 of the Complaint.

34. The applicable sections of the FDA speak for themselves and therefore no response is required to Paragraph 34 of the Complaint.

35. The applicable sections of the FDA speak for themselves and therefore no response is required to Paragraph 35 of the Complaint.

36. The applicable sections of the FDA speak for themselves and therefore no response is required to Paragraph 36 of the Complaint.

1. *Sandoz*

37. The allegations set forth in Paragraph 37 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

38. The allegations set forth in Paragraph 38 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

39. The allegations set forth in Paragraph 39 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

40. The allegations set forth in Paragraph 40 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

41. The allegations set forth in Paragraph 41 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

42. The allegations set forth in Paragraph 42 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

43. The allegations set forth in Paragraph 43 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

44. The allegations set forth in Paragraph 44 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

45. The allegations set forth in Paragraph 45 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

46. The allegations set forth in Paragraph 46 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

47. The allegations set forth in Paragraph 47 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

48. The allegations set forth in Paragraph 48 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

49. The allegations set forth in Paragraph 49 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

50. The allegations set forth in Paragraph 50 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

2. *Accord Healthcare & McKesson*

51. Accord admits the allegations contained in Paragraph 51 of the Complaint.

52. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint and therefore denies them.

53. Accord admits the allegations directed to it in Paragraph 53 of the Complaint. Accord denies the allegations directed to McKesson for lack of knowledge or information sufficient to form a belief as to their truth.

54. Accord denies for lack of knowledge, information, and otherwise each and every allegation in Paragraph 54 of the Complaint. Accord denies the allegations directed to McKesson for lack of knowledge or information sufficient to form a belief as to their truth.

55. In response to Paragraph 55 of the Complaint, Accord admits that it tested, manufactured, labeled, marketed, sold, and/or distributed Docetaxel/Docetaxel Injection approved by the FDA under NDA #201195 and denies the remaining allegations set forth in Paragraph 55 of the Complaint.

56. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of the Complaint and therefore denies them.

57. Accord's New Drug Application ("NDA") and the applicable FDA authority speak for themselves. To the extent any allegations are set forth in Paragraph 57 of the Complaint, Accord denies those allegations.

58. Accord's NDA and the applicable FDA authority speak for themselves. To the extent any allegations are set forth in Paragraph 58 of the Complaint, Accord denies those allegations.

59. Accord admits that it received FDA approval to market Docetaxel/Docetaxel Injection and denies any remaining allegations set forth in Paragraph 59 of the Complaint.

60. Accord states that the FDA approved prescribing information speaks for itself and further answering, Accord denies each and every allegation set forth in Paragraph 60 of the Complaint.

61. Accord states that the FDA submissions speak for themselves and further answering, Accord denies each and every allegation set forth in Paragraph 61 of the Complaint.

62. Accord states that the FDA submissions speak for themselves and further answering, Accord denies each and every allegation set forth in Paragraph 62 of the Complaint .

63. Accord states that the FDA approved prescribing information speaks for itself and further answering, Accord denies each and every allegation set forth in Paragraph 63 of the Complaint.

4. *Hospira Entities*¹

64. The allegations set forth in Paragraph 64 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

65. The allegations set forth in Paragraph 65 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

66. The allegations set forth in Paragraph 66 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

67. The allegations set forth in Paragraph 67 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

68. The allegations set forth in Paragraph 68 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

69. The allegations set forth in Paragraph 69 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

70. The allegations set forth in Paragraph 70 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

¹ Plaintiffs' Complaint did not include a subparagraph 3.

71. The allegations set forth in Paragraph 71 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

72. The allegations set forth in Paragraph 72 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

73. The allegations set forth in Paragraph 73 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

74. The allegations set forth in Paragraph 74 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

5. *Sun Pharma Entities & Caraco Labs*

75. The allegations set forth in Paragraph 75 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

76. The allegations set forth in Paragraph 76 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

77. The allegations set forth in Paragraph 77 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

78. The allegations set forth in Paragraph 78 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

79. The allegations set forth in Paragraph 79 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

80. The allegations set forth in Paragraph 80 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

81. The allegations set forth in Paragraph 81 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

82. The allegations set forth in Paragraph 82 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

83. The allegations set forth in Paragraph 83 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

84. The allegations set forth in Paragraph 84 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

85. The allegations set forth in Paragraph 85 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

6. Pfizer

86. The allegations set forth in Paragraph 86 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

87. The allegations set forth in Paragraph 87 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

88. The allegations set forth in Paragraph 88 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

89. The allegations set forth in Paragraph 89 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

90. The allegations set forth in Paragraph 90 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

91. The allegations set forth in Paragraph 91 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

92. The allegations set forth in Paragraph 92 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

93. The allegations set forth in Paragraph 93 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

94. The allegations set forth in Paragraph 94 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

95. The allegations set forth in Paragraph 95 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

96. The allegations set forth in Paragraph 96 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

7. *Actavis Entities*

97. The allegations set forth in Paragraph 97 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

98. The allegations set forth in Paragraph 98 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

99. The allegations set forth in Paragraph 99 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

100. The allegations set forth in Paragraph 100 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

101. The allegations set forth in Paragraph 101 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

102. The allegations set forth in Paragraph 102 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

103. The allegations set forth in Paragraph 103 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

104. The allegations set forth in Paragraph 104 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

105. The allegations set forth in Paragraph 105 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

106. The allegations set forth in Paragraph 106 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

107. The allegations set forth in Paragraph 107 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

JURISDICTION AND VENUE

108. Paragraph 108 of the Complaint contains statements of law to which no response is required.

109. The allegations in Paragraph 109 of the Complaint state legal conclusions to which no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

110. The allegations in Paragraph 110 of the Complaint state legal conclusions to which no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

111. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 111 of the Complaint.

FACTUAL ALLEGATIONS

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

112. Paragraph 112 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

113. Paragraph 113 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

114. Paragraph 114 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

115. Paragraph 115 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

116. Paragraph 116 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

117. Paragraph 117 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

118. Paragraph 118 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

119. Paragraph 119 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

120. Paragraph 120 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

121. Paragraph 121 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

122. Paragraph 122 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

123. Paragraph 123 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord

denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

124. Paragraph 124 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

125. Paragraph 125 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies any allegations stated.

126. Paragraph 126 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

127. Paragraph 127 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

128. Paragraph 128 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

129. Paragraph 129 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

130. Paragraph 130 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

131. Paragraph 131 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

132. Paragraph 132 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

133. Paragraph 133 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

134. Accord states that the FDA approved prescribing information speaks for itself and further answering, Accord denies each and every allegation set forth in Paragraph 134 of the Complaint.

135. Paragraph 135 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

136. Paragraph 136 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

137. Paragraph 137 of the Complaint does not assert factual allegations against Accord and therefore no response is required. To the extent a response is deemed required, Accord denies the allegations for lack of knowledge or information sufficient to form a belief about their truth.

II. Defendants' Duties Under the FDCA and State Law

138. Accord states that it was subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 138 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 138 of the Complaint.

139. Accord states that it was subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 139 of the Complaint to the extent they suggest

any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 139 of the Complaint.

140. Accord states that it was subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 140 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 140 of the Complaint.

141. Accord states that it was subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 141 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 141 of the Complaint.

142. The applicable FDA law and regulations speak for themselves.

143. Accord states that it was subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 143 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 143 of the Complaint.

144. The applicable FDA law and regulations speak for themselves and further answering, Accord denies each and every allegation set forth in Paragraph 144 of the Complaint.

145. The applicable FDA law and regulations speak for themselves and further answering, Accord denies each and every allegation set forth in Paragraph 145 of the Complaint.

146. The applicable FDA law and regulations speak for themselves and further answering, Accord denies each and every allegation set forth in Paragraph 146 of the Complaint.

147. Accord denies each and every allegation set forth in Paragraph 147 of the Complaint for lack of knowledge or information sufficient to form a belief about their truth. Accord further denies the allegations in Paragraph 147 of the Complaint to the extent they state legal conclusions to which no response is required.

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

148. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 148 of the Complaint and therefore denies them.

149. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 149 of the Complaint and therefore denies them.

150. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 150 of the Complaint and therefore denies them.

151. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 151 of the Complaint and therefore denies them.

152. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 152 of the Complaint and therefore denies them.

153. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 153 of the Complaint and therefore denies them.

154. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 154 of the Complaint and therefore denies them.

155. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 155 of the Complaint and therefore denies them.

156. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 156 of the Complaint and therefore denies them.

157. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 157 of the Complaint and therefore denies them.

158. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 158 of the Complaint and therefore denies them.

159. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 159 of the Complaint and therefore denies them.

160. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 160 of the Complaint and therefore denies them.

161. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 161 of the Complaint and therefore denies them.

162. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 162 of the Complaint and therefore denies them.

163. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 163 of the Complaint and therefore denies them.

164. The FDA approved prescribing information speaks for itself and further answering, Accord denies any allegation stated in Paragraph 164 of the Complaint.

165. The FDA approved prescribing information speaks for itself, and further answering, Accord denies any allegation stated in Paragraph 165 of the Complaint.

166. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 166 of the Complaint and therefore denies them.

167. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167 of the Complaint and therefore denies them.

168. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 168 of the Complaint and therefore denies them.

169. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 169 of the Complaint and therefore denies them.

170. The FDA approved prescribing information speaks for itself and further answering, Accord denies any allegation stated in Paragraph 170 of the Complaint.

171. Accord denies each and every allegation set forth in Paragraph 170 of the Complaint.

172. Accord denies each and every allegation set forth in Paragraph 171 of the Complaint.

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

173. The statements in Paragraph 173 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

174. The statements in Paragraph 174 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

175. The statements in Paragraph 175 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

176. The statements in Paragraph 176 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

177. The statements in Paragraph 177 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

178. The statements in Paragraph 178 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

179. The statements in Paragraph 179 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

180. The statements in Paragraph 180 of the Complaint do not contain allegations; however, to the extent factual allegations against Accord are stated, Accord denies them.

181. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 181 of the Complaint and therefore denies them.

182. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 182 of the Complaint and therefore denies them.

183. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 183 of the Complaint and therefore denies them.

184. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 184 of the Complaint and therefore denies them.

185. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 185 of the Complaint and therefore denies them.

186. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 186 of the Complaint and therefore denies them.

187. Accord states that the FDA approved prescribing information speaks for itself and further answering, Accord denies each and every allegation set forth in Paragraph 187 of the Complaint.

188. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 188 of the Complaint and therefore denies them.

189. Accord states that it was subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 189 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 189 of the Complaint.

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

190. The allegations set forth in Paragraph 190 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

191. The allegations set forth in Paragraph 191 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

192. The allegations set forth in Paragraph 192 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

193. The allegations set forth in Paragraph 193 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

194. The allegations set forth in Paragraph 194 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

195. The allegations set forth in Paragraph 195 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

196. The allegations set forth in Paragraph 196 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

197. The allegations set forth in Paragraph 197 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

198. The allegations set forth in Paragraph 198 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

199. The allegations set forth in Paragraph 199 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

200. The allegations set forth in Paragraph 200 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

201. The allegations set forth in Paragraph 201 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

202. The allegations set forth in Paragraph 202 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

203. The allegations set forth in Paragraph 203 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

204. The allegations set forth in Paragraph 204 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

205. The allegations set forth in Paragraph 205 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

206. The allegations set forth in Paragraph 206 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

207. The allegations set forth in Paragraph 207 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

208. The allegations set forth in Paragraph 208 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

209. The allegations set forth in Paragraph 209 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

210. The allegations set forth in Paragraph 210 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

211. The allegations set forth in Paragraph 211 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

212. The allegations set forth in Paragraph 212 of the Complaint are not directed to Accord and therefore no response is required from this answering Defendant.

VI. Permanent Alopecia is Devastating for Plaintiffs

213. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 213 of the Complaint and therefore denies them.

214. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 214 of the Complaint and therefore denies them.

215. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 215 of the Complaint and therefore denies them.

216. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 216 of the Complaint and therefore denies them.

217. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 217 of the Complaint and therefore denies them.

218. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 218 of the Complaint and therefore denies them.

219. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 219 of the Complaint and therefore denies them.

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

220. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

221. Accord admits that it manufactured, tested, marketed, sold, and/or distributed Docetaxel/Docetaxel Injection. Accord denies the remaining allegations set forth Paragraph 221 of the Complaint.

222. Accord denies each and every allegation in Paragraph 222 of the Complaint

223. Accord lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 223 of the Complaint and therefore denies them.

224. Accord denies each and every allegation in Paragraph 224 of the Complaint.

225. Accord denies each and every allegation in Paragraph 225 of the Complaint.

226. Accord denies each and every allegation in Paragraph 226 of the Complaint.

227. Accord denies each and every allegation in Paragraph 227 of the Complaint.

228. Accord denies each and every allegation in Paragraph 228 of the Complaint.

229. Accord denies each and every allegation in Paragraph 229 of the Complaint.

230. Accord denies each and every allegation in Paragraph 230 of the Complaint and controverts any stated claim for relief.

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

231. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

232. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

233. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

234. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

235. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

236. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

237. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

238. Pursuant to Pretrial Order No. 61, the Court dismissed Count II of the Complaint, so no response is required.

THIRD CLAIM FOR RELIEF
(Negligence -- Against All Defendants)

239. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

240. Accord states that it was subject only to those duties imposed by applicable law and denies the allegations set forth in Paragraph 240 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 240 of the Complaint.

241. Accord states that it was subject only to those duties imposed by applicable law and denies the allegations set forth in Paragraph 241 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 241 of the Complaint.

242. Accord denies each and every allegation in Paragraph 242 of the Complaint, including subparts (a)-(i).

243. Accord admits only that it continues to market, manufacture, distribute, and/or sell Docetaxel/Docetaxel Injection, and denies the remaining allegations in Paragraph 243 of the Complaint.

244. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 244 of the Complaint.

245. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 245 of the Complaint.

246. Accord denies each and every allegation in Paragraph 246 of the Complaint and controverts any stated claim for relief.

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

247. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

248. Accord states that it was subject only to those duties imposed by applicable law and denies the allegations set forth in Paragraph 248 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 248 of the Complaint.

249. Accord denies each and every allegation in Paragraph 249 of the Complaint.

250. Accord denies each and every allegation in Paragraph 250 of the Complaint.

251. Accord denies each and every allegation in Paragraph 251 of the Complaint.

252. Accord denies each and every allegation in Paragraph 252 of the Complaint.

253. Accord denies each and every allegation in Paragraph 253 of the Complaint.

254. Accord denies each and every allegation in Paragraph 254 of the Complaint.

255. Accord denies each and every allegation in Paragraph 255 of the Complaint.

256. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 256 of the Complaint.

257. Accord denies each and every allegation in Paragraph 257 of the Complaint and controverts any stated claim for relief.

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

258. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

259. Accord denies each and every allegation in Paragraph 259 of the Complaint.

260. Accord denies each and every allegation in Paragraph 260 of the Complaint.

261. Accord denies each and every allegation in Paragraph 261 of the Complaint.

262. Accord denies each and every allegation in Paragraph 262 of the Complaint.

263. Accord denies each and every allegation in Paragraph 263 of the Complaint.

264. Accord denies each and every allegation in Paragraph 264 of the Complaint.

265. Accord denies each and every allegation in Paragraph 265 of the Complaint and controverts any stated claim for relief.

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

266. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

267. Accord denies each and every allegation in Paragraph 267 of the Complaint.

268. Accord denies each and every allegation in Paragraph 268 of the Complaint.

269. Accord denies each and every allegation in Paragraph 269 of the Complaint.

270. Accord states that it was subject only to those duties imposed by applicable law and denies the allegations set forth in Paragraph 270 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 270 of the Complaint.

271. Accord denies each and every allegation in Paragraph 271 of the Complaint.

272. Accord denies each and every allegation in Paragraph 272 of the Complaint.

273. Accord denies each and every allegation in Paragraph 273 of the Complaint.

274. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 274 of the Complaint.

275. Accord denies each and every allegation in Paragraph 275 of the Complaint and controverts any stated claim for relief.

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

276. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

277. Accord denies each and every allegation in Paragraph 277 of the Complaint.

278. Accord denies each and every allegation in Paragraph 278 of the Complaint.

279. Accord denies each and every allegation in Paragraph 279 of the Complaint.

280. Accord denies each and every allegation in Paragraph 280 of the Complaint.

281. Accord states that it was subject only to those duties imposed by applicable law and denies the allegations set forth in Paragraph 281 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 281 of the Complaint.

282. Accord states that it was subject only to those duties imposed by applicable law and denies the allegations set forth in Paragraph 282 of the Complaint to the extent they suggest any different or greater duties. Further answering, Accord denies each and every allegation set forth in Paragraph 282 of the Complaint.

283. Accord denies each and every allegation in Paragraph 283 of the Complaint.

284. Accord denies each and every allegation in Paragraph 284 of the Complaint.

285. Accord denies each and every allegation in Paragraph 285 of the Complaint.

286. Accord denies each and every allegation in Paragraph 286 of the Complaint.

287. Accord denies each and every allegation in Paragraph 287 of the Complaint.

288. Accord denies each and every allegation in Paragraph 288 of the Complaint.

289. Accord denies each and every allegation in Paragraph 289 of the Complaint.

290. Accord denies each and every allegation in Paragraph 290 of the Complaint.
291. Accord denies each and every allegation in Paragraph 291 of the Complaint.
292. Accord denies each and every allegation in Paragraph 292 of the Complaint.
293. Accord denies each and every allegation in Paragraph 293 of the Complaint.
294. Accord denies each and every allegation in Paragraph 294 of the Complaint.
295. Accord denies each and every allegation in Paragraph 295 of the Complaint.
296. Accord denies each and every allegation in Paragraph 296 of the Complaint.
297. Accord denies each and every allegation in Paragraph 297 of the Complaint.
298. Accord denies each and every allegation in Paragraph 298 of the Complaint.
299. Accord denies each and every allegation in Paragraph 299 of the Complaint.
300. Accord denies each and every allegation in Paragraph 300 of the Complaint.
301. Accord denies each and every allegation in Paragraph 301 of the Complaint.
302. Accord denies each and every allegation in Paragraph 302 of the Complaint.
303. Accord denies each and every allegation in Paragraph 303 of the Complaint.
304. Accord denies each and every allegation in Paragraph 304 of the Complaint.
305. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 305 of the Complaint.
306. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 306 of the Complaint.
307. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 307 of the Complaint.

308. Accord denies for lack of knowledge, information, and otherwise each and every allegation set forth in Paragraph 308 of the Complaint.

309. Accord denies each and every allegation in Paragraph 309 of the Complaint.

310. Accord denies each and every allegation in Paragraph 310 of the Complaint and controverts any stated claim for relief.

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

311. Accord repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

312. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

313. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

314. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

315. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

316. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

317. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

318. Pursuant to Pretrial Order No. 61, the Court dismissed Count VIII of the Complaint, so no response is required.

PRAYER FOR RELIEF

319. Accord controverts any stated claim for relief.

JURY DEMAND

320. Accord demands a trial by jury on all issues so triable.

AFFIRMATIVE DEFENSES

1. Plaintiffs' First Amended Master Long Form Complaint fails to state a cause of action upon which relief can be granted.

2. Plaintiffs' First Amended Master Long Form Complaint fails to state a claim upon which relief can be granted for costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

3. Plaintiffs' First Amended Master Long Form Complaint fails to state a cause of action upon which relief can be granted because of lack of adequate product identification.

4. Plaintiffs' claims may be barred for lack of subject matter jurisdiction.

5. Plaintiffs' claims may be barred for lack of personal jurisdiction.

6. Plaintiffs may be barred from bringing some of the claims alleged in the Master Long-Form Complaint because Plaintiffs may lack standing or capacity to bring such claims.

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

8. Some or all of Plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of the law of any applicable state.

9. Plaintiffs' claims are barred by the doctrine of federal preemption (express or implied) – as established by statute, state, and federal case law – and are barred by the Supremacy Clause of the United States Constitution because the drug at issue is regulated by the U.S. Food and Drug Administration under the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and other federal statutes and regulations.

10. Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder.

11. Plaintiffs' claims are barred because Accord complied with all applicable state and federal statutes regarding the drug at issue, including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiffs' claims are not barred, Accord is entitled to a presumption that the drug at issue is free from any defect or defective condition as the plans or design for the drug at issue or the methods and techniques of manufacturing, inspecting, and testing the drug at issue was in conformity with government standards established for the industry that were in existence at the time the plans or designs for the drug at issue or the methods and techniques of manufacturing, inspecting, and testing the drug at issue were adopted.

12. Any claims by Plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the first amendment rights of Accord to petition the government.

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

14. Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of the Restatement (Third) of Torts (including comments to those Sections) because Accord complied with all applicable statutes and with the requirements and regulations of the FDA.

15. Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comments j and k.

16. Plaintiffs' claims are barred, in whole or in part, because Accord acted in good faith at all relevant times and gave adequate and complete warnings of all known or reasonably knowable risks associated with the use of its drugs.

17. At all relevant times, the warnings and instructions accompanying the drug at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the drug at issue were presumptively adequate.

18. Plaintiffs' inadequate warning claims are barred because the alleged risk upon which Plaintiffs' claim is based is open, obvious, and/or a matter of common knowledge.

19. Plaintiffs' causes of action are barred by the learned intermediary doctrine and because the end users of the drug at issue, Plaintiffs' physicians, were sophisticated users of the drug.

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

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

22. The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Accord given the state of scientific knowledge and state of the art at the time of the alleged injuries. At all times relevant, the drug at issue conformed to state-of-the-art specifications and state of scientific knowledge for such drugs at that time, as well as all applicable statutes and regulations, including those of the FDA.

23. Plaintiffs' claims are barred in whole or in part because the drug at issue was at all times properly tested, manufactured, labeled, marketed, sold, and/or distributed, and was not defective or unreasonably dangerous.

24. Accord states that the sole proximate cause of the injuries and/or damages alleged by Plaintiffs were the actions, omissions, or negligence of a person or persons, other than Accord, for whose actions, omissions, or negligence Accord is in no way liable. Plaintiffs are therefore not entitled to recover from Accord in this action. As to Plaintiffs or to any other entity or person whose conduct or intervening or superseding negligence may have caused Plaintiffs' alleged injuries and/or damages, if any, Accord expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law, or policy of the applicable states.

25. Accord expressly denies any third party engaging in the acts alleged by Plaintiffs that were acting as Accord's agent or servant, at the instruction of Accord, or within its control. Therefore, Plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

26. Accord's liability, if any, for Plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of the applicable state(s).

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

28. Plaintiffs' claims are barred in whole or in part because the drug at issue did not possess any characteristics that rendered it unreasonably dangerous.

29. Plaintiffs' claims are barred in whole or in part because the drug at issue provided a benefit to users of such drugs and greatly outweighed any risk created by using such drugs, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

30. Plaintiffs' alleged injuries, losses, or damages attributable to the use of the drug at issue in this case, if any, were caused solely by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse that was made of the drug at issue.

31. The drug at issue may have been altered after the drug left the control, custody and possession of Accord, and any said alteration relieves Accord of any and all liability.

32. Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were because of an allergic, idiosyncratic or idiopathic

reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Accord.

33. Plaintiffs' claims may be barred, in whole or in part, from recovery because of spoliation of evidence and the failure to preserve evidence necessary to the determination of the claim.

34. Plaintiffs' claims are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel.

35. Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

36. Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

37. Any recovery by Plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

38. Accord specifically pleads the applicability and exclusivity of the Louisiana Products Liability Act (LPLA), and specifically avers that Plaintiffs are not entitled to recovery under any of the exclusive theories of liability set forth in the LPLA.

39. Accord reserves any and all defenses available to it under the LPLA.

40. To the extent Plaintiffs make a claim for punitive damages, it is barred because the drug at issue was manufactured and labeled in accordance with the terms of FDA's approval of the drug at issue.

41. Plaintiffs' First Amended Master Long Form Complaint fails to state facts sufficient to entitle Plaintiffs to an award of punitive damages. No act or omission of Accord was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

42. The imposition of punitive or exemplary damages would violate Accord's constitutional rights, including but not limited to those under the Due Process Clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the Excessive Fines Clause in the Eighth Amendment to the Constitution of the United States and the Double Jeopardy Clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent *de novo* review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal

standards and in conformity with the United States Constitution as amended or any applicable state constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Accord's conduct within the State where Plaintiffs reside, or in any other way, they would subject Accord to impermissible multiple punishment for the same alleged wrong.

43. With respect to Plaintiffs' demand for punitive damages, Accord specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *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 Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Phillip Morris USA v. Williams*, 549 U.S. 346 (2007); and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under the applicable state's law.

44. To the extent that the applicable state law permits punitive damages to be measured by net worth or financial status of the defendant, and imposes greater punitive damages on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishment, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and by the similar and applicable provisions of the Constitution, law, and public policy of the applicable state's law.

45. Accord specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

46. Accord asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the applicable states.

47. Plaintiffs' claims may be barred and/or limited by the statutes of any state whose law is deemed to apply in this case, and/or under common law principles of any state whose law is deemed to apply in this case.

48. Accord specifically pleads as to Plaintiffs' strict liability claims, all affirmative defenses available to Accord under the rules and statutes of any state whose law is deemed to apply in this case, and under common law principles of any state whose law is deemed to apply in this case.

49. Accord specifically pleads as to Plaintiffs' negligence claims all affirmative defenses available to Accord under the rules and statutes of any state whose law is deemed to apply in this case, and under common law principles of any state whose law is deemed to apply in this case.

50. Accord specifically pleads as to Plaintiffs' fraud and misrepresentation claims, all affirmative defenses available to Accord under the rules and statutes of any state whose law is deemed to apply in this case, and under common law principles of any state whose law is deemed to apply in this case.

51. Accord reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

52. Accord is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in this state and any other state whose law is deemed to apply in this case.

53. Accord hereby gives notice that it intends to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and thus reserves the right to amend its Answer to assert such defenses.

Dated: October 16, 2017

Respectfully submitted,

/s/Julie A. Callsen

Julie A. Callsen (0062287)
Brandon D. Cox (0089815)
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5009
E-mail: julie.callsen@tuckerellis.com
brandon.cox@tuckerellis.com

/s/ Chad S. Sullivan

Chad S. Sullivan (27657)
KEOGH, COX & WILSON, LTD.
701 Main Street
Baton Rouge, LA 70802
Telephone: 225.383.3796
Facsimile: 225.343.9612
E-mail: csullivan@keoghcox.com

*Attorneys for Defendant
Accord Healthcare, Inc.*

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 who are CM/ECF participants.

/s/ Julie A. Callsen

Julie A. Callsen

015418\000001\3429876.2