

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: BENICAR (OLMESARTAN  
PRODUCTS LIABILITY LITIGATION**

**THIS DOCUMENT RELATES TO ALL  
ACTIONS**

**HON. ROBERT B. KUGLER**

**Civil No. 16-2606 (RBK) (JS)**

**MASTER ANSWER OF DEFENDANTS  
DAIICHI SANKYO, INC. AND DAIICHI  
SANKYO U.S. HOLDINGS, INC. AND  
JURY DEMAND**

Defendants Daiichi Sankyo, Inc. and Daiichi Sankyo U.S. Holdings, Inc. (collectively, “Daiichi U.S. Defendants”), respond to Plaintiffs’ Master Long Form Complaint (“Master Complaint”) as follows.

1. The Master Complaint speaks for itself. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor® and Tribenzor® are products of Daiichi Sankyo, Inc. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 1 of the Master Complaint.

2. The Daiichi U.S. Defendants admit that the medicines were promoted in accordance with the prescribing information. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 2 of the Master Complaint.

3. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 3 of the Master Complaint.

4. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 4 of the Master Complaint.

5. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 5 of the Master Complaint.
6. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 6 of the Master Complaint.
7. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor® and Tribenzor® are products of Daiichi Sankyo, Inc. in the United States. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 7 of the Master Complaint.
8. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. has pharmaceutical products which are sold in the United States and in New Jersey. All remaining allegations contained in Paragraph 8 of the Master Complaint are denied.
9. The Daiichi U.S. Defendants deny that the medicines at issue were and are defective and dangerous, and deny the allegations contained in Paragraph 9 of the Master Complaint.
10. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 10 of the Master Complaint.
11. The Daiichi U.S. Defendants admit that Plaintiffs claim damages in excess of \$75,000 exclusives of interest and costs but deny liability for same.
12. The Transfer Order filed by the Judicial Panel on Multidistrict Litigation on April 3, 2015 speaks for itself.
13. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 13 of the Master Complaint.
14. The Master Complaint speaks for itself. All remaining allegations contained in Paragraph 14 of the Master Complaint are denied.

15. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 15 of the Master Complaint.

16. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 16 of the Master Complaint.

17. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 17 of the Master Complaint.

18. The Daiichi U.S. Defendants deny the allegations in Paragraph 18 of the Master Complaint.

19. The Master Complaint speaks for itself. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 19 of the Master Complaint.

20. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. is a Delaware corporation with its principal place of business in New Jersey. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 20 of the Master Complaint.

21. The Daiichi U.S. Defendants admit that certain entities enumerated in Paragraph 21 were legacy companies, but deny the remaining allegations contained in Paragraph 21 of the Master Complaint.

22. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. has pharmaceutical products which are sold in the United States and in New Jersey. All remaining allegations contained in Paragraph 22 of the Master Complaint are denied.

23. The Daiichi U.S. Defendants admit that Daiichi Sankyo Pharma Development was in Edison, New Jersey and that Daiichi Sankyo Pharma Development had a group named Daiichi Sankyo Research Institute in Edison, New Jersey, which no longer exists. Further answering, the

Daiichi U.S. Defendants state that Daiichi Sankyo Pharma Development never is or was a legal entity. All remaining allegations contained in Paragraph 23 of the Master Complaint are denied.

24. The Daiichi U.S. Defendants admit that Daiichi Sankyo U.S. Holdings, Inc. is a Delaware corporation with its principal place of business in New Jersey. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 24 of the Master Complaint.

25. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. is a wholly-owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc.

26. The Daiichi U.S. Defendants admit that Daiichi Sankyo U.S. Holdings, Inc. operates as a holding company. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 26 of the Master Complaint.

27. The Daiichi U.S. Defendants admit that Daiichi Sankyo Company, Limited is a Japanese corporation with its principal place of business in Japan. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 27 of the Master Complaint.

28. The allegations contained in Paragraph 28 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary.

29. The allegations contained in Paragraph 29 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary.

30. The allegations contained in Paragraph 30 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they are directed to the Daiichi U.S. Defendants they are denied except that the Daiichi U.S. Defendants admit that Daiichi Sankyo Company, Limited is the parent company of Daiichi Sankyo U.S. Holdings, Inc., which is in turn the parent company of Daiichi Sankyo, Inc.

31. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. operates as the U.S. commercial home office and corporate headquarters of Daiichi Sankyo Company, Limited. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 31 of the Master Complaint.

32. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 32 of the Master Complaint.

33. The Daiichi U.S. Defendants admit that the Master Complaint refers to Daiichi Sankyo Japan, Daiichi Sankyo U.S., and Daiichi Sankyo U.S. Holdings, Inc. collectively as “Daiichi Sankyo,” but deny that it is appropriate because each is a distinct legal entity.

34. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. and are sold in the United States, including in the State of New Jersey. The remaining allegations contained in Paragraph 34 of the Master Complaint are denied as stated.

35. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. All the remaining allegations contained in Paragraph 35 of the Master Complaint are denied.

36. The allegations contained in Paragraph 36 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

37. The allegations contained in Paragraph 37 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

38. The allegations contained in Paragraph 38 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

39. The allegations contained in Paragraph 39 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

40. The allegations contained in Paragraph 40 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

41. The allegations contained in Paragraph 41 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

42. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. and Forest Laboratories, LLC entered into a Co-Promotion Agreement. The remaining allegations contained in Paragraph 42 of the Master Complaint are denied.

43. The Co-Promotion Agreements and addenda relating to Benicar® and Benicar HCT® speak for themselves. The Daiichi U.S. Defendants admit that Forest Laboratories, Inc. and Sankyo Pharma, Inc. entered into a Co-Promotion Agreement on December 11, 2001 relating to Benicar® and Benicar HCT®, which ended on May 31, 2008. The remaining allegations contained in Paragraph 43 of the Master Complaint are denied as stated.

44. The Co-Promotion Agreements and addenda relating to Azor® speak for themselves. The Daiichi U.S. Defendants admit that Forest Laboratories, Inc. and Daiichi Sankyo, Inc. entered into a Co-Promotion Agreement on October 12, 2007 relating to Azor®,

which ended on June 30, 2008. The remaining allegations contained in Paragraph 44 of the Master Complaint are denied as stated.

45. The allegations contained in Paragraph 45 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

46. The Daiichi U.S. Defendants admit that the Master Complaint refers to all defendants collectively, but deny that it is appropriate because each is a distinct legal entity.

47. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. has pharmaceutical products which are sold in New Jersey and that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. All remaining allegations contained in Paragraph 47 of the Master Complaint are denied.

48. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 48 of the Master Complaint.

49. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. has pharmaceutical products which are sold in the United States and that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. The remaining allegations contained in Paragraph 49 of the Master Complaint are denied as stated.

50. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 49 of the Master Complaint, as if fully set forth herein.

51. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 51 of the Master Complaint.

52. The Daiichi U.S. Defendants admit that olmesartan medoxomil is an angiotensin II receptor blocker (“ARB”) and that olmesartan medoxomil was the seventh entrant to the ARB

market. All the remaining allegations contained in Paragraph 52 of the Master Complaint are denied.

53. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 53 of the Master Complaint.

54. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. is a licensee under the '599 patent and is marketing and selling medicines containing olmesartan medoxomil throughout the United States, including within the State of New Jersey. All remaining allegations are denied as stated.

55. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 55 of the Master Complaint.

56. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 56 of the Master Complaint.

57. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 57 of the Master Complaint.

58. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 58 of the Master Complaint.

59. The Daiichi U.S. Defendants admit that "olmesartan medoxomil" is the generic name used for an active ingredient in Benicar®, Benicar HCT®, Azor®, and Tribenzor®. All remaining allegations contained in Paragraph 59 of the Master Complaint are denied.

60. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 60 of the Master Complaint.



61. The FDA-approved labeling speaks for itself. The Daiichi U.S. Defendants' marketing materials also speak for themselves. The Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 61 of the Master Complaint.

62. The Daiichi U.S. Defendants admit the allegations contained in Paragraph 62 of the Master Complaint.

63. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 63 of the Master Complaint.

64. The FDA-approved labeling speaks for itself. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 64 of the Master Complaint.

65. The allegations contained in Paragraph 65 of the Master Complaint cannot be answered in the manner in which they are stated and are therefore denied.

66. The Daiichi U.S. Defendants deny Plaintiffs have fairly or accurately characterized in Paragraph 66 of the Master Complaint FDA's statements. The FDA documents and the Mayo Clinic paper speak for themselves. All remaining allegations contained in Paragraph 66 of the Master Complaint, including subparts a through k are denied as stated.

67. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 67 of the Master Complaint, including subparts a through f.

68. The Daiichi U.S. Defendants deny that Plaintiffs have fairly or accurately characterized the statements in the publications identified in Paragraph 68 of the Master Complaint. The publications speak for themselves. The Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 68 of the Master Complaint.

69. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 69 of the Master Complaint.

70. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 70 of the Master Complaint.

71. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 71 of the Master Complaint.

72. The Daiichi U.S. Defendants admit that a very large number of people in the United States suffer from hypertension and are under treatment. The Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 72 of the Master Complaint.

73. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. has spent money promoting its products, but deny as stated the remaining allegations contained in Paragraph 73 of the Master Complaint.

74. The Co-Promotion Agreements speak for themselves. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 74 of the Master Complaint.

75. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 75 of the Master Complaint.

76. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 76 of the Master Complaint.

77. Communications from the FDA speak for themselves. Further answering, the Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 77 of the Master Complaint.

78. Communications from the FDA speak for themselves. Further answering, the Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 78 of the Master Complaint.

79. The Daiichi U.S. Defendants admit that certain promotional materials were discontinued. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 79 of the Master Complaint.

80. Communications from the FDA speak for themselves. Further answering, the Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 80 of the Master Complaint.

81. Communications from the FDA speak for themselves. Further answering, the Daiichi U.S. Defendants deny as stated the remaining allegations contained in Paragraph 81 of the Master Complaint.

82. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 82 of the Master Complaint.

83. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 83 of the Master Complaint.

84. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. was named as a party to the action in the United States District Court for the District of Massachusetts case captioned *United States, et al., ex rel. Fragoules v. Daiichi Sankyo, Inc., et al.*, Civil Action No. 10.10420-NG. Said Complaint speaks for itself. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 84 of the Master Complaint.

85. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. received a subpoena from the United States Department of Justice which speaks for itself. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 85 of the Master Complaint.

86. The allegations contained in Paragraph 86 of the Master Complaint are not directed to the Daiichi U.S. Defendants and therefore no response is necessary. To the extent they may be read to assert allegations as to the Daiichi U.S. Defendants, they are denied.

87. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. received a subpoena from the Office of the California Insurance Commissioner. Said subpoena speaks for itself. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 87 of the Master Complaint.

88. The allegations of the Fragoules Complaint speak for themselves. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 88 of the Master Complaint.

89. The allegations of the Fragoules Complaint speak for themselves. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 89 of the Master Complaint.

90. The Corporate Integrity Agreement, Settlement Agreement, and the Signed Stipulation of Dismissal speak for themselves. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 90 of the Master Complaint.

91. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 91 of the Master Complaint and therefore deny them.

92. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 92 of the Master Complaint and therefore deny them.

93. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 93 of the Master Complaint and therefore deny them.

94. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 94 of the Master Complaint and therefore deny them.

95. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 95 of the Master Complaint.

96. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 96 of the Master Complaint.

97. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 97 of the Master Complaint.

98. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 98 of the Master Complaint.

99. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 99 of the Master Complaint and therefore deny them. Further answering, the Daiichi U.S. Defendants specifically deny that their products caused any injury to Plaintiffs. The remaining allegations contained in Paragraph 99 are denied.

100. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 99 of the Master Complaint, as if fully set forth herein.

101. The Daiichi U.S. Defendants deny the allegations in Paragraph 101 of the Master Complaint.

102. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 102 of the Master Complaint.

103. Paragraph 103 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 103 of the Master Complaint.

104. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 104 of the Master Complaint.

105. The Daiichi U.S. Defendants deny that the products at issue were defective. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 105 of the Master Complaint.

106. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 106 of the Master Complaint.

107. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 107 of the Master Complaint.

108. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 107 of the Master Complaint, as if fully set forth herein.

109. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 109 of the Master Complaint.

110. The Daiichi U.S. Defendants admit that Daiichi Sankyo, Inc. has pharmaceutical products which are sold in the United States and that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 110 of the Master Complaint.

111. The Daiichi U.S. Defendants admit that they expect the products of Daiichi Sankyo, Inc. to reach patients to whom they are prescribed without substantial or material change. The Daiichi U.S. Defendants lack knowledge or information sufficient to form a belief as to the truth

of the allegation that the olmesartan products reached Plaintiffs without substantial change in condition and therefore deny those allegations. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 111 as stated.

112. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 112 of the Master Complaint.

113. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 113 of the Master Complaint, including subparts a through h.

114. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 114 of the Master Complaint.

115. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 115 of the Master Complaint.

116. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 116 of the Master Complaint.

117. Paragraph 117 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations in Paragraph 117 of the Master Complaint.

118. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 118 of the Master Complaint.

119. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 119 of the Master Complaint and therefore deny them.

120. The Daiichi U.S. Defendants deny that the products at issue were defective. The remaining allegations are denied as stated.

121. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 121 of the Master Complaint.

122. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 122 of the Master Complaint.

123. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 123 of the Master Complaint.

124. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 124 of the Master Complaint.

125. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 125 of the Master Complaint.

126. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 126 of the Master Complaint.

127. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 127 of the Master Complaint.

128. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 128 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

129. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 128 of the Master Complaint, as if fully set forth herein.



130. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. and are sold in the United States. The remaining allegations contained in Paragraph 130 of the Master Complaint are denied as stated.

131. Paragraph 131 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. and are sold in the United States. The remaining allegations contained in Paragraph 131 of the Master Complaint are denied as stated.

132. The Daiichi U.S. Defendants admit that the medicines should reach the patients without any substantial change in condition. The Daiichi U.S. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation that the product at issue reached Plaintiffs and Plaintiffs' prescribing healthcare professionals without substantial change in condition and therefore deny those allegations. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 132 as phrased.

133. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 133 of the Master Complaint.

134. The Daiichi U.S. Defendants deny that the products at issue were defective. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 134 of the Master Complaint.

135. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 135 of the Master Complaint.

136. The Daiichi U.S. Defendants deny that the products at issue were defective. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 136 of the Master Complaint.

137. Paragraph 137 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 137 of the Master Complaint.

138. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 138 of the Master Complaint.

139. Paragraph 139 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 139 of the Master Complaint.

140. Paragraph 140 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 140 of the Master Complaint.

141. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 141 of the Master Complaint.

142. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 142 of the Master Complaint.

143. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 143 of the Master Complaint.

144. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 144 of the Master Complaint.

145. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 145 of the Master Complaint.

146. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 146 of the Master Complaint.

147. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 147 of the Master Complaint.

148. Paragraph 148 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 148 of the Master Complaint.

149. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 149 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

150. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 149 of the Master Complaint, as if fully set forth herein.

151. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 151 of the Master Complaint.

152. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 152 of the Master Complaint.

153. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 153 of the Master Complaint.

154. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 154 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

155. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 154 of the Master Complaint, as if fully set forth herein.

156. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 156 of the Master Complaint.

157. Paragraph 157 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 157 of the Master Complaint.

158. Paragraph 158 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 158 of the Master Complaint.

159. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 159 of the Master Complaint.

160. Paragraph 160 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 160 of the Master Complaint.

161. Paragraph 161 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 161 of the Master Complaint.

162. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 162 of the Master Complaint.

163. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 163 of the Master Complaint.

164. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 164 of the Master Complaint.

165. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 165 of the Master Complaint.

166. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 166 of the Master Complaint.

167. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 167 of the Master Complaint.

168. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 168 of the Master Complaint.

169. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 169 of the Master Complaint.

170. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 170 of the Master Complaint, including subparts a through u.

171. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 171 of the Master Complaint.

172. The Daiichi U.S. Defendants deny that the products at issue were defective. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 172 of the Master Complaint.

173. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 173 of the Master Complaint.

174. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 174 of the Master Complaint.

175. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 175 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

176. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 175 of the Master Complaint, as if fully set forth herein.

177. Paragraph 177 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 177 of the Master Complaint.

178. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 178 of the Master Complaint.

179. Paragraph 179 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 179 of the Master Complaint.

180. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 180 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against Defendant.

181. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 180 of the Master Complaint, as if fully set forth herein.

182. Paragraph 182 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 182 of the Master Complaint.

183. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 183 of the Master Complaint.

184. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 184 of the Master Complaint.

185. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 185 of the Master Complaint.

186. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 186 of the Master Complaint.

187. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 187 of the Master Complaint.

188. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 188 of the Master Complaint.

189. Paragraph 189 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 189 of the Master Complaint.

190. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 190 of the Master Complaint.

191. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 191 of the Master Complaint.

192. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 192 of the Master Complaint.

193. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 193 of the Master Complaint.

194. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 194 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

195. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 194 of the Master Complaint, as if fully set forth herein.

196. Paragraph 196 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 196 of the Master Complaint.

197. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 197 of the Master Complaint, including subparts a through h.

198. The Daiichi U.S. Defendants admit that they expect the products of Daiichi Sankyo, Inc. to reach patients to whom they are prescribed without substantial or material change. The Daiichi U.S. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation that the olmesartan products reached consumers, handlers, and persons coming into contact with the medicines at issue without substantial change in condition and therefore deny those allegations. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 198 as stated.



199. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 199 of the Master Complaint.

200. Paragraph 200 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 200 of the Master Complaint.

201. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 201 of the Master Complaint and therefore deny them.

202. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 202 of the Master Complaint.

203. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 203 of the Master Complaint.

204. The Daiichi U.S. Defendants deny that the products at issue were defective. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 204 of the Master Complaint.

205. The Daiichi U.S. Defendants deny that the products at issue were defective. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 205 of the Master Complaint.

206. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 206 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

207. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 206 of the Master Complaint, as if fully set forth herein.

208. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 208 of the Master Complaint.

209. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 209 of the Master Complaint.

210. Paragraph 210 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations in Paragraph 210 of the Master Complaint, including subparts a through c.

211. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 211 of the Master Complaint.

212. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 212 of the Master Complaint.

213. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 213 of the Master Complaint.

214. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 214 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

215. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 214 of the Master Complaint, as if fully set forth herein.

216. The Daiichi U.S. Defendants deny as stated the allegations contained in Paragraph 216 of the Master Complaint.

217. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 217 of the Master Complaint.

219. [sic] The Daiichi U.S. Defendants deny the allegations contained in Paragraph 219 of the Master Complaint.

220. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 220 of the Master Complaint.

221. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 221 of the Master Complaint.

222. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 222 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

223. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 222 of the Master Complaint, as if fully set forth herein.

224. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 224 of the Master Complaint.

225. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 225 of the Master Complaint.

226. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 226 of the Master Complaint.

227. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 227 of the Master Complaint, including subparts a through i.

228. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 228 of the Master Complaint.

229. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 229 of the Master Complaint.

230. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 230 of the Master Complaint.

231. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 231 of the Master Complaint.

232. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 232 of the Master Complaint.

233. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 233 of the Master Complaint.

234. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 234 of the Master Complaint.

235. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 235 of the Master Complaint.

236. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 236 of the Master Complaint.

237. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 237 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

238. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 237 of the Master Complaint, as if fully set forth herein.

239. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 239 of the Master Complaint.

240. Paragraph 240 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants further deny the allegations contained in Paragraph 240 of the Master Complaint.

241. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 241 of the Master Complaint.

242. Paragraph 242 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 242 of the Master Complaint.

243. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 243 of the Master Complaint.

244. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 244 of the Master Complaint.

245. Paragraph 245 contains legal statements or conclusions to which no response is required. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 245 of the Master Complaint, including subparts a through c.

246. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 246 of the Master Complaint.

247. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 247 of the Master Complaint.

248. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 248 of the Master Complaint.

249. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 249 of the Master Complaint.

250. The Daiichi U.S. Defendants are without knowledge or information as to the truth of the allegations contained in Paragraph 250 of the Master Complaint and they are therefore denied.

251. The Daiichi U.S. Defendants deny any falsity or incompleteness in statements or representations they made with regard to olmesartan products. The Daiichi U.S. Defendants further deny the allegations contained in Paragraph 251 of the Master Complaint.

252. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 252 of the Master Complaint.

253. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 253 of the Master Complaint.

254. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 254 of the Master Complaint.

255. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 255 of the Master Complaint.

256. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 256 of the Master Complaint.

257. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 257 of the Master Complaint.

258. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 258 of the Master Complaint.

259. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 259 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

260. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 259 of the Master Complaint, as if fully set forth herein.

261. The Daiichi U.S. Defendants admit that Benicar®, Benicar HCT®, Azor®, and Tribenzor® are products of Daiichi Sankyo, Inc. All the remaining allegations contained in Paragraph 261 of the Master Complaint are denied.

262. Paragraph 262 contains legal statements or conclusions to which no response is required, and is therefore denied.

263. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 263 of the Master Complaint.

264. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 264 of the Master Complaint.

265. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 265 of the Master Complaint.

266. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 266 of the Master Complaint.

267. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 267 of the Master Complaint.

268. The Daiichi U.S. Defendants admit that they expect the products of Daiichi Sankyo, Inc. to reach patients to whom they are prescribed without substantial or material change. The Daiichi U.S. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation that the olmesartan products reached Plaintiffs without substantial change in condition and therefore deny those allegations. The Daiichi U.S. Defendants deny the remaining allegations contained in Paragraph 268.

269. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 269 of the Master Complaint.

270. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 270 of the Master Complaint and therefore deny them.

271. The Daiichi U.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 271 of the Master Complaint and therefore deny them.

272. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 272 of the Master Complaint.



273. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 273 of the Master Complaint.

274. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 274 of the Master Complaint.

275. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 275 of the Master Complaint.

276. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 276 of the Master Complaint.

277. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 277 of the Master Complaint.

278. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 278 in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

279. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 278 of the Master Complaint, as if fully set forth herein.

280. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 280 of the Master Complaint.

281. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 281 of the Master Complaint.

282. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 282 of the Master Complaint.

283. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 283 of the Master Complaint.

284. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 284 of the Master Complaint.

285. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 285 of the Master Complaint.

286. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 286 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

287. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 286 of the Master Complaint, as if fully set forth herein.

288. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 288 of the Master Complaint.

289. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 289 of the Master Complaint.

290. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 290 of the Master Complaint.

291. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 291 of the Master Complaint.

292. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 292 of the Master Complaint.

293. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 293 of the Master Complaint.

294. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 294 of the Master Complaint.

295. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 295 of the Master Complaint.

296. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 296 of the Master Complaint.

297. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 297 of the Master Complaint.

298. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 298 of the Master Complaint.

299. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 299 of the Master Complaint.

300. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 300 of the Master Complaint.

301. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 301 of the Master Complaint.

302. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 302 of the Master Complaint.

303. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 303 of the Master Complaint.

304. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 304 of the Master Complaint.

305. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 305 of the Master Complaint.

306. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 306 of the Master Complaint.

307. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 307 of the Master Complaint.

308. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 308 of the Master Complaint.

309. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 309 of the Master Complaint.

310. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 310 of the Master Complaint.

311. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 311 of the Master Complaint.

312. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 312 of the Master Complaint.

313. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 313 of the Master Complaint.

314. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 314 of the Master Complaint.

315. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 315 of the Master Complaint.

316. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 316 of the Master Complaint.

317. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 317 of the Master Complaint.

318. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 318 of the Master Complaint.

319. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 319 of the Master Complaint.

320. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 320 of the Master Complaint.

321. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 321 of the Master Complaint.

322. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 322 of the Master Complaint.

323. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 323 of the Master Complaint.

324. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 324 of the Master Complaint.

325. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 325 of the Master Complaint.

326. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 326 of the Master Complaint.

327. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 327 of the Master Complaint.

328. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 328 of the Master Complaint.

329. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 329 of the Master Complaint.

330. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 330 of the Master Complaint.

331. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 331 of the Master Complaint.

332. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 332 of the Master Complaint.

333. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 333 of the Master Complaint.

334. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 334 of the Master Complaint.

335. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 335 of the Master Complaint.

336. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 336 of the Master Complaint.

337. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 337 of the Master Complaint.

338. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 338 of the Master Complaint.

339. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 339 of the Master Complaint.

340. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 340 of the Master Complaint.

341. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 341 of the Master Complaint.

342. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 342 in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

343. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 342 of the Master Complaint, as if fully set forth herein.

344. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 344 of the Master Complaint.

345. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 345 of the Master Complaint.

346. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 346 of the Master Complaint.

347. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 347 of the Master Complaint.

348. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 348 of the Master Complaint.

349. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 349 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

350. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 349 of the Master Complaint, as if fully set forth herein.

351. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 351 of the Master Complaint.

352. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 352 of the Master Complaint.

353. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 353 of the Master Complaint.

354. The Daiichi U.S. Defendants are without knowledge or information as to the allegations contained in Paragraph 354 of the Master Complaint, and therefore deny all allegations contained in Paragraph 354 of the Master Complaint. The Daiichi U.S. Defendants specifically deny any liability to Plaintiffs, their lawful heirs, and their representatives/administrators. All remaining allegations are denied as stated.

355. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 355 of the Master Complaint.

356. The Daiichi U.S. Defendants are without knowledge or information as to the allegations contained in Paragraph 356 of the Master Complaint, and therefore deny all allegations contained in Paragraph 356 of the Master Complaint. The Daiichi U.S. Defendants specifically deny any



liability to Plaintiffs, their lawful heirs, and their representatives/administrators. All remaining allegations are denied as stated.

357. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 357 of the Master Complaint.

358. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 358 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

359. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 358 of the Master Complaint, as if fully set forth herein.

360. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 360 of the Master Complaint.

361. The Daiichi U.S. Defendants are without knowledge or information as to the allegations contained in Paragraph 361 of the Master Complaint, and therefore deny all allegations contained in Paragraph 361 of the Master Complaint. The Daiichi U.S. Defendants specifically deny any liability to Plaintiffs, their beneficiaries, and their representatives/administrators. All remaining allegations are denied as stated.

362. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 362 of the Master Complaint.

363. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 363 of the Master Complaint.

The Daiichi U.S. Defendants deny the allegations in the unnumbered paragraph at the conclusion of this section of the Master Complaint in which Plaintiffs include a prayer for relief against the Daiichi U.S. Defendants.

364. The Daiichi U.S. Defendants incorporate their responses to the allegations contained in Paragraphs 1 through 363 of the Master Complaint, as if fully set forth herein.

365. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 365 of the Master Complaint.

366. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 366 of the Master Complaint.

367. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 367 of the Master Complaint.

368. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 368 of the Master Complaint.

369. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 369 of the Master Complaint.

370. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 370 of the Master Complaint.

371. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 371 of the Master Complaint.

372. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 372 of the Master Complaint.

373. The Daiichi U.S. Defendants deny the allegations contained in Paragraph 373 of the Master Complaint.

The Daiichi U.S. Defendants incorporate by reference as if fully set forth their responses to the allegations contained in Paragraphs 1 through 373 of the Master Complaint.

The Daiichi U.S. Defendants deny that Plaintiffs are entitled to any of the damages requested in the Master Complaint, including each subpart identified in the “Relief Requested” section of the Master Complaint.

### **SEPARATE DEFENSES**

Having answered the allegations in the Master Complaint and having denied any liability whatsoever, the Daiichi U.S. Defendants further deny any allegations that have not been expressly admitted and assert the following separate defenses:

#### **FIRST SEPARATE DEFENSE**

Plaintiffs’ Master Complaint fails, in whole or in part, to state a cause of action upon which relief may be granted.

#### **SECOND SEPARATE DEFENSE**

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

#### **THIRD SEPARATE DEFENSE**

Plaintiffs’ alleged injuries attributable to the use of the products at issue in this case, if any, were not caused by the products at issue, but instead were caused by intervening and superseding causes or circumstances.

#### **FOURTH SEPARATE DEFENSE**

The Daiichi U.S. Defendants did not make to Plaintiffs nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs relied on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with the Daiichi U.S. Defendants and/or for failure of Plaintiffs, or Plaintiffs’

representatives, to give timely notice to the Daiichi U.S. Defendants of any alleged breach of warranty. The Daiichi U.S. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future.

#### **FIFTH SEPARATE DEFENSE**

At the time of sale or delivery, the products conformed to state-of-the-art for such products at that time.

#### **SIXTH SEPARATE DEFENSE**

Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

#### **SEVENTH SEPARATE DEFENSE**

Plaintiffs' claims against the Daiichi U.S. Defendants are barred in whole or any part by the applicable statute of limitations, statutes of repose, and doctrine of laches.

#### **EIGHTH SEPARATE DEFENSE**

Any claim for punitive or exemplary damages against the Daiichi U.S. Defendants is unconstitutional in that recovery of punitive or exemplary damages in this case would violate the Daiichi U.S. Defendants' constitutional rights to due process and equal protection under the Fourteenth Amendment to the Constitution of the United States and similar protections afforded by the New Jersey state constitution, and any other state whose law is deemed to apply in this case, and that any law of the state of New Jersey, whether enacted by that state's legislature or founded upon a decision or decisions of the courts, or that of any other state whose law is deemed to apply in this case, that would permit recovery of punitive or exemplary damages, is unconstitutional under these provisions.

### **NINTH SEPARATE DEFENSE**

Any claim for punitive or exemplary damages against the Daiichi U.S. Defendants is unconstitutional in that the standards for granting and asserting punitive or exemplary damages do not prohibit other plaintiffs from seeking and recovering such damages against the Daiichi U.S. Defendants for the same allegations of defect in the same products, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of the Daiichi U.S. Defendants' property without due process of law and will result in unjustified windfalls for Plaintiffs and Plaintiffs' counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the New Jersey state constitution, and that of any other state whose law is deemed to apply in this case.

### **TENTH SEPARATE DEFENSE**

Any claim for punitive damages against the Daiichi U.S. Defendants cannot be maintained because an award of punitive damages under current New Jersey law, and any other state's law deemed to apply to this action, would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Eighth and Fourteenth Amendments to the United States Constitution, the due process provisions of the New Jersey state constitution, and the common law and public policies of the state of New Jersey, and similar protections afforded by any other state whose law is deemed to apply in this case.

### **ELEVENTH SEPARATE DEFENSE**

To the extent that the laws of New Jersey, and any other state whose law is deemed to apply in this case, permit punishment to be measured by the net worth or financial status of the Daiichi U.S. Defendants and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, allows punishment to be imposed based on lawful profits and conduct of the Daiichi U.S. Defendants in other states, 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, the state laws and constitutional provisions of New Jersey, and similar protections afforded by any other state whose law is deemed to apply in this case.

### **TWELFTH SEPARATE DEFENSE**

The Daiichi U.S. Defendants are entitled to the protections and limitations afforded under the New Jersey Punitive Damages Act, N.J.S.A. §§ 2A:15-5.9, *et seq.* and the New Jersey Product Liability Act, N.J.S.A. §§ 2A:58C-1, *et seq.*

### **THIRTEENTH SEPARATE DEFENSE**

The Daiichi U.S. Defendants are entitled to, and claim the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in the Plaintiffs' alleged states of citizenship and residence, and any other state whose law is deemed to apply in this case. The Daiichi U.S. Defendants reserve the right to assert any additional defenses in which may be disclosed during the course of additional investigation and discovery.

#### **FOURTEENTH SEPARATE DEFENSE**

Plaintiffs' claims, with the exception of Plaintiffs' claims for punitive damages (as currently pled in the Master Complaint), are governed by the law of the home states of the Plaintiffs.

#### **FIFTEENTH SEPARATE DEFENSE**

The claims of Plaintiffs should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence and the New Jersey Joint Tortfeasors Law, N.J.S.A. § 2A:53A-3, *et seq.* and/or the applicable comparative negligence law of the Plaintiffs' home states.

#### **SIXTEENTH SEPARATE DEFENSE**

The injuries and damages claimed by Plaintiffs, if any, were caused in whole or in part by the acts or omissions of persons over whom the Daiichi U.S. Defendants have no control or right of control.

#### **SEVENTEENTH SEPARATE DEFENSE**

Plaintiffs' claims are barred by the equitable doctrine of estoppel.

#### **EIGHTEENTH SEPARATE DEFENSE**

Upon information and belief, if the injuries referred to in the Master Complaint were caused by the prescription medicine alleged to be at issue here, which is denied, the injuries are the result of an idiosyncratic reaction to the products.

#### **NINETEENTH SEPARATE DEFENSE**

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

#### **TWENTIETH SEPARATE DEFENSE**

Benicar®, Benicar HCT®, Azor®, and Tribenzor® are prescription medical products. They fall under the auspices of the Food, Drug, and Cosmetic Act and regulations promulgated by the federal Food and Drug Administration, and all causes of action are therefore preempted by Federal Law. *See* 21 U.S.C. §§ 301 to 399, 71 Fed. Reg. 3922 (January 24, 2006). Plaintiffs' causes of action against the Daiichi U.S. Defendants related to Benicar®, Benicar HCT®, Azor®, and Tribenzor®, therefore, fail to state a claim upon which relief can be granted; such claim, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

#### **TWENTY-FIRST SEPARATE DEFENSE**

Plaintiffs have failed to plead allegations of fraud, mistake, or deception with the specificity or detail required.

#### **TWENTY-SECOND SEPARATE DEFENSE**

Plaintiffs' claims are barred in whole or in part by the learned intermediary doctrine.

#### **TWENTY-THIRD SEPARATE DEFENSE**

Plaintiffs' right to recover damages in this action, if any, is statutorily limited by the applicable state's wrongful death statute.

#### **TWENTY-FOURTH SEPARATE DEFENSE**

Plaintiffs' claims are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited to, § 402A, comment k.

#### **TWENTY-FIFTH SEPARATE DEFENSE**

The Daiichi U.S. Defendants rely upon all rights, defenses, and presumptions accorded to them under the terms and provisions of the Restatement (Second) of Torts: Products Liability §



402A and comments thereto (including, but not limited to, comment k) and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4, and 6 and comments thereto, and other applicable law.

**TWENTY-SIXTH SEPARATE DEFENSE**

Plaintiffs' Master Complaint fails to state a claim under any applicable state's consumer protection law, including the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, *et seq.*

**TWENTY-SEVENTH SEPARATE DEFENSE**

The Daiichi U.S. Defendants reserve their right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substance of law.

**JURY DEMAND**

Defendants Daiichi Sankyo, Inc. and Daiichi Sankyo U.S. Holdings, Inc. request a trial by jury on all issues so triable.

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