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Attorneys for Defendant  
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

<p>PLAINTIFF(S),</p> <p style="text-align: center;">Plaintiff(s),</p> <p>v.</p> <p>JOHNSON &amp; JOHNSON, JOHNSON &amp; JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, L.L.C., and ORTHO-MCNEIL PHARMACEUTICAL, INC.</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>LEVAQUIN LITIGATION</p> <p>CASE CODE NUMBER 286 (MT)</p> <p><b>DEFENDANT ORTHO-MCNEIL- JANSSEN PHARMACEUTICALS, INC.'S MASTER ANSWER TO MASTER LONG FORM COMPLAINT, AFFIRMATIVE DEFENSES, DESIGNATION OF TRIAL COUNSEL, AND JURY DEMAND</b></p>
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Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"), named in the Complaint as Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known as OMJPI, by and through its attorneys, Drinker Biddle & Reath LLP, hereby answers Plaintiffs' Master Long Form Complaint and says:

Defendant denies each and every allegation, statement, matter and thing contained in Plaintiffs' Master Long Form Complaint except as is hereinafter expressly admitted or alleged.

1. The allegations contained in paragraph 1 of Plaintiffs' Master Long Form Complaint are legal conclusions to which no response is necessary.

2. Defendant denies the allegations of paragraph 2 of Plaintiffs' Master Long Form Complaint.

**PLAINTIFFS**

3. Defendant denies the allegations in paragraph 3 of Plaintiffs' Master Long Form Complaint.

4. The allegations contained in paragraph 4 of Plaintiffs' Master Long Form Complaint are legal conclusions to which no response is necessary.

**DEFENDANTS**

5. Defendant admits the allegations in paragraph 5 of Plaintiffs' Master Long Form Complaint.

6. Defendant admits the allegations in paragraph 6 of Plaintiffs' Master Long Form Complaint.

7. Defendant denies the allegations in paragraph 7 of Plaintiffs' Master Long Form Complaint as stated.

8. Defendant denies the allegations in paragraph 8 of Plaintiffs' Master Long Form Complaint as stated.

9. Defendant denies the allegations in paragraph 9 of Plaintiffs' Master Long Form Complaint.

10. Defendant admits the allegations in paragraph 10 of Plaintiffs' Master Long Form Complaint.

11. Defendant denies the allegations in paragraph 11 of Plaintiffs' Master Long Form Complaint as stated.

12. Defendant denies the allegations in paragraph 12 of Plaintiffs' Master Long Form Complaint as stated.

13. Defendant denies the allegations in paragraph 13 of Plaintiffs' Master Long Form Complaint as stated.

14. In response to paragraph 14 of Plaintiffs' Master Long Form Complaint, Defendant admits part of the allegations and denies part of the allegations, and states that (1) Johnson & Johnson Pharmaceutical Research & Development, LLC ("J&JPRD") did research, development and testing on Levaquin®; and (2) J&JPRD did not manufacture, market, sell or distribute Levaquin®.

15. Defendant admits the allegations in paragraph 15 of Plaintiffs' Master Long Form Complaint.

16. In response to paragraph 16 of Plaintiff's Complaint, Defendant admits that OMJPI is a Pennsylvania corporation with its principal place of business in Raritan, New Jersey. Defendant further states that all assets of OMP were transferred to OMJPI on December 31, 2007.

17. Defendant denies the allegations in paragraph 17 of Plaintiffs' Master Long Form Complaint as stated.

18. Defendant denies the allegations in paragraph 18 of Plaintiffs' Master Long Form Complaint as stated.

19. Defendant denies the allegations in paragraph 19 of Plaintiffs' Master Long Form Complaint as stated.

20. In response to paragraph 20 of Plaintiffs' Master Long Form Complaint, defendant admits part of the allegations and denies part of the allegations, and states that Levaquin® was a product of OMP and is now a product OMJPI.

21. Defendant admits the allegations in paragraph 21 of Plaintiffs' Master Long Form Complaint.

### FACTUAL ALLEGATIONS

22. In response to paragraph 22 of Plaintiffs' Master Long Form Complaint, Defendant admits part of the allegations and denies part of the allegations. Defendant admits that J&JPRD did research, development and testing on Levaquin® but denies that it manufactures, markets, sells or distributes Levaquin®.

23. Defendant admits the allegations in paragraph 23 of Plaintiffs' Master Long Form Complaint.

24. Defendant denies the allegations in paragraph 24 of Plaintiffs' Master Long Form Complaint.

25. Defendant admits that Levaquin® is a frequently prescribed medicine and puts Plaintiffs to their strict burden of proving the remaining allegations contained in paragraph 25 of Plaintiffs' Master Long Form Complaint.

26. Defendant admits that Levaquin® is a frequently prescribed medicine and puts Plaintiffs to their strict burden of proving the remaining allegations contained in paragraph 26 of Plaintiffs' Master Long Form Complaint.

27. Defendant admits that Levaquin® is a frequently prescribed medicine and puts Plaintiffs to their strict burden of proving the remaining allegations contained in paragraph 27 of Plaintiffs' Master Long Form Complaint.

28. Defendant admits that Levaquin® is a frequently prescribed medicine and puts Plaintiffs to their strict burden of proving the remaining allegations contained in paragraph 28 of Plaintiffs' Master Long Form Complaint.

29. Defendant admits that Levaquin® is a frequently prescribed medicine and puts Plaintiffs to their strict burden of proving the remaining allegations contained in paragraph 29 of Plaintiffs' Master Long Form Complaint.

30. Defendant admits the allegations in paragraph 30 of Plaintiffs' Master Long Form Complaint.

31. Defendant denies the allegations in paragraph 31 of Plaintiffs' Master Long Form Complaint.

32. Defendant denies the allegations in paragraph 32 of Plaintiffs' Master Long Form Complaint.

33. Defendant denies the allegations in paragraph 33 of Plaintiffs' Master Long Form Complaint.

34. Defendant denies the allegations in paragraph 34 of Plaintiffs' Master Long Form Complaint.

35. Defendant denies the allegations in paragraph 35 of Plaintiffs' Master Long Form Complaint.

36. In response to the allegations in paragraph 36 of Plaintiffs' Master Long Form Complaint, defendant admits that Levaquin® was developed by Daiichi, that it has a licensing agreement with Daiichi, and that OMP, now known as OMJPI, manufactured and marketed and now OMJPI manufactures and markets Levaquin® pursuant to a licensing agreement, but denies the remaining allegations of paragraph 36 of Plaintiffs' Master Long Form Complaint.

37. Defendant denies the allegations in paragraph 37 of Plaintiffs' Master Long Form Complaint.

38. Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of Plaintiffs' Master Long Form Complaint.

39. Defendant denies the allegations in paragraph 39 of Plaintiffs' Master Long Form Complaint as stated. The chemical composition of Levofloxacin is stated in the package insert.

40. Defendant admits the allegations in paragraph 40 of plaintiffs' Master Long Form Complaint.

41. Defendant denies the allegations in paragraph 41 of Plaintiffs' Master Long Form Complaint.

42. Defendant denies the allegations in paragraph 42 of Plaintiffs' Master Long Form Complaint as stated. The allegations are an incomplete description of the scientific knowledge regarding Fluoroquinolones. Defendant states that the scientific literature and studies regarding Fluoroquinolones speak for themselves. Defendant further states that the scientific literature and reported research on Levaquin® form part of the basis of the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

43. Defendant denies the allegations in paragraph 43 of Plaintiffs' Master Long Form Complaint.

44. Defendant denies the allegations in paragraph 44 of Plaintiffs' Master Long Form Complaint

45. Defendant denies the allegations in paragraph 45 of Plaintiffs' Master Long Form Complaint.

46. Defendant denies the allegations in paragraph 46 of Plaintiffs' Master Long Form Complaint.

47. In response to the allegations in paragraph 47 of Plaintiffs' Master Long Form Complaint, Defendant states that foreign studies speak for themselves as to product studies and conclusions of such studies.

48. In response to the allegations in paragraph 48 of Plaintiffs' Master Long Form Complaint, Defendant states that foreign studies speak for themselves as to product studies and conclusions of such studies. Defendant denies the remaining allegations in paragraph 48 of Plaintiffs' Master Long Form Complaint.

49. Defendant does not market Levaquin® in Italy and therefore denies the allegations in paragraph 49 of Plaintiffs' Master Long Form Complaint. Any foreign publications or statements from regulatory agencies speak for themselves.

50. Defendant denies the allegations in paragraph 50 of Plaintiffs' Master Long Form Complaint. The allegations are an incomplete description of the scientific knowledge regarding Fluoroquinolones. Defendant states that the scientific literature and studies regarding Fluoroquinolones speak for themselves. Defendant further states that the scientific literature and reported research on Levaquin® form part of the basis of the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

51. Defendant denies the allegations of paragraph 51 of Plaintiffs' Master Long Form Complaint as stated. The allegations are an incomplete description of the scientific knowledge regarding Fluoroquinolones. Defendant states that the scientific literature and studies regarding Fluoroquinolones speak for themselves. Defendant further states that the scientific literature and reported research on Levaquin® form part of the basis for the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

52. Defendant does not market Levaquin® in Belgium and therefore denies the allegations in paragraph 52 of Plaintiffs' Master Long Form Complaint. Any foreign publications or statements from regulatory agencies speak for themselves.

53. Defendant denies the allegations in paragraph 53 of Plaintiffs' Master Long Form Complaint. The allegations are an incomplete description of the scientific knowledge regarding Fluoroquinolones. Defendant states that the scientific literature and studies regarding Fluoroquinolones speak for themselves. Defendant further states that the scientific literature and reported research on Levaquin® form part of the basis of the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

54. Defendant denies the allegations in paragraph 54 of Plaintiffs' Master Long Form Complaint and states that the 2001 label speaks for itself. Defendant affirmatively asserts that OMP and OMJPI have complied with all FDA labeling requirements.

55. Defendant denies the allegations in paragraph 55 of Plaintiffs' Master Long Form Complaint as stated, but admits that Daiichi shares post-marketing surveillance data with its licensees of Levaquin®.

56. Defendant denies the allegations in paragraph 56 of Plaintiffs' Master Long Form Complaint.

57. Defendant denies the allegations in paragraph 57 of Plaintiffs' Master Long Form Complaint.

58. Defendant denies the allegations in paragraph 58 of Plaintiffs' Master Long Form Complaint.



59. Defendant denies the allegations in paragraph 59 of Plaintiffs' Master Long Form Complaint as stated. Defendant does not market Levaquin® in EMEA countries, and further states that the statements or reports of foreign regulatory agencies speak themselves.

60. Defendant does not market Levaquin® in Europe and therefore denies the allegations in paragraph 60 of Plaintiffs' Master Long Form Complaint. Defendant further states that the statements of all reports of foreign regulatory agencies speak for themselves.

61. Defendant admits the allegations in paragraph 61 of Plaintiffs' Master Long Form Complaint.

62. Defendant denies the allegations in paragraph 62 of Plaintiffs' Master Long Form Complaint as they do not relate to this Defendant. Defendant further states that the studies regarding Fluoroquinolones speak for themselves.

63. Defendant denies the allegations in paragraph 63 of Plaintiffs' Master Long Form Complaint. Defendant further states that the studies regarding Fluoroquinolones speak for themselves.

64. Defendant denies the allegations in paragraph 64 of Plaintiffs' Master Long Form Complaint as stated. Defendant further states that the studies regarding Fluoroquinolones speak for themselves.

65. Defendant denies the allegations in paragraph 65 of Plaintiffs' Master Long Form Complaint as stated. Defendant further states that the studies regarding Fluoroquinolones speak for themselves.

66. Defendant denies the allegations in paragraph 66 of Plaintiffs' Master Long Form Complaint as stated. Defendant states that the reports or statements of foreign regulatory agencies speak for themselves.

67. Defendant denies the allegations in paragraph 67 of Plaintiffs' Master Long Form Complaint as stated. Defendant states that the reports or statements of foreign regulatory agencies speak for themselves.

68. Defendant denies the allegations in paragraph 68 of Plaintiffs' Master Long Form Complaint.

69. Defendant denies the allegations in paragraph 69 of Plaintiffs' Master Long Form Complaint.

70. Defendant denies the allegations in paragraph 70 of Plaintiffs' Master Long Form Complaint as stated. Defendant states that the study speaks for itself as to its findings and conclusions.

71. Defendant denies the allegations in paragraph 71 of Plaintiffs' Master Long Form Complaint as stated. Defendant states that the study speaks for itself as to its findings and conclusions.

72. Defendant denies the allegations in paragraph 72 of Plaintiffs' Master Long Form Complaint.

73. Defendant denies the allegations in paragraph 73 of Plaintiffs' Master Long Form Complaint.

74. Defendant admits that OMP, now known as OMJPI, changed the Levaquin® label in 2004, but denies the remaining allegations in paragraph 74 of Plaintiffs' Master Long Form Complaint. Defendant affirmatively asserts that OMP, now known as OMJPI, and OMJPI have complied with FDA labeling requirements at all times.

75. Defendant denies the allegations in paragraph 75 of Plaintiffs' Master Long Form Complaint.

76. Defendant denies the allegations in paragraph 76 of Plaintiffs' Master Long Form Complaint.

77. Defendant denies the allegations in paragraph 77 of Plaintiffs' Master Long Form Complaint.

78. Defendant denies the allegations in paragraph 78 of Plaintiffs' Master Long Form Complaint and states that the petition speaks for itself.

79. Defendant denies the allegations in paragraph 79 of Plaintiffs' Master Long Form Complaint and states that the petition speaks for itself.

80. Defendant denies the allegations in paragraph 80 of Plaintiffs' Master Long Form Complaint and states that the petition speaks for itself.

81. Defendant denies the allegations in paragraph 81 of Plaintiffs' Master Long Form Complaint and states that the petition speaks for itself.

82. Defendant denies the allegations in paragraph 82 of Plaintiffs' Master Long Form Complaint and states that the article speaks for itself.

83. Defendant denies the allegations in paragraph 83 of Plaintiffs' Master Long Form Complaint and states that the article speaks for itself.

84. Defendant denies the allegations in paragraph 84 of Plaintiffs' Master Long Form Complaint and states that the 2007 label speaks for itself. Defendant affirmatively asserts that OMP and OMJPI have complied with all FDA labeling requirements.

85. Defendant denies the allegations in paragraph 85 of Plaintiffs' Master Long Form Complaint.

86. Defendant denies the allegations in paragraph 86 of Plaintiffs' Master Long Form Complaint and states that the 2007 label speaks for itself.

87. Defendant denies the allegations in paragraph 87 of Plaintiffs' Master Long Form Complaint and states that the 2008 label speaks for itself.

88. Defendant denies the allegations in paragraph 88 of Plaintiffs' Master Long Form Complaint and states that the 2008 label speaks for itself. Defendant affirmatively asserts that OMP and OMJPI have complied with all FDA labeling requirements.

89. Defendant denies the allegations in paragraph 89 of Plaintiffs' Master Long Form Complaint and states that the 2008 label speaks for itself. Defendant affirmatively asserts that OMP and OMJPI have complied with all FDA labeling requirements.

90. Defendant denies the allegations in paragraph 90 of Plaintiffs' Master Long Form Complaint. Defendant affirmatively asserts that OMP, now known as OMJPI, and OMJPI have complied with all FDA labeling requirements.

91. Defendant denies the allegations in paragraph 91 of Plaintiffs' Master Long Form Complaint. Defendant affirmatively asserts that OMP, now known as OMJPI, and OMJPI have complied with all FDA labeling requirements.

92. Defendant denies the allegations in paragraph 92 of Plaintiffs' Master Long Form Complaint.

93. Defendant denies the allegations in paragraph 93 of Plaintiffs' Master Long Form Complaint.

94. Defendant denies the allegations in paragraph 94 of Plaintiffs' Master Long Form Complaint.

95. Defendant denies the allegations in paragraph 95 of Plaintiffs' Master Long Form Complaint.

**COUNT I**  
**PRODUCT LIABILITY- FAILURE TO WARN (N.J.S.A. 2A:58C-1 et seq.)**

96. In response to the allegations in paragraph 96 of Plaintiffs' Master Long Form Complaint, Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 95 of its Answer to Plaintiffs' Master Long Form Complaint.

97. Defendant denies the allegations in paragraph 97 of Plaintiffs' Master Long Form Complaint, except to admit that J&JPRD did research, development and testing on Levaquin®, and that Levaquin® was a product of OMP, now known as OMJPI, and is now a product of OMJPI.

98. In response to the allegations in paragraph 98 of Plaintiffs' Master Long Form Complaint, Defendant admits that OMP, now known as OMJPI, marketed Levaquin® to physicians. Defendant denies the remaining allegations of paragraph 98 of Plaintiffs' Master Long Form Complaint.

99. In response to paragraph 99 of Plaintiffs' Master Long Form Complaint, Defendant acknowledges all duties imposed by law, and denies violating same.

100. Defendant denies the allegations in paragraph 100 of Plaintiffs' Master Long Form Complaint.

101. Defendant denies the allegations in paragraph 101 of Plaintiffs' Master Long Form Complaint.

102. Defendant denies the allegations in paragraph 102 of Plaintiffs' Master Long Form Complaint.

103. Defendant denies the allegations in paragraph 103 of Plaintiffs' Master Long Form Complaint.

104. Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 104 of Plaintiffs' Master Long Form Complaint.

105. Defendant denies the allegations in paragraph 105 of Plaintiffs' Master Long Form Complaint.

106. Defendant denies the allegations in paragraph 106 of Plaintiffs' Master Long Form Complaint.

107. In response to paragraph 107 of Plaintiffs' Master Long Form Complaint, Defendant states that the allegations contained therein call for a legal conclusion to which no response is necessary, but responding further, Defendant denies those allegations to the extent they seek to impose obligations on Defendant beyond those required by law.

108. Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 108 of Plaintiffs' Master Long Form Complaint, and puts Plaintiffs to their strict burden of proof as to the allegations contained therein.

109. In response to paragraph 109 of Plaintiffs' Master Long Form Complaint, Defendant states that the allegations contained therein call for a legal conclusion to which no response is necessary, but, responding further, Defendant denies those allegations to the extent they seek to impose obligations on Defendant beyond those required by law.

110. Defendant denies the allegations in paragraph 110 of Plaintiffs' Master Long Form Complaint.

111. Defendant denies the allegations in paragraph 111 of Plaintiffs' Master Long Form Complaint.

112. Defendant denies the allegations in paragraph 112 of Plaintiffs' Master Long Form Complaint.

113. Defendant denies the allegations in paragraph 113 of Plaintiffs' Master Long Form Complaint.

114. Defendant denies the allegations in paragraph 114 of Plaintiffs' Master Long Form Complaint.

**COUNT II**  
**PRODUCT LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1 et seq.)**

115. Defendant restates, re-alleges and incorporates by reference paragraph 1 through 114 of its Answer to Plaintiffs' Master Long Form Complaint.

116. Defendant denies the allegations in paragraph 116 of Plaintiffs' Master Long Form Complaint.

117. Defendant denies the allegations in paragraph 117 of Plaintiffs' Master Long Form Complaint.

118. Defendant denies the allegations in paragraph 118 of Plaintiffs' Master Long Form Complaint.

119. Defendant denies the allegations in paragraph 119 of Plaintiffs' Master Long Form Complaint.

120. Defendant denies the allegations in paragraph 120 of Plaintiffs' Master Long Form Complaint.

121. Defendant denies the allegations in paragraph 121 of Plaintiffs' Master Long Form Complaint.

122. Defendant denies the allegations in paragraph 122 of Plaintiffs' Master Long Form Complaint.

**COUNT III**  
**PRODUCT LIABILITY-MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1 et seq.)**

123. In response to paragraph 123 of Plaintiffs' Master Long Form Complaint, Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 122 of its Answer to Plaintiffs' Master Long Form Complaint.

124. In response to paragraph 124 of Plaintiffs' Master Long Form Complaint, Defendant admits part of the allegations and denies part of the allegations, and states that (1) J&JPRD did research, development and testing on Levaquin®; (2) J&JPRD did not manufacture, market, sell, or distribute Levaquin®; (3) Johnson & Johnson did not design, test, manufacture, market, sell or distribute Levaquin®; and (4) Levaquin® was a product of OMP and is now a product of OMJPI. Defendant denies the remaining allegations in paragraph 124 of Plaintiffs' Master Long Form Complaint.

125. Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125 of Plaintiffs' Master Long Form Complaint and puts Plaintiffs to their strict burden of proving the allegations contained therein.

126. Defendant denies the allegations in paragraph 126 of Plaintiffs' Master Long Form Complaint.

127. Defendant denies the allegations in paragraph 127 of Plaintiffs' Master Long Form Complaint.

**COUNT IV**  
**BREACH OF EXPRESS WARRANTY**

128. Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 127 of its Answer to Plaintiffs' Master Long Form Complaint.



129. Defendant denies the allegations in paragraph 129 of Plaintiffs' Master Long Form Complaint.

130. Defendant denies the allegations in paragraph 130 of Plaintiffs' Master Long Form Complaint.

131. Defendant denies the allegations in paragraph 131 of Plaintiffs' Master Long Form Complaint and denies that it extended any express warranties to Plaintiffs.

132. Defendant denies the allegations in paragraph 132 of Plaintiffs' Master Long Form Complaint.

133. Defendant denies the allegations in paragraph 133 of Plaintiffs' Master Long Form Complaint.

**COUNT V**  
**NEGLIGENT MISREPRESENTATION**

134. In response to the allegations in paragraph 134 of Plaintiffs' Master Long Form Complaint, Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 133 of its Answer to Plaintiffs' Master Long Form Complaint.

135. In response to the allegations in paragraph 135 of Plaintiffs' Master Long Form Complaint, Defendant acknowledges all duties imposed by law, and denies violating same.

136. In response to the allegations in paragraph 136 of Plaintiffs' Master Long Form Complaint, Defendant acknowledges all duties imposed by law, but denies violating same.

137. Defendant denies the allegations in paragraph 137 of Plaintiffs' Master Long Form Complaint.

138. Defendant denies the allegations in paragraph 138 of Plaintiffs' Master Long Form Complaint.

139. Defendant denies the allegations in paragraph 139 of Plaintiffs' Master Long Form Complaint.

140. Defendant denies the allegations in paragraph 140 of Plaintiffs' Master Long Form Complaint.

141. Defendant denies the allegations in paragraph 141 of Plaintiffs' Master Long Form Complaint.

**COUNT VI**  
**NEW JERSEY CONSUMER FRAUD ACT (N.J.S.A. 56:A-1 et seq.)**

142. In response to the allegations in paragraph 142 of Plaintiffs' Master Long Form Complaint, Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 141 in its Answer to the Plaintiffs' Master Long Form Complaint.

143. The allegations contained in paragraph 143 of Plaintiffs' Master Long Form Complaint are legal conclusions to which no response is necessary. To the extent a response is deemed necessary, Defendant denies the allegations in paragraph 143 of Plaintiffs' Master Long Form Complaint.

144. In response to paragraph 144 of Plaintiffs' Master Long Form Complaint, Defendant states that the allegations contained therein call for a legal conclusion to which no response is necessary, but responding further, Defendant denies those allegations to the extent they seek to impose obligations on Defendant beyond those required by law.

145. In response to paragraph 145 of Plaintiffs' Master Long Form Complaint, Defendant admits part of the allegations and denies part of the allegations, and states that (1) J&JPRD did research, development and testing on Levaquin®; (2) J&JPRD did not manufacture, market, sell, or distribute Levaquin®; (3) Johnson & Johnson did not design, test, manufacture, market, sell, or distribute Levaquin®; and (4) Levaquin® was a product of OMP and is now a

product of OMJPI. Defendant denies the remaining allegations of paragraph 145 of Plaintiffs' Master Long Form Complaint.

146. Defendant denies the allegations in paragraph 146 of Plaintiffs' Master Long Form Complaint.

147. Defendant denies the allegations in paragraph 147 of Plaintiffs' Master Long Form Complaint.

148. Defendant denies the allegations in paragraph 148 of Plaintiffs' Master Long Form Complaint.

149. Defendant denies the allegations in paragraph 149 of Plaintiffs' Master Long Form Complaint.

150. In response to the allegations in paragraph 150 of Plaintiffs' Master Long Form Complaint, Defendant denies knowledge or information sufficient to form a belief as to whether Plaintiffs' physician prescribed and or otherwise provided Plaintiffs with Levaquin® and whether Plaintiffs consumed Levaquin®. Defendant denies the remaining allegations in paragraph 150 of Plaintiffs' Master Long Form Complaint.

151. Defendant denies the allegations in paragraph 151 of Plaintiffs' Master Long Form Complaint.

152. Defendant denies the allegations in paragraph 152 of Plaintiffs' Master Long Form Complaint.

153. Defendant denies the allegations in paragraph 153 of Plaintiffs' Master Long Form Complaint.

154. Defendant denies the allegations in paragraph 154 of Plaintiffs' Master Long Form Complaint.

155. Defendant denies the allegations in paragraph 155 of Plaintiffs' Master Long Form Complaint.

156. Defendant denies the allegations in paragraph 156 of Plaintiffs' Master Long Form Complaint.

157. Defendant denies the allegations in paragraph 157 of Plaintiffs' Master Long Form Complaint.

158. Defendant denies the allegations in paragraph 158 of Plaintiffs' Master Long Form Complaint.

159. Defendant denies the allegations in paragraph 159 of Plaintiffs' Master Long Form Complaint.

160. Defendant denies the allegations in paragraph 160 of Plaintiffs' Master Long Form Complaint.

**COUNT VII**  
**PUNITIVE DAMAGES UNDER COMMON LAW AND PRODUCTS LIABILITY ACT**  
**(N.J.S.A. 2A 58C-1 et seq.)**

161. In response to the allegations of paragraph 161 of Plaintiffs' Master Long Form Complaint, Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 160 of its Answer to Plaintiffs' Master Long Form Complaint.

162. Defendant denies the allegations in paragraph 162 of Plaintiffs' Master Long Form Complaint.

163. Defendant denies the allegations in paragraph 163 of Plaintiffs' Master Long Form Complaint.

164. Defendant denies the allegations in paragraph 164 of Plaintiffs' Master Long Form Complaint.

165. Defendant denies the allegations in paragraph 165 of Plaintiffs' Master Long Form Complaint.

166. Defendant denies the allegations in paragraph 166 of Plaintiffs' Master Long Form Complaint.

**COUNT VIII**  
**LOSS OF CONSORTIUM/PER QUOD CLAIM**

167. In response to the allegations of paragraph 167 of Plaintiffs' Master Long Form Complaint, Defendant restates, re-alleges and incorporates by reference paragraphs 1 through 166 of its Answer to Plaintiffs' Master Long Form Complaint.

168. Defendant denies the allegations of paragraph 168 of Plaintiff's Master Long Form Complaint.

169. Defendant denies the allegations of paragraph 169 of Plaintiffs' Master Long Form Complaint.

**AFFIRMATIVE DEFENSES**

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. states for its affirmative defenses to Plaintiffs' Master Long Form Complaint:

**FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' Master Long Form fails to state a claim upon which relief may be granted.

**SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the applicable statute of limitations.

**THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' choice of forum and venue is improper.

**FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are not governed by the laws of the state of New Jersey.

**FIFTH AFFIRMATIVE DEFENSE**

Any purported injury of which Plaintiffs complain in the Master Long Form were not caused by Defendant, but were caused by the actions or inactions of a person or persons or entities over whom Defendant had neither control nor right of control. Plaintiffs' recovery should be barred or, at a minimum, should be reduced or apportioned in accordance with the principles of comparative negligence and New Jersey's Joint Tortfeasor Contribution Act.

**SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' alleged damages or injuries, if any, were caused in whole or in part by Plaintiffs' unreasonable, unforeseeable, inappropriate, and/or improper use of the product.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to mitigate their damages, if any.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to state a claim upon which attorney fees may be awarded.

**NINTH AFFIRMATIVE DEFENSE**

The product identified in Plaintiffs' Master Long Form was approved by the FDA and other government authorities and Defendant acted at all times in compliance with the rules and regulations of the FDA and other governmental authorities.

**TENTH AFFIRMATIVE DEFENSE**

Levaquin® is a prescription medical product. It falls 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 Defendant related to Levaquin® (levofloxacin), 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.

**ELEVENTH AFFIRMATIVE DEFENSE**

The product identified in Plaintiffs' Master Long Form was in conformity with the state of the art and/or the state of scientific knowledge at the relevant times involved.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred because the benefits relevant to the product outweighed the risks.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the learned intermediary doctrine.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by their assumption of the risk.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the doctrine of laches and/or estoppel.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' injuries are the result of a superseding cause.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs have failed to allege fraud, concealment, or misrepresentation with sufficient particularity.

**NINETEENTH AFFIRMATIVE DEFENSE**

No privity of contract existed between Plaintiffs and this answering Defendant.

### **TWENTIETH AFFIRMATIVE DEFENSE**

Affirmatively and alternatively, Defendant pleads the application of Comment K to the Restatement of Torts (Second) Section 402A and Restatement (Third) Torts; Products Liability Section 6.

### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' Master Long Form fails to state a claim upon which relief in the form of punitive damages can be granted and an award of punitive damages in this case would violate this answering Defendant's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, Article I, and similar provisions of the New Jersey Constitution, and would be improper under the common law and public policies of the state of New Jersey.

### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

Any award of punitive damages in this case against Defendant is barred to the extent that the amount of such an award violates the Constitution of the United States or the Constitution of the State of New Jersey.

### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

A claim for punitive damages against Defendant in this case cannot be sustained because any award of punitive damages under New Jersey law without bifurcating the trial and trying all punitive damage issues only if and after liability on the merits has been found would violate Defendant's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution, and would be improper under the common law and public policies of New Jersey.



#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Defendant in this case cannot be sustained because any award of punitive damages under New Jersey law subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury would impose would violate Defendant's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process provisions of the New Jersey Constitution, and would be improper under the common law and public policies of New Jersey.

#### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Without reference to or waiver of any conflicts of law arguments by Defendant, the Plaintiffs cannot state a claim under the New Jersey Consumer Fraud Act because all claims for harm caused by a product are governed by the New Jersey Products Liability Act, pursuant to the New Jersey Supreme Court's decision in *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 948 A.2d 587, 596 (N.J. 2008).

#### **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

To the extent not stated above, Defendant raises all affirmative defenses available under the law of the forum in which each respective claim arose.

#### **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Defendant specifically reserves the right to present other and further defenses after further discovery and investigation herein.

**WHEREFORE**, Defendant demands judgment in its favor dismissing the Master Long Form Complaint with prejudice and for such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Defendant demands a trial by jury of all issues so triable.

**DESIGNATION OF TRIAL COUNSEL**

Susan M. Sharko, Esq. is hereby designated as trial counsel.

DRINKER BIDDLE & REATH LLP  
Attorneys for Defendant Ortho-McNeil-Janssen  
Pharmaceuticals, Inc.

Dated: August \_\_, 2009

By: \_\_\_\_\_  
Susan M. Sharko

**CERTIFICATION PURSUANT TO R. 4:5-1**

Pursuant to R. 4:5-1, I hereby certify, that to the best of my knowledge, the above-captioned action is not the subject of any other action pending in any court or the subject of a pending arbitration proceeding, and no other action or arbitration proceeding is contemplated. I further certify that, to the best of my knowledge, no other parties need be joined in this matter. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

DRINKER BIDDLE & REATH LLP  
Attorneys for Defendant Ortho-McNeil-Janssen  
Pharmaceuticals, Inc.

Dated: August \_\_ 2009

By: \_\_\_\_\_  
Daniel B. Carroll