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McCARTER & ENGLISH, LLP

Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4096
(973) 622-4444
Attorneys for Defendants

IN RE: REZULIN LITIGATION

Plaintiff(s),

v.

**PFIZER INC., WARNER-LAMBERT
COMPANY, and PARKE-DAVIS, a division of
WARNER-LAMBERT; JANE/JOHN DOE; A, B,
C AND D, fictitious defendants**

Defendant(s).

: **SUPERIOR COURT OF NEW JERSEY**
: **LAW DIVISION: MIDDLESEX**
: **COUNTY ACTION**

: CASE CODE 246
: REZULIN LITIGATION

: **CIVIL ACTION**

: ANSWER AND DEFENSES OF WARNER-
LAMBERT COMPANY AND
PFIZER INC.
TO MASTER COMPLAINT

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Defendants WARNER-LAMBERT COMPANY, a corporation of the State of Delaware with its principal place of business in New Jersey (including its unincorporated Parke-Davis Division) and PFIZER INC., a corporation of the State of Delaware with its principal place of business in New York, hereinafter referred to as “defendants,” by way of Answer to Plaintiffs’ Master Complaint, say:

1. These allegations constitute legal conclusions to which no response is required. To the extent that a response is required, defendants are without knowledge or information sufficient to form a belief as to the truth of these allegations and, therefore, deny the same.
2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the complaint and, therefore, deny the same.
3. Defendants admit that Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Defendants deny the remaining allegations in

paragraph 3 of the complaint.

4. Defendants admit that Warner-Lambert Company (hereinafter “Warner-Lambert”) is a Delaware corporation with its principal place of business at 201 Tabor Road, Morris Plains, New Jersey. Defendants deny the remaining allegations in paragraph 4 of the complaint.

5. Defendants admit that Parke-Davis is an unincorporated division of Warner-Lambert Company and, thus, is an entity incapable of being sued. Defendants deny the remaining allegations in paragraph 5 of the complaint.

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6. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of the complaint and, therefore, deny the same.

7. These allegations constitute legal conclusions to which no response is required. To the extent that a response is required, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the complaint with respect to any particular plaintiffs whose actions are included in this coordinated proceeding.

8. These allegations constitute legal conclusions to which no response is required. To the extent that a response is required, defendants deny the allegations contained in paragraph 8 of the complaint.

9. Defendants deny each and every allegation contained in paragraph 9 of the complaint.

10. Responding to the allegations in paragraph 10 of the complaint, defendants state that said allegations do not require a response by defendants. To the extent a response is required, defendants admit the allegations in paragraph 10 of the complaint.

11. Defendants admit that on July 31, 1996, Warner-Lambert submitted a new drug application for Rezulin® with the FDA. Defendants deny the remaining allegations in paragraph 11 of the complaint.

12. Defendants admit that Rezulin® was selected as one of two drugs to be tested in a National Institute of Health clinical study. Defendants do not have information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 12 of the complaint, and therefore deny same.

13. Defendants deny each and every allegation contained in paragraph 13 of the complaint.

14. Defendants admit that Dr. Richard C. Eastman was Director of NIH’s Division of Diabetes, Endocrinology and Metabolic Diseases and had some responsibility for the DPP study. Defendants deny the remaining allegations contained in paragraph 14 of the complaint.

15. Defendants admit that John L. Gueriguian, M.D. was assigned as the Chief Medical Officer to oversee the priority review of Rezulin®. Defendants deny the remaining allegations contained in paragraph 15 of the complaint.
16. Defendants admit that Dr. Gueriguian recommended against approval of the drug in a draft evaluation dated October 9, 1996. Defendants deny the remaining allegations contained in paragraph 16 of the complaint.
17. Defendants admit that this statement was reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegation and, therefore, deny the same.
18. Defendants deny each and every allegation contained in paragraph 18 of the complaint.
19. Defendants admit that Dr. Gueriguian expressed certain concerns in his October 9, 1996 evaluation about heart problems. Defendants deny the remaining allegations contained in paragraph 19 of the complaint and deny that Rezulin® can potentially cause heart problems.
20. Defendants state the Dr. Gueriguian's review speaks for itself. Defendants deny the remaining allegations contained in paragraph 20 of the complaint.
21. Defendants admit that Dr. Gueriguian, in a meeting held with Warner-Lambert representatives in September of 1996, used inappropriate language to describe Rezulin®'s "prospects." Defendants deny the remaining allegations contained in paragraph 21 of the complaint.
22. Defendants admit that Dr. Gueriguian was removed from the Rezulin® review after the FDA conducted an internal investigation. Defendants deny the remaining allegations contained in paragraph 22 of the complaint.
23. Defendants admit that this statement was reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegation and, therefore, deny the same.
24. Defendants admit that this statement was reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegation and, therefore, deny the same.
25. Defendants admit that Dr. Gueriguian was replaced by Dr. G. Alexander Fleming, an FDA team drug review leader. Defendants admit that the quoted statement was reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegation and, therefore, deny the same.

26. Defendants admit that Dr. Robert L. Misbin assisted Dr. Fleming. Defendants deny the remaining allegations contained in paragraph 26 of the complaint.
27. Defendants admit that Dr. Fleming made a presentation to the Endocrinologic and Metabolic Drug Advisory Committee (“EMDAC”) on or about December 11, 1996 regarding Rezulin®. Defendants further admit that the EMDAC voted to recommend that the FDA approve Rezulin® and that, on or about January 29, 1997, the FDA approved Rezulin®. Defendants deny the remaining allegations contained in paragraph 27 of the complaint.
28. Defendants admit such statements were reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, deny the same.
29. Defendants state that in March of 1997, Warner-Lambert, through its unincorporated Parke-Davis Division, began marketing the medication Rezulin®. Defendants further admit that they issued certain press releases, the contents of which speak for themselves. Defendants deny the remaining allegations contained in paragraph 29 of the complaint.
30. Defendants admit that the FDA sent a letter to Warner-Lambert regarding the press release. Said letter speaks for itself. Defendants deny the remaining allegations contained in paragraph 30 of the complaint.
31. Defendants admit that advertisements for Rezulin® ran in both English and Spanish and that Rezulin® was indicated for once-a-day dosing. Defendants deny the remaining allegations contained in paragraph 31 of the complaint.
32. Defendants admit that it placed certain advertisements in the May 7, 1997 and May 29, 1997 issues of the *New England Journal of Medicine*. Defendants deny the remaining allegations contained in paragraph 32 of the complaint.
33. Defendants deny each and every allegation contained in paragraph 33 of the complaint.
34. Defendants admit the allegations contained in paragraph 34 of the complaint.
35. Defendants deny the allegations contained in paragraph 35 of the complaint, specifically denying that they had evidence of serious and potentially life-threatening health problems associated with Rezulin, but had failed to inform the FDA.
36. Defendants admit that Dr. Misbin evaluated certain adverse event reports made in connection with the use of Rezulin®. Defendants admit that the quoted statements were reported in the Los

Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, deny the same.

37. Defendants deny the allegations contained in paragraph 37 of the complaint, specifically denying that they had evidence of serious and potentially life-threatening health problems associated with Rezulin, but had failed to inform the FDA.

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38. Defendants deny each and every allegation contained in paragraph 38 of the complaint.

39. Defendants admit that the quoted statement was reported by CBS News, but are without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, deny the same.

40. Defendants admit that Warner-Lambert implemented FDA-approved revisions to the label for Rezulin®. Defendants deny the remaining allegations contained in paragraph 40 of the complaint.

41. Defendants admit that a label change was made on or about November 3, 1997, which recommended that serum transaminase levels be checked within the first one to two months and then every three months during the first year of Rezulin® therapy, and periodically thereafter. Defendants deny the remaining allegations contained in paragraph 41 of the complaint.

42. Defendants admit that the referenced statement was reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, deny the same. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, deny the same.

43. Defendants admit statements regarding “Lumpkin’s e-mail” were reported in the Los Angeles Times, but Defendants are without knowledge or sufficient information to form a belief as to the truth of the allegation regarding “Lumpkin’s e-mail” and, therefore, deny the allegations.

44. Defendants admit that Romozin® was voluntarily withdrawn from the market in Great Britain by Glaxo-Wellcome on December 1, 1997. Defendants further admit that Warner-Lambert implemented a second FDA-approved label change on or about December 1, 1997. Defendants deny the remaining allegations contained in paragraph 44 of the complaint.

45. Defendants admit that label changes were accompanied by letters to doctors warning them of possible risks of liver toxicity associated with Rezulin®. Defendants deny the remaining allegations contained in paragraph 45 of the complaint.

46. Defendants admit that Rezulin® remained in the DPP study. Defendants deny the remaining

allegations contained in paragraph 46 of the complaint.

47. Defendants admit that Mrs. Jones was part of the DPP study and took Rezulin®. Defendants deny the remaining allegations contained in paragraph 46 of the complaint.

48. Defendants deny each and every allegation contained in paragraph 48 of the complaint.
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49. Defendants deny each and every allegation contained in paragraph 49 of the complaint.

50. Defendants admit that Rezulin® was withdrawn from the DPP study. Defendants deny the remaining allegations contained in paragraph 50 of the complaint.

51. Defendants deny each and every allegation contained in paragraph 51 of the complaint.

52. Defendants admit that in July of 1998, they implemented the third FDA-approved label change which recommended that serum transaminase levels be checked at the start of therapy, monthly for the first eight months of therapy, every two months for the remainder of the first year of Rezulin® therapy, and periodically thereafter. Defendants deny the remaining allegations contained in paragraph 52 of the complaint.

53. Defendants deny each and every allegation contained in paragraph 53 of the complaint.

54. Defendants deny each and every allegation contained in paragraph 54 of the complaint.

55. Defendants deny each and every allegation contained in paragraph 55 of the complaint.

56. Defendants admit that on March 26, 1999, the FDA convened an EMDAC committee meeting, which meeting was the subject of a transcript that speaks for itself. Defendants deny the remaining allegations contained in paragraph 56 of the complaint.

57. Defendants admit that Dr. Graham addressed the committee. His statements are part of a transcript that speaks for itself. Defendants deny the remaining allegations contained in paragraph 57 of the complaint.

58. Defendants admit that on June 16, 1999, they implemented the fourth FDA-approved label change. Defendants deny the remaining allegations contained in paragraph 58 of the complaint.

59. Defendants are without information or knowledge sufficient to admit or deny statements relating to the FDA's knowledge. Defendants deny the remaining allegations contained in paragraph 59 of the complaint.

60. Defendants admit that Dr. Janet McGill was formerly employed by Warner-Lambert and that she served as deputy principal investigator on the DPP study. Defendants further admit that Dr. McGill wrote a letter that speaks for itself. Defendants deny the remaining allegations contained in paragraph 60 of the complaint.

61. Defendants admit that Dr. Janet McGill was formerly employed by Warner-Lambert and that she served as deputy principal investigator on the DPP study. Defendants further admit that Dr. McGill wrote a letter that speaks for itself. Defendants deny the remaining allegations contained in paragraph 61 of the complaint.

62. Defendants admit that such statements were reported in the Los Angeles Times, but are without knowledge or information sufficient to form a belief as to the truth of the statements and, therefore, deny the same.

63. Defendants admit that Rezulin® was voluntarily withdrawn from the market in March 2000. Defendants deny the remaining allegations contained in paragraph 63 of the complaint.

64. Defendants deny each and every allegation contained in paragraph 64 of the complaint.

65. Defendants deny each and every allegation contained in paragraph 65 of the complaint.

COUNT I

66. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

67. This allegation states a conclusion of law to which no response is necessary. To the extent that any statements may be deemed to be allegations directed against Defendants, they are denied.

68. Defendants deny each and every allegation contained in paragraph 68 of the complaint.

69. This allegation states a conclusion of law to which no response is necessary. To the extent that any statements may be deemed to be allegations directed against Defendants, they are denied.

70. Defendants deny each and every allegation contained in paragraph 70 of the complaint, including all sub-parts.

71. Defendants deny each and every allegation contained in paragraph 71 of the complaint, including all sub-parts.

72. Defendants deny each and every allegation contained in paragraph 72 of the complaint.
73. Defendants deny each and every allegation contained in paragraph 73 of the complaint.
74. Defendants deny each and every allegation contained in paragraph 74 of the complaint.
75. Defendants deny each and every allegation contained in paragraph 75 of the complaint.
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76. Defendants deny each and every allegation contained in paragraph 76 of the complaint.
77. Defendants deny each and every allegation contained in paragraph 77 of the complaint.
78. Defendants deny each and every allegation contained in paragraph 78 of the complaint.

COUNT II

79. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

80. This allegation states a conclusion of law to which no response is necessary. To the extent that any statements may be deemed to be allegations directed against Defendants, Defendants admit that through its unincorporated division, Parke-Davis, Warner-Lambert manufactured, packaged, marketed, sold and distributed Troglitazone under its trade name Rezulin® in the United States for use upon prescription only through licensed physicians for particular indications in accordance with FDA-approved prescribed information and subject to the precautions, warnings, contraindications and other information contained therein. Defendants deny the remaining allegations contained in paragraph 80 of the complaint.

81. Defendants deny each and every allegation contained in paragraph 81 of the complaint.
82. Defendants deny each and every allegation contained in paragraph 82 of the complaint.
83. Defendants deny each and every allegation contained in paragraph 83 of the complaint.
84. Defendants deny each and every allegation contained in paragraph 84 of the complaint.
85. Defendants deny each and every allegation contained in paragraph 85 of the complaint.
86. Defendants deny each and every allegation contained in paragraph 86 of the complaint.
87. Defendants deny each and every allegation contained in paragraph 87 of the complaint.

88. Defendants deny each and every allegation contained in paragraph 88 of the complaint.
89. Defendants deny each and every allegation contained in paragraph 89 of the complaint.
90. Defendants deny each and every allegation contained in paragraph 90 of the complaint.
91. Defendants deny each and every allegation contained in paragraph 91 of the complaint.
92. Defendants deny each and every allegation contained in paragraph 92 of the complaint.

COUNT III

93. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.
94. Defendants deny each and every allegation contained in paragraph 94 of the complaint.
95. Defendants deny each and every allegation contained in paragraph 95 of the complaint.
96. Defendants deny each and every allegation contained in paragraph 96 of the complaint.
97. Defendants deny each and every allegation contained in paragraph 97 of the complaint.
98. Defendants deny each and every allegation contained in paragraph 98 of the complaint.
99. Defendants deny each and every allegation contained in paragraph 99 of the complaint.
100. Defendants deny each and every allegation contained in paragraph 100 of the complaint.
101. Defendants deny each and every allegation contained in paragraph 101 of the complaint.
102. Defendants deny each and every allegation contained in paragraph 102 of the complaint.
103. Defendants deny each and every allegation contained in paragraph 103 of the complaint.
104. Defendants deny each and every allegation contained in paragraph 104 of the complaint.
105. Defendants deny each and every allegation contained in paragraph 105 of the complaint.
106. Defendants deny each and every allegation contained in paragraph 106 of the complaint.

- 107. Defendants deny each and every allegation contained in paragraph 107 of the complaint.
- 108. Defendants deny each and every allegation contained in paragraph 108 of the complaint.
- 109. Defendants deny each and every allegation contained in paragraph 109 of the complaint.
- 110. Defendants deny each and every allegation contained in paragraph 110 of the complaint.

COUNT IV

- 111. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.
- 112. Defendants deny each and every allegation contained in paragraph 112 of the complaint.
- 113. Defendants deny each and every allegation contained in paragraph 113 of the complaint.
- 114. Defendants deny each and every allegation contained in paragraph 114 of the complaint.
- 115. Defendants deny each and every allegation contained in paragraph 115 of the complaint.
- 116. Defendants deny each and every allegation contained in paragraph 116 of the complaint.
- 117. Defendants deny each and every allegation contained in paragraph 117 of the complaint.
- 118. Defendants deny each and every allegation contained in paragraph 118 of the complaint.
- 119. Defendants deny each and every allegation contained in paragraph 119 of the complaint.
- 120. Defendants deny each and every allegation contained in paragraph 120 of the complaint.
- 121. Defendants deny each and every allegation contained in paragraph 121 of the complaint.

COUNT V

- 122. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.
- 123. Defendants deny each and every allegation contained in paragraph 123 of the complaint.

124. Defendants deny each and every allegation contained in paragraph 124 of the complaint.

COUNT VI

125. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

126. These allegations constitute legal conclusions to which no response is required. To the extent that a response is required, defendants deny plaintiffs are entitled to any damages.

COUNT VII

127. Defendants adopt and incorporate herein by reference its responses to all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

128. Defendants deny each and every allegation contained in paragraph 128 of the complaint.

129.¹ Defendants deny each and every allegation contained in first paragraph numbered 129 of the complaint, including all sub-parts.

129. Defendants deny each and every allegation contained in the second paragraph numbered 129 of the complaint.

130. Defendants deny each and every allegation contained in paragraph 130 of the complaint.

131. Defendants deny each and every allegation contained in paragraph 131 of the complaint, including all sub-parts.

132. Defendants deny each and every allegation contained in paragraph 132 of the complaint.

133. Defendants deny each and every allegation contained in paragraph 133 of the complaint.

134. Defendants deny each and every allegation contained in paragraph 134 of the complaint.

135. Defendants deny each and every allegation contained in paragraph 135 of the complaint.

136. Defendants deny each and every allegation contained in paragraph 136 of the complaint.

¹ There are two paragraphs numbered "129" in the complaint.

137. Defendants deny each and every allegation contained in paragraph 137 of the complaint.

138. Defendants deny each and every allegation contained in paragraph 138 of the complaint.

AFFIRMATIVE DEFENSES

By alleging the matters set forth below Defendants do not allege or admit that they have the burden of proof and/or the burden of persuasion with respect to any of these matters. Defendants allege as follows:

AS AND FOR A FIRST SEPARATE AND AFFIRMATIVE DEFENSE

The Complaint, and each cause of action therein, fails to state a cause of action upon which relief may be granted.

AS AND FOR A SECOND SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries, damages and/or losses were proximately caused by the negligence and/or fault of Plaintiffs and/or entities other than Defendants, and this comparatively reduces or bars the negligence and/or fault, if any, attributable to Defendants.

AS AND FOR A THIRD SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs had full knowledge of, accepted, and/or assumed all risks and possible adverse effects related to the use of Rezulin®. Plaintiffs' recovery, therefore, is barred, diminished, reduced, or offset under the principles of assumption of the risk and/or informed consent.

AS AND FOR A FOURTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs cannot recover from Defendants because their injuries and damages, if any, were caused by misuse of Rezulin®.

AS AND FOR A FIFTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the Learned Intermediary doctrine.

AS AND FOR A SIXTH SEPARATE AND AFFIRMATIVE DEFENSE

To the extent that plaintiffs are alleging fraud or similar conduct, Plaintiffs have failed to plead fraud with sufficient particularity.

AS AND FOR A SEVENTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs used Rezulin® after learning of its alleged defect(s).

AS AND FOR AN EIGHTH SEPARATE AND AFFIRMATIVE DEFENSE

The causes of action alleged in the Complaint are preempted by the federal statutes and regulations that exclusively regulate Rezulin®. Granting the relief requested in the Complaint would impermissibly infringe upon and/or conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

AS AND FOR A NINTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the methods, standards and techniques used in formulating Rezulin® and in issuing warnings and instructions about its use conformed to the generally recognized, reasonably available, and reliable state of knowledge in the field at the time Rezulin® was manufactured.

AS AND FOR A TENTH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants' liability, if any, for non-economic damages is several rather than joint, and should be prorated.

AS AND FOR AN ELEVENTH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants are entitled to contribution from any person and/or entity whose negligence or other fault contributed to Plaintiffs' alleged injuries and damages if Plaintiffs receive a verdict against Defendants.

AS AND FOR A TWELFTH SEPARATE AND AFFIRMATIVE DEFENSE

The benefits of the design of Rezulin® outweigh the risk of danger, if any, inherent in the design, in light of all relevant factors.

AS AND FOR A THIRTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering from Defendants because independent, intervening, and/or superseding forces and/or actions of third parties, unrelated to any conduct of defendants, caused or contributed to Plaintiffs' alleged losses and/or damages.

AS AND FOR A FOURTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs failed to mitigate their damages, if any, despite full knowledge of them.

AS AND FOR A FIFTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants' liability, if any, will not result from their own conduct, but instead, will derive solely from an obligation imposed by law. As such, Defendants are entitled to complete and total express and/or implied indemnity from other defendants and/or third-parties that are not yet party to

this action.

AS AND FOR A SIXTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

The Complaint is subject to the limitations on the doctrine of strict product liability for a purported design defect and breach of warranty as set forth in the Restatement Second of Torts, Section 402A, comment k.

AS AND FOR A SEVENTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

The Complaint, and each of its causes of action, is barred by the applicable statutes of limitations and/or repose.

AS AND FOR AN EIGHTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' injuries and damages, if any, were due to Plaintiffs' idiosyncratic reaction to Rezulin® for which Defendants cannot be held responsible.

AS AND FOR A NINETEENTH SEPARATE AND AFFIRMATIVE DEFENSE

The design, manufacture, and distribution of Rezulin® complied with all applicable industry and governmental standards and regulations, and reflected the current state of the art at the time it was designed, manufactured, sold and distributed. Consequently, there can be no liability imposed against Defendants.

AS AND FOR A TWENTIETH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants did not make to Plaintiffs, nor did defendants breach, any express or implied warranties and did not breach any warranties created by law. To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are barred for lack of privity with Defendants and/or for failure of Plaintiffs, or their representatives, to give timely notice to Defendants of any alleged breach of warranty.

AS AND FOR A TWENTY-FIRST SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' Complaint is barred by the doctrines of laches, waiver, and/or estoppel.

AS AND FOR A TWENTY-SECOND SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' Complaint is equitably barred because Plaintiffs' failure to join all indispensable parties precludes the Court from granting complete relief to those who are parties to the action and will result in prejudice to Defendants.

AS AND FOR A TWENTY-THIRD SEPARATE AND AFFIRMATIVE DEFENSE

Notwithstanding the claims and contentions of Plaintiffs, Plaintiffs received and will in the future receive all or substantially all of the benefit from Rezulin® that Plaintiffs hoped and intended to

receive, and to that extent any damages and/or restitution that Plaintiffs might be entitled to recover from Defendants must be correspondingly reduced.

AS AND FOR A TWENTY-FOURTH SEPARATE AND AFFIRMATIVE DEFENSE

While Defendants, and each of them, deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained because an award of punitive damages would violate Defendants' rights guaranteed by the Due Process Clause of the Fourteenth Amendment to the United States Constitution. The Due Process Clause requires that adversarial proceedings be fundamentally fair. It would violate fundamental fairness to permit Defendants to be punished by way of a punitive damages award in this action.

AS AND FOR A TWENTY-FIFTH SEPARATE AND AFFIRMATIVE DEFENSE

Any alleged injuries were caused by a pre-existing or unrelated medical condition, disease or illness of the Plaintiffs.

AS AND FOR A TWENTY-SIXTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq* of the Restatement (Third) of Torts: Product Liability because Rezulin® complied with applicable product safety statutes and administrative regulations.

AS AND FOR A TWENTY-SEVENTH AFFIRMATIVE DEFENSE

In the event of a finding of any liability in favor of Plaintiffs, or settlement, or judgment against any defendant, then Defendants should be held liable, if at all, only for the proportion of damages sustained by that Plaintiffs, if any, as is determined by the jury to be the result of the allocable percentage of fault or negligence on the part of Defendants. Defendants further state that they should not and cannot be held jointly liable to Plaintiffs for the negligence or fault of others since such joint liability would violate certain constitutional principles, statutes and common law rules.

AS AND FOR A TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Should Defendants, or any of them, be held liable to Plaintiffs, which liability is specifically denied, Defendants would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in plaintiffs' complaint.

AS AND FOR A TWENTY-NINTH SEPARATE AND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by Sections 6(c) and (d) of the Restatement (Third) of Torts: Product Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Rezulin® would have prescribed and did prescribe Rezulin® for classes of patients. In addition, Warner-Lambert provided reasonable instructions and/or warnings to prescribing physicians.

AS AND FOR A THIRTIETH SEPARATE AND AFFIRMATIVE DEFENSE

The Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive damages.

AS AND FOR A THIRTY-FIRST SEPARATE AND AFFIRMATIVE DEFENSE

While Defendants deny that they, or any of them, are liable for any punitive damages in this case, Defendants further state that any award of punitive damages cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Defendants; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding plaintiffs' burden of proof with respect to each and every element of a claim for punitive damages; and/or (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Defendants' due process and equal protection rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution and similar provisions of the New Jersey Constitution, and would be improper under the law and public policies of New Jersey or other relevant state.

AS AND FOR A THIRTY-SECOND SEPARATE AND AFFIRMATIVE DEFENSE

While Defendants deny that they, or any of them, are liable for any punitive damages in this case, Defendants state that Plaintiffs' claims for punitive damages cannot be sustained because an award of punitive damages, which is not subject to 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, and which provides no protection against multiple awards for the same course of conduct, would violate Defendants' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and by similar provisions of New Jersey Constitution, and would also violate Defendants' right not to be subjected to an excessive award in violation of the Eighth Amendment to the United States Constitution, and similar provisions of New Jersey Constitution, and would be improper under the law and public policies of New Jersey or other relevant state.

AS AND FOR A THIRTY-THIRD SEPARATE AND AFFIRMATIVE DEFENSE

While Defendants, and each of them, deny that they are liable for any punitive damages in this case, Defendants state that Plaintiffs' claims for punitive damages cannot be sustained because laws regarding the standards for determining liability for punitive damages failed to give Defendants prior notice of the conduct for which punitive damages may be imposed and are void for vagueness in violation of Defendants' due process rights guaranteed by the Fifth and Fourteenth Amendments to the

United States Constitution and similar provisions of New Jersey Constitution, and would be improper under the law and public policies of New Jersey or other relevant state.

AS AND FOR A THIRTY-FOURTH SEPARATE AND AFFIRMATIVE DEFENSE

While Defendants, and each of them, deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained because any award of punitive damages under New Jersey law, which are penal in nature, without according to Defendants the same protections that are accorded to criminal defendants, including the protection against unreasonable searches and seizures, self-incrimination, and the right to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Defendants' rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and similar provisions of the New Jersey Constitution, and would be improper under the law and public policies of New Jersey or other relevant state.

AS AND FOR A THIRTY-FIFTH SEPARATE AND AFFIRMATIVE DEFENSE

While Defendants, and each of them, deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained because an award of punitive damages under New Jersey law which allows Plaintiffs to prejudicially emphasize the corporate status of Defendants violates Defendants' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and similar provisions of the New Jersey Constitution, and would be improper under the law and public policies of New Jersey or other relevant state.

AS AND FOR A THIRTY-SIXTH SEPARATE AND AFFIRMATIVE DEFENSE

The individual complaint of any plaintiff is barred by application of the doctrine of forum non conveniens, where appropriate.

AS AND FOR A THIRTY-SEVENTH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants are entitled to the special protections afforded to manufacturers of prescription pharmaceuticals by the New Jersey Product Liability Act.

AS AND FOR A THIRTY-EIGHTH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants claim the benefit of any payments received by plaintiffs from collateral sources, pursuant to N.J.S.A. 2A: 15-97.

AS AND FOR A THIRTY-NINTH SEPARATE AND AFFIRMATIVE DEFENSE

Defendants give notice that they intend to rely upon other affirmative defenses that may become apparent during the course of the litigation.

WHEREFORE, Defendants demand judgment dismissing the Plaintiffs' Complaint, that they be awarded costs, disbursements, and attorney's fees, and that the Court grant such other, further and different relief as it may deem just and proper.

McCARTER & ENGLISH, LLP
Attorneys for Defendants

By: _____
John F. Brenner
A Member of the Firm

Dated: _____, 2001

We certify that a copy of this pleading was served upon Arthur Penn, Esq., liaison counsel for plaintiffs, by first class mail, on January 12, 2001.

McCARTER & ENGLISH, LLP
Attorneys for Defendant

By: _____
John F. Brenner
A Member of the Firm

Dated: _____, 2001

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