

STATE OF WISCONSIN

Plaintiff,

v.

Case No: 04-CV-1709

ABBOTT LABORATORIES, et al.,

Defendants.

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**ANSWER AND AFFIRMATIVE DEFENSES OF  
AVENTIS PHARMACEUTICALS INC. TO THE  
STATE OF WISCONSIN'S SECOND AMENDED COMPLAINT**

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Defendant Aventis Pharmaceuticals Inc. (“Aventis”), by and through its attorneys,  
states as follows:

**Preface**

The State purports to bring this action on behalf of the citizens of Wisconsin, alleging that the State and some of its citizens have paid “inflated prices” for prescription drugs. (S.A. Compl. ¶ 1). The State alleges, in essence, that Aventis and other defendants provided inflated drug pricing information, including its Average Wholesale Prices (“AWP”) and Wholesale Acquisition Prices (“WAC”) to various third-party publishers, and those prices then became the basis for calculating the cost at which providers are reimbursed by the State of Wisconsin. (S.A. Compl. ¶¶ 1, 53). The State further contends that Aventis and other defendants use secret discounts and rebates to keep the prices of their drugs secret and thereby wrongfully profit at the expense of the State and its citizens. (S.A. Compl. ¶¶ 1, 53). Aventis denies the allegations.

To begin with, Aventis avers that it plays absolutely no role in the State’s

decisions concerning whether and how to reimburse physicians, pharmacists and other providers. The State alone sets the reimbursement levels under various state programs, consistent with the State's obligations under federal law. The State did so, moreover, with full knowledge, developed over decades, that AWP does not represent an actual average of wholesale prices of drugs. The State's allegation that the State overpaid for prescription drugs manufactured by Aventis also fails to account for certain federally-mandated rebates that Aventis, and all defendants who participate in Wisconsin Medicaid, must extend to the State. These rebates effectively insulate the State from price increases greater than the consumer price index and ensure that the State is given the benefit of price discounts that are comparable, if not better, than the discounts extended to Aventis's most favored commercial customers.

In addition to the foregoing deficiencies, the Second Amended Complaint contains allegations that are vague, ambiguous, inflammatory or otherwise improper. Aventis responds only to the extent that such allegations are susceptible to a response and to the extent that Aventis has information sufficient to form a belief as to the allegations. Except where an allegation is expressly admitted, Aventis denies each and every allegation in the Second Amended Complaint. For example, to the extent that "Defendants" are lumped together or an allegation relates to the other parties, Aventis is unable to respond to those allegations and denies them. Aventis also denies all allegations that contain legal arguments and conclusions of law as those allegations do not require a response.

The following are Aventis's specific answers and defenses to the State's Second Amended Complaint.

## **I. NATURE OF THE ACTION**

1. Admitted in part; denied in part. Aventis admits only that Plaintiff brought this

action against Aventis. Aventis specifically denies the existence of or participation in an “unlawful scheme” or any of the “deceptive practices” alleged. Aventis further denies that the State is entitled to any damages or other form of relief from Aventis. Aventis denies any remaining allegations.

## **II. PARTIES AND JURISDICTION**

2. Admitted in part, denied in part. Aventis admits only that Plaintiff has brought this action against Aventis. Aventis specifically denies engaging in any “unlawful conduct.”

3. Denied. This paragraph is directed to parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies involvement in any “deceptive scheme” that has resulted in inflated prices for drugs sold to the State or its citizens.

4. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

5. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

6. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

7. Admitted. Aventis admits that it is a Delaware corporation with its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey.

8. Denied. This paragraph is directed at parties other than Aventis and, therefore,

Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

9. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

10. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

11. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

12. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

13. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

14. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

15. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

16. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

17. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

18. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

19. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

20. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

21. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

22. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

23. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are

denied.

24. Denied. This paragraph sets forth conclusions of law to which no response is required. To the extent a response is required, these allegations are denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterizations thereof are denied.

25. Denied. This paragraph sets forth conclusions of law to which no response is required. To the extent a response is required, these allegations are denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterizations thereof are denied.

### **III. FACTUAL BACKGROUND**

#### **A. The Market for Prescription Drugs**

26. Admitted in part; denied in part. Aventis admits that there are over 65,000 separate National Drug Codes (“NDCs”) and that physicians, hospitals, and pharmacies are typically called “providers.” After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the remainder of the averments and, therefore, denies the same.

27. Denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and, therefore, denies the same.

28. Admitted in part; denied in part. Aventis admits that in the prescription drug market, the decision to prescribe a drug is usually made by a physician, hospital or place where a person is treated, including long-term care facilities. After reasonable investigation, Aventis is without knowledge or information to form a belief as to the remainder of the averments and,

therefore, denies the same.

29. Admitted in part; denied in part. Aventis admits that in a typical market the ultimate consumer of the product usually pays for it directly. After reasonable investigation, Aventis is without knowledge or information to form a belief as to the truth of the remaining averments contained in this paragraph and, therefore, denies the same.

30. Denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and, therefore, denies the same. Specifically, Aventis denies the existence of and any part in an “unlawful scheme.”

**B. The Purpose of the Medicaid Program and How it Responds to the Complexity of the Drug Markets**

31. Admitted, on information and belief.

32. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required, these allegations are denied.

33. Denied. To the extent that the averments in this paragraph refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent a response is required, these allegations are denied.

34. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required, these allegations are denied.

35. Denied. To the extent that the averments in this paragraph refer to written materials, those sources speak for themselves, and any characterizations thereof are denied. To the extent a response is required, these allegations are denied.

36. Denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph

and, therefore, denies the same.

37. Denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph and, therefore, denies the same.

38. Denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph and, therefore, denies the same.

39. Denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph and, therefore, denies the same.

**C. Defendant's Corruption of the Government Medicaid Assistance Programs**

40. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies the existence of or involvement in any "scheme."

41. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

42. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

43. Denied. This paragraph is directed to parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it inflated "average wholesale prices." Aventis further

avers that it has been common knowledge and universally understood for years, including by the State and/or its agents, that AWP is a benchmark or reference price that does not equal an actual average of wholesale prices.

44. Denied. This paragraph is directed to parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of these averments and, therefore, denies the same.

45. Denied. This paragraph is directed to parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of these averments and, therefore, denies the same.

46. Admitted in part; denied in part. Aventis admits that attached to plaintiff's Second Amended Complaint is a list of drugs. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of these averments and, therefore, denies the same.

47. Denied. This paragraph is directed to parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

48. Admitted in part; denied in part. Aventis admits that attached to plaintiff's Second Amended Complaint is a list of drugs and the drugs' alleged reported and actual wholesale prices. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of these averments and, therefore, denies the same.

49. Denied. This paragraph is directed to parties other than Aventis and, therefore,

Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it “misrepresented and inflated” the WAC prices of its drugs.

**IV. DEFENDANTS’ EXACERBATION OF THE COMPLEXITIES OF THE MARKET AND AFFIRMATIVE CONCEALMENT OF THEIR WRONGDOING**

50. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies the existence of any “drug pricing scheme” or “purposely concealing” such “scheme” from the State.

51. Admitted in part; denied in part. Aventis admits that there are thousands of NDC numbered drugs. As to the remaining averments, Aventis is without knowledge or information sufficient to form a belief as to the truth of these averments and, therefore, denies the same.

52. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required, these allegations are denied. Aventis specifically denies the existence of or engagement in “marketing schemes which conceal the true price” of its drugs.

53. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies the existence of or engagement in any “scheme,” intended to “create the impression that the ‘wholesale price’ of the drug is higher than it really is.”

54. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

55. Denied. This paragraph is directed at parties other than Aventis and, therefore,

Aventis need not respond. To the extent a response is required of Aventis, after reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of these averments and, therefore, denies the same. Aventis specifically denies obscuring the true prices for its drugs.

56. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies the existence of any “phony grants.”

57. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies the existence of an “inflated AWP” or “phony price spread,” or intentionally manipulating the nation’s drug reimbursement system.

58. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies the existence of or participation in any “scheme” or “inflated spread.”

59. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. To the extent that the averments in this paragraph refer to written materials, those sources speak for themselves, and any characterizations thereof are denied.

60. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has engaged in an “unlawful scheme” or an “insidious, deceptive scheme” causing Wisconsin and its citizens to pay more than they should for

prescription drugs.

**V. THE INJURY TO GOVERNMENTAL HEALTH PLANS CAUSED BY DEFENDANTS' FALSE WHOLESALE PRICES**

**A. The Wisconsin Medicaid Program**

61. Admitted in part; denied in part. Aventis admits that the Wisconsin Medicaid program is a joint state and federal program that pays for medical care, including prescription drug benefits. After reasonable investigation, Aventis is without knowledge or information sufficient to form a belief as to the truth of the remainder of the averments contained in this paragraph, and therefore, the allegations are denied.

62. Admitted in part, denied in part. Aventis admits that for certain years the Wisconsin Medicaid Program reimbursed pharmacies and physicians for certain drugs at AWP minus a percentage, plus a dispensing fee. Aventis is without knowledge or information sufficient to form a belief as to whether the Wisconsin Medicaid Program has always reimbursed drugs at AWP minus a percentage. To the extent that the averments in this paragraph rely on statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent a response is required, these allegations are denied.

63. Admitted in part, denied in part. To the extent the allegations in Paragraph 63 of the Complaint state legal conclusions, no response is required. Aventis admits that the Wisconsin Medicaid Program reimburses certain drugs based on the State Maximum Acquisition Cost ("MAC") program. Aventis is without knowledge or sufficient information to form a belief as the truth of the remaining allegations in Paragraph 63 of the Complaint and on that basis denies the allegations. To the extent that the averments in this paragraph refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent a response is required, these allegations are denied.

64. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required, these allegations are denied.

65. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has “published false and inflated wholesale prices” causing Wisconsin and its citizens to pay more than they should for prescription drugs.

66. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied.

**B. Medicare**

67. Admitted, on information and belief.

68. Admitted in part; denied in part. Aventis admits that Medicare is an optional program that provides coverage for some healthcare services for Wisconsin’s participating elderly and disabled. Aventis is without knowledge or information sufficient to form a belief as to the truth of the remainder of the averments in this paragraph and, therefore, denies the same.

69. Admitted, on information and belief.

70. Denied. To the extent that the averments in this paragraph refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent a response is required, these allegations are denied.

71. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has “published false and inflated AWP’s” causing Wisconsin and its citizens to pay more than they should for prescription drugs.

## **VI. DEFENDANTS' CONDUCT WAS INTENTIONALLY IN DISREGARD OF ESTABLISHED LAW**

72. Denied. This paragraph sets forth conclusions of law to which no response is required. To the extent a response is required, these allegations are denied.

73. Denied. This paragraph sets forth conclusions of law to which no response is required. To the extent a response is required, these allegations are denied. To the extent that the averments in this paragraph refer to established case law, those sources speak for themselves, and any characterizations thereof are denied.

74. Denied. This paragraph sets forth conclusions of law to which no response is required. To the extent a response is required, these allegations are denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterizations thereof are denied.

75. Denied. After reasonable investigation, Aventis is without knowledge or information to form a belief as to the remainder of the averments and therefore, denies the same.

76. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has ignored: 1) its duty to behave with "scrupulous honesty," 2) case law, 3) Wisconsin statutes and 4) the "reprimands of Congress."

77. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that penalties and forfeitures are mandated in this case.

## **VII. HARM TO WISCONSIN CITIZENS**

78. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are

denied. Aventis specifically denies that it has engaged in any “unlawful activities.”

**COUNT I – Violation of Wis. Stat. § 100.18(1)**

79. Aventis repeats and incorporates, as if fully set forth herein, each and every response to the preceding paragraphs 1 through 78.

80. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it made any “untrue, deceptive or misleading” representations.

81. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that its conduct violated any Wisconsin statutes or laws.

82. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it engaged in any deceptive conduct such as falsely inflating the wholesale prices of its prescription drugs.

Aventis further denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph following Count I of the Second Amended Complaint. Aventis further denies that the State has asserted any viable claims that would necessitate a trial by jury.

**COUNT II – Violation of Wis. Stat. § 100.18(10)(b)**

83. Aventis repeats and incorporates, as if fully set forth herein, each and every

response to the preceding paragraphs 1 through 82.

84. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it engaged in any deceptive acts including publishing inflated wholesale prices for its drugs.

85. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it violated any Wisconsin statutes or laws against elderly and disabled Wisconsin citizens.

86. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it engaged in any conduct that harmed Wisconsin and its citizens participating in Wisconsin's Medicare Part B program.

Aventis further denies that the State is entitled to a judgment or any other relief as requested in the unnumbered "WHEREFORE" paragraph following Count II of the Second Amended Complaint. Aventis further denies that the State has asserted any viable claims that would necessitate a trial by jury.

### **COUNT III – Violation of the Wisconsin Trust And Monopolies Act**

87. Aventis repeats and incorporates, as if fully set forth herein, each and every response to the preceding paragraphs 1 through 86.

88. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has given any “secret discounts, rebates, and other economic benefits with the intent and effect of artificially inflating the private payer market for its products.”

89. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has engaged in any “unlawful activities.”

90. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has violated any Wisconsin statutes or laws.

91. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that Wisconsin and its citizens have been damaged by Aventis.

Aventis further denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph following Count III of the Second Amended Complaint. Aventis further denies that the State has asserted any viable claims that would necessitate a trial by jury.

**COUNT IV – Violation of Wis. Stat. § 49.49(4m)(a)(2) Medical Assistance Fraud**

92. Aventis repeats and incorporates, as if fully set forth herein, each and every response to the preceding paragraphs 1 through 91.

93. Admitted, on information and belief.

94. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it “knowingly made or caused to be made false statements or representations of material fact.”

95. Denied. To the extent that the averments in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterization thereof are denied. To the extent that a response is required of Aventis, these allegations are denied. Aventis specifically denies that it “used a variety of schemes, devices, agreements and false statements, and misrepresentations.”

Aventis further denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph following Count IV of the Second Amended Complaint. Aventis further denies that the State has asserted any viable claims that would necessitate a trial by jury.

#### **COUNT V – Unjust Enrichment**

96. Aventis repeats and incorporates, as if fully set forth herein, each and every response to the preceding paragraphs 1 through 95.

97. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has utilized any “misleading pricing information.”

98. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are

denied. Aventis specifically denies that it has utilized any “misleading pricing information” or that it in any way contributed to or caused Wisconsin and its citizens to be overcharged.

99. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has engaged in any “unlawful conduct.”

100. Denied. This paragraph is directed at parties other than Aventis and, therefore, Aventis need not respond. To the extent a response is required of Aventis, these allegations are denied. Aventis specifically denies that it has received any excessive payments or profits.

Aventis further denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph following Count V of the Second Amended Complaint. Aventis further denies that the State has asserted any viable claims that would necessitate a trial by jury.

#### **AVENTIS’S AFFIRMATIVE DEFENSES**

By asserting the matters set forth below, Aventis does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that Plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As for its affirmative defenses, Aventis reasserts and reincorporates, as if fully set forth herein, its responses to paragraphs 1 through 100 above:

### FIRST AFFIRMATIVE DEFENSE

The State and/or its agents knew and were aware that AWP was not an average wholesale price or the actual acquisition cost of drugs. Legal and equitable principles preclude this action for damages and injunctive relief, and the Due Process Clause of the U.S. Constitution and Section 2 of the Wisconsin Constitution preclude Plaintiff from bringing claims and seeking damages as alleged in the Second Amended Complaint.

### SECOND AFFIRMATIVE DEFENSE

Some or all of the State's claims against Aventis arise from the State's failure to follow its federal and state statutory and regulatory obligations to properly establish appropriate reimbursement rates. To the extent that the State established Medicaid reimbursement rates by reference to AWP, the State violated federal law in failing to establish Medicaid reimbursement rates as prescribed by federal law. The State is precluded by federal law from seeking damages, especially by reference to a different, lower AWP as alleged.

### THIRD AFFIRMATIVE DEFENSE

The State was required by federal law to conduct surveys and have statistics and data justifying, and to represent and warrant to the federal government, that its Medicaid reimbursement rates for single source drugs was necessary and appropriate, as a condition to obtaining federal funds. This action, with respect to single source drugs, is inconsistent with and precluded by the State's actions, representations and promises, and assumes that, with respect to single source drugs, the State made false claims to the federal government to obtain federal funds.

### FOURTH AFFIRMATIVE DEFENSE

The claims alleged herein, based on the facts alleged, are barred by the State's

comparative negligence and contributory negligence. Among other things, the claims disregard the State's obligations under federal law, and they ignore the State's affirmative misstatements and declarations that were intended to cover up and hide from view of the federal regulatory authority, and the State's citizens and taxpayers, the State's failings referred to herein, as well as other inappropriate conduct by the State.

#### FIFTH AFFIRMATIVE DEFENSE

The State's reimbursement rates for drugs for Medicaid recipients were filed with, reviewed, and approved by a federal regulatory agency with authority to do so under the Medicaid Act. Actions in a state court seeking relief, including alleged damages, contending that rates approved by a federal regulatory agency do not apply or are not binding are, as the United States Supreme Court directed, precluded by the Supremacy Clause. This action is barred by the Supremacy Clause of the Constitution.

#### SIXTH AFFIRMATIVE DEFENSE

The State's claims are preempted by the dormant Commerce Clause of the United State Constitution.

#### SEVENTH AFFIRMATIVE DEFENSE

The State's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

#### EIGHTH AFFIRMATIVE DEFENSE

The State's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or

conduct by Aventis in judicial, legislative, or administrative proceedings of any kind or at any level of government.

NINTH AFFIRMATIVE DEFENSE

The State fails to state a claim against Aventis upon which relief may be granted.

TENTH AFFIRMATIVE DEFENSE

The State has no standing or capacity to bring some or all of the claims raised in this suit to recover expenditures by Wisconsin Medicaid or to seek injunctive relief.

ELEVENTH AFFIRMATIVE DEFENSE

The State has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Aventis as alleged in the Second Amended Complaint.

TWELFTH AFFIRMATIVE DEFENSE

To the extent that the State obtains, or is barred from, recovery in any other case predicated on the same factual allegations, the State is barred from seeking recovery against Aventis based on the Second Amended Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

THIRTEENTH AFFIRMATIVE DEFENSE

The State's claims are barred, in whole or in part, to the extent that the State has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

FOURTEENTH AFFIRMATIVE DEFENSE

Any and all actions taken by Aventis with respect to any of the matters alleged in the Second Amended Complaint were taken in good faith and in accordance with established industry practice.

FIFTEENTH AFFIRMATIVE DEFENSE

The State's claims against Aventis are barred because Aventis has complied with all applicable regulations of the federal and state governments.

SIXTEENTH AFFIRMATIVE DEFENSE

The State's claims against Aventis are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

SEVENTEENTH AFFIRMATIVE DEFENSE

The State's claims are barred, in whole or in part, because they violate Aventis's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Wisconsin, insofar as the State seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

EIGHTEENTH AFFIRMATIVE DEFENSE

Aventis's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by the State.

NINETEENTH AFFIRMATIVE DEFENSE

The State's claims against Aventis for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

TWENTIETH AFFIRMATIVE DEFENSE

The State's claims for injunctive relief against Aventis are barred by the doctrines of *in pari delicto* and/or unclean hands.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The State's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third

parties.

TWENTY-SECOND AFFIRMATIVE DEFENSE

The State's claims against Aventis are barred, in whole or in part, due to the State's failure to join indispensable parties.

TWENTY-THIRD AFFIRMATIVE DEFENSE

The State's claims against Aventis are misjoined with the State's claims against other defendants and must be severed.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

The State's claims against Aventis for damages are barred, in whole or in part: (1) because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of Plaintiff and the allocation of any fault, if any exists, attributable to Aventis; (2) because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Second Amended Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has paid for products manufactured, marketed and sold by Aventis after the filing of the State's original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of the alleged damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Aventis is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by the State, with respect to the same alleged injuries.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

The applicable statutory ceilings on recoverable damages, forfeitures or penalties

must limit any damages recovered by the State from Aventis.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

The State fails to allege facts or a cause of action against Aventis sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Aventis denies that it has engaged in any conduct that entitles the State to recover penalty assessments and avers that the State's Second Amended Complaint fails to state a claim upon which penalty assessments may be awarded to the State.

TWENTY-NINTH AFFIRMATIVE DEFENSE

The claims contained in the Second Amended Complaint, which seek the recovery of penalty assessments, under present Wisconsin law, violate the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on the following grounds:

- a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose penalty assessments, which are penal in nature, against a civil defendant upon the State's satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- b) the procedures pursuant to which any penalty assessments would be awarded fail to provide a reasonable limit on the amount of the award against Aventis, which violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- c) the procedures pursuant to which any penalty assessments would be awarded fail to provide specific standards for the amount of the award of penalty assessments, which violates the Due Process Clause of the Fourteenth Amendment of the United States

Constitution;

d) the procedures pursuant to which any penalty assessments would be awarded result in the imposition of different penalties for the same or similar acts, and thus violates the Equal Protection Clause of the Fourteenth Amendment of the United States

Constitution;

e) the procedures pursuant to which any penalty assessments would be awarded permit the imposition of penalty assessments in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and

f) the procedures pursuant to which any penalty assessments would be awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution.

#### THIRTIETH AFFIRMATIVE DEFENSE

The recovery of penalty assessments by the State in this action would violate Article I, Section 1, 6, 7, 8 and 11 of the Wisconsin Constitution on the following grounds:

a) it is a violation of Section 2 to impose penalty assessments, which are penal in nature, upon a civil defendant upon the State satisfying a burden of proof less than the “beyond a reasonable doubt” burden of proof required in criminal cases;

b) the procedures pursuant to which any penalty assessments would be awarded fail to provide a limit on the amount of the award against Aventis;

c) the procedures pursuant to which any penalty assessments would be awarded are unconstitutionally vague;

d) the procedures pursuant to which any penalty assessments would be awarded fail to provide specific standards for the amount of the award of penalty assessments; and

e) the award of penalty assessments in this case would constitute a deprivation of property without due process.

#### THIRTY-FIRST AFFIRMATIVE DEFENSE

The procedures pursuant to which any penalty assessments would be awarded permit the imposition of an excessive fine in violation of Article 1, Section 6 of the Wisconsin Constitution.

#### THIRTY-SECOND AFFIRMATIVE DEFENSE

The State fails to state with particularity facts to support claims of fraud against Aventis contained in the Second Amended Complaint.

#### THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent that the State attempts to seek equitable relief against Aventis, the State is not entitled to such relief because the State has an adequate remedy at law.

#### THIRTY-FOURTH AFFIRMATIVE DEFENSE

The State's unjust enrichment claims are barred, in whole or in part, because Aventis did not collect or retain any money belonging to the State as a result of any alleged overpayments as required under Wisconsin law.

#### THIRTY-FIFTH AFFIRMATIVE DEFENSE

The State's unjust enrichment claims are barred, in whole or in part, because the State has no authority to bring such claims either on behalf of itself or on behalf of Medicare Part B participants.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

The State's unjust enrichment claims are barred, in whole or in part, by contracts to which the State and Aventis are parties.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Aventis hereby adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein. Aventis hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

The State fails to allege facts or a cause of action against Aventis sufficient to support a claim for prejudgment interest or any other relief.

THIRTY-NINTH AFFIRMATIVE DEFENSE

The State's claims are barred, in whole or in part, by the filed rate doctrine.

FORTIETH AFFIRMATIVE DEFENSE

The State's claims against Aventis are barred, in whole or in part, because Aventis did not make any false statements to the State or its agents. As to any statement asserted against Aventis that the State alleges to be false or misleading, Aventis had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

FORTY-FIRST AFFIRMATIVE DEFENSE

The State's claims are barred in whole or in part because Aventis' conduct was neither "deceptive," "misleading," "unlawful," nor "illegal."

FORTY-SECOND AFFIRMATIVE DEFENSE

The State's claims are barred in whole or in part because the State did not rely on the allegedly fraudulent statements or conduct of Aventis.

FORTY-THIRD AFFIRMATIVE DEFENSE

The State's claims are barred in whole or in part with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed in whole or in part by a person and/or entity that purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiff.

FORTY-FOURTH AFFIRMATIVE DEFENSE

The State's claims against Aventis are barred because Aventis did not directly or indirectly engage in any conduct in violation of state or federal law.

FORTY-FIFTH AFFIRMATIVE DEFENSE

The State's claims against Aventis are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Second Amended Complaint.

FORTY-SIXTH AFFIRMATIVE DEFENSE

The State has no authority to seek restitution for third parties based on any alleged violation of section 49.49(4m)(a)(2).

FORTY-SEVENTH AFFIRMATIVE DEFENSE

The State's claims are barred in whole or in part because it did not consult with the Governor of the State of Wisconsin and/or the Department of Agriculture, Trade and Consumer Protection prior to bringing this suit.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

The State's claims under Wis. Stat. § 49.49 are barred because Aventis did not

possess the requisite mental state required under that statute.

FORTY-NINTH AFFIRMATIVE DEFENSE

Aventis has made no assertion, representation or statement of fact which is “untrue,” “deceptive,” or “misleading,” as required under Wis. Stat. §§ 100.18(1) and 100.18(10)(b).

FIFTIETH AFFIRMATIVE DEFENSE

The State’s claims under Wis. Stat. 100.18 are barred, in whole or part, to the extent the claims involve the insurance business.



