



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

- (1) PURDUE PHARMA L.P.;
- (2) PURDUE PHARMA, INC.;
- (3) THE PURDUE FREDERICK COMPANY;
- (4) TEVA PHARMACEUTICALS
USA, INC.;
- (5) CEPHALON, INC.;
- (6) JOHNSON & JOHNSON;
- (7) JANSSEN PHARMACEUTICALS, INC.;
- (8) ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS, INC.;
- (9) JANSSEN PHARMACEUTICA, INC.,
n/k/a JANSSEN PHARMACEUTICALS,
INC.;
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,
f/k/a ACTAVIS, INC., f/k/a WATSON
PHARMACEUTICALS, INC.;
- (11) WATSON LABORATORIES, INC.;
- (12) ACTAVIS LLC; and
- (13) ACTAVIS PHARMA, INC.,
f/k/a WATSON PHARMA, INC.,

Defendants.

STATE OF OKLAHOMA }
CLEVELAND COUNTY } S.S.

FILED

AUG 31 2018

In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816

Honorable Thad Balkman

AMENDED ANSWER OF DEFENDANT TEVA
PHARMACEUTICALS USA, INC. TO PLAINTIFF'S PETITION

Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”), by and through its undersigned attorneys, hereby answers Plaintiff’s (the “State’s”) Petition and asserts additional defenses.

PRELIMINARY STATEMENT

The following matters are incorporated by reference into the responses of Teva USA to each paragraph of the Petition.

A. Teva USA submits this Answer and Additional Defenses only on behalf of itself. Where allegations are made against “Defendants” as a group, the responses of Teva USA apply only to it.

B. Except as otherwise expressly stated herein, Teva USA expressly denies each and every allegation contained in the Petition, including without limitation any allegations contained in the preamble, unnumbered paragraphs, headings, subheadings, and footnotes of the Petition, and specifically denies any liability to the State.

C. Teva USA expressly reserves the right to seek to amend and/or supplement its Answer as may be appropriate or necessary.

ADMISSIONS AND DENIALS

AND NOW, incorporating the foregoing, Teva USA responds to the specific allegations of the Petition as follows:

I. INTRODUCTION¹

1. Teva USA admits that the use of opioids carries with it a risk of addiction. This is why the FDA-approved labels for Teva USA’s opioid products warn prescribers and patients in clear and explicit terms that the products carry a “risk for misuse, abuse, addiction, and

¹ Some headings and subheadings in Teva USA’s Response to Specific Allegations are included for convenience and correspond to headings and subheadings listed in the State’s Petition. To the extent any heading or subheading is construed to be an allegation, Teva USA denies the same.

overdose.” See ACTIQ label, attached hereto as Exhibit A; Fentora label, attached hereto as Exhibit B. Teva USA denies the remaining allegations in Paragraph 1.

2. To the extent that the allegations in Paragraph 2 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Teva USA denies the remaining allegations in Paragraph 2.

3. To the extent that the allegations in Paragraph 3 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Teva USA denies the remaining allegations in Paragraph 3.

4. To the extent that the allegations in Paragraph 4 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Teva USA denies the remaining allegations in Paragraph 4.

5. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 5 and therefore denies the same. Teva USA expressly denies that it engaged in “false and deceptive marketing campaigns” and that its actions “caused” any “damage” to the State.

6. Teva USA has no knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 6 and therefore denies the same. Teva USA expressly denies that its actions “caused” any “costs” incurred by the State.

7. Paragraph 7 states conclusions of law to which no response is required. To the extent that a response is required, Teva USA denies the allegations in Paragraph 7.

II. JURISDICTION AND VENUE

8. Teva USA admits that the State is asserting the claims set forth in Section V below, one of which is the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053.1-7. Teva USA further admits that Paragraph 8 contains a partial quote from §5053.7 of the OMFCA. Teva USA denies that the State has adequately pled any claim against it, or is entitled to any recovery against it.

9. Paragraph 9 states conclusions of law to which no response is required. To the extent that a response is required, Teva USA denies the allegations in Paragraph 9.

10. Paragraph 10 states conclusions of law to which no response is required. To the extent that a response is required, Teva USA denies the allegations in Paragraph 10, but does not contest venue in this Court.

11. Paragraph 11 states conclusions of law to which no response is required. To the extent that a response is required, Teva USA denies the allegations in Paragraph 11, but does not contest venue in this Court.

III. PARTIES

A. Plaintiff

12. Paragraph 12 states conclusions of law to which no response is required. To the extent that a response is required, Teva USA admits that Oklahoma was established as the 46th State in the Union on November 16, 1907. Teva USA is without knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 12 and therefore denies the same.

B. Defendants

i. The Purdue Defendants

13. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 13 and therefore denies the same.

14. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 14 and therefore denies the same.

ii. The Actavis Defendants

15. Teva USA admits only that the Acquired Actavis Entities became affiliated with the Teva Defendants by virtue of a corporate transaction that was finalized in August 2016, and that the Acquired Actavis Entities manufacture and sell generic opioids which they do not promote. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 15 and therefore denies the same.

16. Teva USA admits only that the Acquired Actavis Entities became affiliated with the Teva Defendants by virtue of a corporate transaction that was finalized in August 2016, and that at various times the Acquired Actavis Entities have been in the business of manufacturing, selling, and distributing certain generic opioids to various customers. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 16 and therefore denies the same.

iii. The Cephalon Defendants

17. Teva USA admits only that it is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA denies the remaining allegations in Paragraph 17.

18. Teva USA admits only that Cephalon has been in the business of manufacturing, selling, and distributing ACTIQ and Fentora to various customers at various times. Teva USA denies the remaining allegations in Paragraph 18.

iv. The Janssen Defendants

19. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 19 and therefore denies the same.

20. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 20 and therefore denies the same.

IV. FACTUAL ALLEGATIONS

21. To the extent that the allegations in Paragraph 21 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Teva USA denies the remaining allegations in Paragraph 21.

22. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in Paragraph 22 and therefore denies the same.

23. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 23 and therefore denies the same. Teva USA expressly denies that it engaged in “deceptive marketing of opioids.”

24. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 24 and therefore denies the same.

25. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 25 and therefore denies the same.

26. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 26 and therefore denies the same.

27. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 27 and therefore denies the same.

28. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 28 and therefore denies the same.

29. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 29 and therefore denies the same.

30. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 30 and therefore denies the same. Teva USA expressly denies that its actions caused the alleged effects on Oklahoma citizens.

31. Paragraph 31 states conclusions of law to which no response is required. To the extent that the allegations in Paragraph 31 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 31 and therefore denies the same. Teva USA specifically denies that it engaged in a “deceptive marketing campaign” or otherwise caused the alleged harm.

32. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 32 and therefore denies the same. Teva USA expressly denies that its actions have “caused” “costs” and “losses” in Oklahoma.

33. Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 33 and therefore denies the same.

34. To the extent that the allegations in Paragraph 34 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 34 and therefore denies the same. Teva USA specifically denies that it engaged in a “deceptive and misleading marketing campaign” or otherwise caused the alleged harm.

35. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 and therefore denies the same.

36. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 and therefore denies the same.

37. Paragraph 37 states conclusions of law to which no response is required. Further, to the extent that a response is required, Teva USA denies the allegations in Paragraph 37.

38. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 and therefore denies the same.

39. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 and therefore denies the same.

40. Paragraph 40 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 40 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the

allegations in Paragraph 40 and therefore denies the same. Teva USA specifically denies that its conduct caused the alleged harm.

41. Paragraph 41 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 41 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 41. Teva USA specifically denies that it engaged in a “false and deceptive marketing campaign” or otherwise caused the alleged harm.

42. Paragraph 42 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 42 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 42 and therefore denies the same. Teva USA specifically denies that its conduct caused the alleged harm.

43. Paragraph 43 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 43 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 43 and therefore denies the same. Teva USA specifically denies that its conduct caused the alleged harm.

44. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 and therefore denies the same.

45. Paragraph 45 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 45 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 45 and therefore denies the same. Teva USA specifically denies that it engaged in a “deceptive marketing campaign” or that its conduct caused the alleged harm.

46. Paragraph 46 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 46 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 46 and therefore denies the same. Teva USA specifically denies that it engaged in a “deceptive marketing campaign” or that its conduct caused the alleged harm.

47. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 and therefore denies the same.

48. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 and therefore denies the same.

49. Paragraph 49 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 49 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those

allegations and therefore denies the same. To the extent that a response is required, Teva USA has no knowledge or information sufficient to form a belief regarding the truth of the allegations in Paragraph 49 and therefore denies the same. Teva USA specifically denies that it engaged in a “false and deceptive prescription opioid marketing campaign” or that its conduct caused the alleged harm.

50. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 50 and therefore denies the same. Teva USA specifically denies that its conduct caused the alleged harm.

51. Paragraph 51 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 51 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 51.

52. Paragraph 52 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 52 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 52.

53. Paragraph 53 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 53 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that the allegations in Paragraph 53 concern the characterization of documents, the documents speak for themselves and Plaintiff's

characterizations of same are denied. To the extent that a response is required, Teva USA denies the allegations in Paragraph 53.

54. Paragraph 54 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 54 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 54.

55. To the extent that the allegations in Paragraph 55 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 55.

56. Paragraph 56 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 56 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 56.

57. Paragraph 57 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 57 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 57.

58. Paragraph 58 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 58 relate to Defendants other than Teva USA, Teva

USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 58.

59. Paragraph 59 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 59 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 59.

60. To the extent that the allegations in Paragraph 60 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 60.

61. Teva USA admits only that Dr. Portenoy is the former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York. The remaining allegations in Paragraph 61 state conclusions of law to which no response is required. Further, Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 61 concerning statements made by Dr. Portenoy and therefore denies the same. To the extent that the allegations in Paragraph 61 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 61.

62. Teva USA admits only that Dr. Webster is the former Chief Medical Director of Lifetree Clinical Research, a pain clinic in Utah. The remaining allegations in Paragraph 62 state

conclusions of law to which no response is required. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 concerning statements made by Dr. Webster and therefore denies the same. To the extent that the allegations in Paragraph 62 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 62.

63. Paragraph 63 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 63 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 63.

64. Paragraph 64 states conclusions of law to which no response is required. To the extent that the allegations in Paragraph 64 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that the allegations in Paragraph 64 concern the characterization of documents, the documents speak for themselves and Plaintiff's characterizations of same are denied. To the extent that a response is required, Teva USA denies the allegations in Paragraph 64.

65. To the extent that the allegations in Paragraph 65 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 65.

66. Paragraph 66 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 66 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 66.

67. Paragraph 67 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 67 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 67.

68. Paragraph 68 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 68 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68 and therefore denies the same. Teva USA expressly denies that it made representations that were “false, deceptive, and unsupported.”

69. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 and therefore denies the same. Further, to the extent that the allegations in Paragraph 69 concern the characterization of documents, the documents speak for themselves and Plaintiff’s characterizations of same are denied.

70. Teva USA admits that the FDA-approved labels on its products clearly disclosed that the products carried certain risks. Indeed, the labels for Teva USA’s opioid products warn

prescribers and patients in clear and explicit terms that the products carry a “risk for misuse, abuse, addiction, and overdose.” *See* Ex. A (ACTIQ label); Ex. B (Fentora label). The remaining allegations in Paragraph 70 are denied. Paragraph 70 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 70 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the remaining allegations in Paragraph 70.

71. Paragraph 71 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 71 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 71 and therefore denies the same. Teva USA specifically denies that it made representations that were “false.”

72. Paragraph 72 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 72 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 72.

V. CAUSES OF ACTION

A. **Oklahoma Medicaid False Claims Act, 63 Okl. St. §§ 5053.1-7**

73. Teva USA reasserts its responses to Paragraphs 1 through 72.

74. Paragraph 74 states conclusions of law to which no response is required.

i. Count 1

75. Paragraph 75 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 75 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 75.

76. Paragraph 76 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 76 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 76.

77. Paragraph 77 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 77 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 77.

78. Paragraph 78 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 78 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 78.

79. Paragraph 79 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 79 relate to Defendants other than Teva USA, Teva

USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 79.

80. Paragraph 80 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 80 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 80.

81. Paragraph 81 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 81 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 81.

82. Paragraph 82 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 82 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 82.

ii. Count 2

83. Paragraph 83 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 83 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those

allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 83.

84. Paragraph 84 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 84 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 84.

85. Paragraph 85 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 85 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 85.

86. Paragraph 86 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 86 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 86.

87. Paragraph 87 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 87 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 87.

88. Paragraph 88 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 88 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 88.

89. Paragraph 89 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 89 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 89.

90. Paragraph 90 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 90 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 90.

91. Paragraph 91 states conclusions of law to which no response is required.

B. Oklahoma Medicaid Program Integrity Act, 56 Ok. St. §§ 1001-1008

92. Teva USA reasserts its responses to Paragraphs 1 through 91.

93. Paragraph 93 states conclusions of law to which no response is required.

94. Paragraph 94 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 94 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those

allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 94.

95. Paragraph 95 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 95 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 95.

96. Paragraph 96 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 96 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 96.

97. Paragraph 97 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 97 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 97.

98. Paragraph 98 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 98 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 98.

99. Paragraph 99 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 99 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 99.

100. Paragraph 100 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 100 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 100.

101. Paragraph 101 states conclusions of law to which no response is required.

C. Oklahoma Consumer Protection Action, 15 Okl. St. §§ 751-65

102. Teva USA reasserts its responses to Paragraphs 1 through 101.

103. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

104. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

105. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

106. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

i. Count 1

107. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017)

108. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

109. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

ii. Count 2

110. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

111. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

112. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

113. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

114. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

115. The State's claim under the Oklahoma Consumer Protection Act has been dismissed with prejudice and therefore no response is required. *See Order, Oklahoma ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dec. 6, 2017).

D. Public Nuisance, 50 Okl. St. § 2

116. Teva USA reasserts its responses to Paragraphs 1 through 115.

117. Paragraph 117 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 117 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 117.

118. Paragraph 118 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 118 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 118.

119. Paragraph 119 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 119 relate to Defendants other than Teva

USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 119 and is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same.

120. Paragraph 120 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 120 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 120. Teva USA specifically denies that it created a public nuisance.

E. Fraud (Actual and Constructive) and Deceit

121. Teva USA reasserts its responses to Paragraphs 1 through 120.

122. Paragraph 122 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 122 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 122.

123. Paragraph 123 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 123 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 123.

124. Paragraph 124 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 124 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 124.

125. Paragraph 125 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 125 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 125.

126. Paragraph 126 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 126 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 126.

127. Paragraph 127 states conclusions of law to which no response is required.

128. Paragraph 128 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 128 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 128.

129. Paragraph 129 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 129 relate to Defendants other than Teva

USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 129.

F. Unjust Enrichment

130. Paragraph 130 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 130 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 130.

131. Paragraph 131 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 131 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 131.

132. Paragraph 132 states conclusions of law to which no response is required. Further, to the extent that the allegations in Paragraph 132 relate to Defendants other than Teva USA, Teva USA is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. To the extent that a response is required, Teva USA denies the allegations in Paragraph 132.

133. Paragraph 133 states conclusions of law to which no response is required.

VI. JURY DEMAND

134. Paragraph 134 states conclusions of law to which no response is required.

VII. PRAYER

WHEREFORE, Teva USA respectfully requests that judgment be entered in its favor against the State and further request that it be awarded costs and attorneys' fees and such other further relief that the Court deems appropriate and just.

ADDITIONAL DEFENSES

Teva USA hereby asserts additional defenses to the allegations and claims in the State's Petition. By asserting the matters below, Teva USA does not admit that the State is relieved of its burden to prove each element of its claims and the damages or relief sought.

FIRST ADDITIONAL DEFENSE: FAILURE TO STATE A CLAIM

The State's claims are barred because the Petition fails to state a claim upon which relief can be granted, fails to state facts sufficient to constitute a cause of action, and fails to plead a legally cognizable injury.

SECOND ADDITIONAL DEFENSE: STATUTE OF LIMITATIONS

The State's claims are barred, in whole or in part, by the applicable statute(s) of limitations and/or statute(s) of repose, including but not limited to 12 Okla. Stat. § 95(A) and 63 Okla. Stat. § 5053.6. Under Oklahoma law, a cause of action accrues when the State knew or reasonably should have known of a wrongly caused injury to itself or to Oklahoma consumers. Here, the State alleges wrongfully-caused injuries that occurred over an unspecified period of time. *See* Pet. ¶¶ 4-6, 21-34, 40-51. The State and/or Oklahoma consumers would have known of, or reasonably should have known of, at least some of these purported injuries outside of the relevant limitations period. To the extent that the State knew or reasonably should have known of any wrongfully caused injuries outside of the applicable limitations period, the State's claims are time-barred.

THIRD ADDITIONAL DEFENSE: PRIMARY JURISDICTION

The State's claims are barred by the doctrine of primary jurisdiction. The State's allegations implicate medical and scientific issues that are outside the conventional experience of judges and particularly within the FDA's expertise, discretion, and regulatory authority.

FOURTH ADDITIONAL DEFENSE: VIOLATIONS OF DUE PROCESS BASED ON CONTINGENT FEE COUNSEL

The rights of Teva USA under the Due Process Clause of the U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding. *See, e.g., Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980). Any contingency fee arrangement between the State and any third party in connection with this litigation gives that third party a financial interest in the outcome of this proceeding and violates the due process rights of Teva USA.

FIFTH ADDITIONAL DEFENSE: FAILURE TO JOIN INDISPENSABLE PARTIES

The State has failed to join one or more necessary and indispensable parties, including without limitation governmental agencies, commissions, departments, subdivisions or entities claiming entitlement to relief arising from or related to the allegations of the Petition and health care providers, prescribers, patients, and other third parties whom the State alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Oklahoma. *See, e.g., Pet.* ¶¶ 3, 27, 51, 59-67, 72. These third parties have a legal interest in the subject matter of the litigation to the extent they assert a right or claim to relief or to the extent they facilitated and/or participated in the opioid misuse, abuse, and related misconduct alleged in the Petition. The State has failed to name any such third parties as

plaintiffs or as defendants, respectively, nor has the State alleged how, if at all, it would be infeasible to join one or more indispensable but absent parties.

SIXTH ADDITIONAL DEFENSE: FEDERAL PREEMPTION

The State's claims are barred because they are preempted by federal law. Federal law authorized Teva USA to promote opioid products for their FDA-approved indications. To the extent the State's claims seek to hold Teva USA liable for promoting opioid products for their FDA-approved uses, the claims are preempted. Granting such relief would impede, impair, frustrate, or burden the effectiveness of federal law and would violate the Supremacy Clause of the United States Constitution. To the extent the State's claims are inconsistent with the determinations of FDA based on the information provided to FDA, or otherwise assert that incorrect, incomplete or inaccurate information was provided to the FDA, the claims are also preempted. *See, e.g., Buckman v. Pls.' Legal Comm.*, 531 U.S. 341 (2001); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015); *Yates v. OrthoMcNeil-Janssen Pharms., Inc.*, 808 F.3d 281 (6th Cir. 2015).

SEVENTH ADDITIONAL DEFENSE: LACHES, WAIVER, EQUITABLE ESTOPPEL, UNCLEAN HANDS

The State's claims are barred by the doctrines of laches, waiver, equitable estoppel, and/or unclean hands. The State complains of injuries and conduct that predate the commencement of this action by decades. The State admits that at the time it commenced the instant action, it was continuing to reimburse opioid prescriptions written for indications that the State now contends are not medically necessary, reasonably required, and/or dispensed for an FDA-approved purpose, precluding the State from claiming it was misled by Teva USA's alleged misconduct. Upon information and belief, the State did not reject, disapprove, or object to claims for reimbursement of Teva USA's opioids for off-label indications before it filed its

Petition. The State's claims against Teva USA thus are barred by the doctrines of waiver and/or estoppel. The State's failure to exercise diligence in bringing this action has prejudiced Teva USA by depriving it the opportunity to alter its allegedly improper practices, if necessary. As a matter of equity, therefore, the doctrine of laches should bar the State from recovering on its claims. Further, the inequitable conduct of the State alleged above precludes the State from entitlement to any equitable remedies under the doctrine of unclean hands.

EIGHTH ADDITIONAL DEFENSE: REMEDY AT LAW

With respect to the State's claim for unjust enrichment, and to the extent the State seeks any additional equitable relief, such relief is unavailable to the extent the State is also deemed to have an adequate remedy at law.

NINTH ADDITIONAL DEFENSE: LEARNED INTERMEDIARY

The State's claims are barred by the learned intermediary doctrine. At all relevant times herein, the physicians and other health care providers who prescribed Teva USA's opioid products at issue were in the position of learned intermediaries, who are presumed to have knowledge of a drug label's contents and who used their informed, independent medical judgment in making their prescribing and treatment decisions for a given patient. These prescribers had many sources of information about those products available to them, including the products' FDA-approved labeling, which informed prescribers of the risks and benefits of Teva USA's products, *see, e.g.*, Pet. ¶¶ 53, 67, 70, and these prescribers relied on a variety of factors separate from and unrelated to Teva USA's alleged misrepresentations in making their prescribing decisions, *see, e.g., id.* ¶¶ 47-48. Regardless of the learned intermediary doctrine's origination in product liability law, its principles still establish a superseding interruption in the necessary chain of causation between any alleged conduct by Teva USA and the State's alleged

injuries, and/or preclude the State from establishing that physicians and other health care providers reasonably relied on any alleged misrepresentations by Teva USA inconsistent with the providers' informed and independent medical judgment.

TENTH ADDITIONAL DEFENSE: MISJOINDER AND SEVERANCE

The State's claims against Teva USA and other Defendants do not arise out of the same transaction, occurrence, or series of transactions or occurrences as required by 12 Okla. Stat. § 2020 for joinder of parties. The State fails to connect any of the alleged marketing activities of Teva USA to those of other Defendants, nor could it. Accordingly, the Court should sever or dismiss the State's claims against Teva USA pursuant to 12 Okla. Stat. §§ 2020 and 2021.

ELEVENTH ADDITIONAL DEFENSE: RATIFICATION

The State's alleged loss, damage, injury, harm, expense, diminution, or deprivation, if any, was caused in whole or in part by the State's ratification of Teva USA's allegedly deceptive or misleading conduct. Such ratification would include, for example, the State's continuing reimbursement of opioid prescriptions after it had concluded such prescriptions were ineffective or harmful to Oklahoma consumers, medically unnecessary, or otherwise ineligible for payment by the State.

TWELTH ADDITIONAL DEFENSE: THIRD-PARTY ACTIONS

The State's claims against Teva USA are barred to the extent that any rely on or implicate the negligent, intentional, malicious, criminal, and/or otherwise unlawful acts or omissions of the State or third parties that are not subject to Teva USA's control or authority and for which Teva USA is not responsible and cannot be held liable. These include but are not limited, to health care providers, prescribers, patients, and other third parties whom the State alleges engaged in the unauthorized, illicit, or unlawful distribution, prescription, dispensing, diversion, use, misuse,

or abuse of prescription opioid products in Oklahoma. Teva USA's liability, if any, therefore must be reduced or negated to the extent that third parties have contributed to, or caused, the State's injuries.

THIRTEENTH ADDITIONAL DEFENSE: CORPORATE IDENTITY

To the extent the State's claims are based the alleged conduct of other Defendants, and the State seeks to impose liability on Teva USA only by virtue of Teva USA's ownership of another Defendant's shares, membership within another Defendant's unincorporated entity, or similar affiliation, the State has failed to plead allegations sufficient to support a claim to pierce the corporate veil, or to otherwise hold Teva USA liable merely by virtue of its corporate affiliation with other Defendants.

FOURTEENTH ADDITIONAL DEFENSE: PROTECTED SPEECH

The State's claims are barred by, in whole or in part, the applicable provisions of the United States Constitution and the Oklahoma Constitution, including but not limited to the First Amendment to the United States Constitution and/or Article II, Section 22 of the Oklahoma Constitution. The State's claims rely on allegations that Teva USA engaged in various marketing activities relating to opioid products, including advertisements, detailing, speaker programs, and other promotional efforts. These activities concern lawful activity, are neither false nor misleading, and thus constitute constitutionally protected commercial speech.

**FIFTEENTH ADDITIONAL DEFENSE:
LACK OF PROXIMATE CAUSE**

The State's claims, or at a minimum, its requests for relief are barred because Teva USA's alleged misrepresentations, or any other allegedly injurious conduct, were not the proximate or legal cause of the purported injuries or damages incurred by the State or any other party. The physicians and other health care Professionals who prescribed Teva USA's opioid

product(s) at issue in the Petition had many sources of information about those products available to them, including the products' FDA-approved labeling, which informed physicians of the risks and benefits of these products, and these prescribers relied on a variety of factors separate from Teva USA's alleged misrepresentations in making their prescribing decisions, if they relied upon Teva USA's marketing at all. Furthermore, prescriber decisions were also affected by other independent superseding causes and/or intervening events that broke any causal chain, including individual patients' preferences, patients' decision to fill a prescription, patients' decision whether and how to use the medication, and the State's decision whether and when to cover the drug for the particular indication and reimburse for the particular prescription. As a consequence, the alleged injuries asserted by the State are too remote from the alleged conduct or omissions of Teva USA to be a basis for liability as a matter of law and due process. *See* U.S. Const. Amend. V.

SIXTEENTH ADDITIONAL DEFENSE: ASSUMPTION OF RISK

The State's claims are barred to the extent providers prescribed and/or their patients used Teva USA's products after becoming aware of their alleged risks. Further, the State's claims are barred to the extent the State reimbursed Medicaid claims, or incurred any other form of alleged damages, after becoming aware of the alleged risks associated with Teva USA's products.

SEVENTEENTH ADDITIONAL DEFENSE: CONTRIBUTORY OR COMPARATIVE NEGLIGENCE

The State's claims are barred, in whole or in part, by the doctrines of contributory or comparative negligence, and/or contributory or comparative fault.

EIGHTEENTH ADDITIONAL DEFENSE: MITIGATION

The State's claims are barred or limited by the State's failure to mitigate its alleged damages. To the extent the State mitigated, minimized, or avoided damages allegedly sustained,

or unreasonably failed to mitigate, minimize, or avoid any damages, any economic damages attributable to the conduct of Teva USA must be reduced by that amount.

NINETEENTH ADDITIONAL DEFENSE: OUTSIDE SCOPE

To the extent any agents, employees, or contractors of Teva USA caused any of the damages alleged by the State, such agents, employees, or contractors were acting outside the scope of the agency employment, or contract with Teva USA, and any recovery against Teva USA must be reduced by the proportionate fault of such agents, employees, or contractors.

TWENTIETH ADDITIONAL DEFENSE: SET OFF

Any damage or injury to the State must be set off against the benefits to the State as a result of Teva USA's lawful activity. Further, in the event Teva USA is held liable to the State, Teva USA would be entitled to a set-off for all sums of money received or available from or on behalf of any other parties liable for the same alleged injury.

TWENTY-FIRST ADDITIONAL DEFENSE: PRODUCT WARNINGS

The State's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from any failure of providers or their patients to read and heed warnings provided with Teva USA's products. *See* Restatement (Second) of Torts § 402A, Comment j; Restatement (Third) of Torts: Products Liability § 6. Because Teva USA's products are safe for use if such warnings are read and followed, as a matter of law, Teva USA's products can be neither defective nor unreasonably unsafe. *Id.*

TWENTY-SECOND ADDITIONAL DEFENSE: UNAVOIDABLY UNSAFE PRODUCTS

The State's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from known risks or dangers associated with Teva USA's products which are unavoidable even within the scope of prescribed and intended use, but which are reasonable in

comparison to the benefits conferred. *See* Restatement (Second) of Torts § 402A, Comment k; Restatement (Third) of Torts: Products Liability § 6.

TWENTY-THIRD ADDITIONAL DEFENSE: UNCONTROLLABLE CIRCUMSTANCES

The State's damages, if any, were the direct result of pre-existing medical conditions, idiosyncratic reactions to the medications, and/or were incurred by operation of nature or as a result of circumstances over which Teva USA had and continues to have no control.

TWENTY-FOURTH ADDITIONAL DEFENSE: PRODUCT MISUSE

The State's claims are barred, in whole or in part, by any alteration, modification, or misuse of Teva USA's products by prescribing providers, their patients, or any other third parties, for which Teva USA cannot be held responsible.

TWENTY-FIFTH ADDITIONAL DEFENSE: ILLICIT USE OR ABUSE

The State's claims are barred to the extent they allege harms resulting from any illicit use or abuse of Teva USA's products on the part of the medication users, for which Teva USA cannot be held responsible.

TWENTY-SIXTH ADDITIONAL DEFENSE: FAILURE TO PLEAD SPECIAL MATTERS WITH PARTICULARITY

To the extent the State asserts claims premised on actual or constructive fraud, false representation, deceit, concealment, or similar alleged misconduct, the State fails to state its claims with particularity, including, but not limited to, the time, place, and content of the alleged misrepresentations or concealments, and the specific misrepresentations or concealments of each separate Defendant. 12 Okla. Stat. § 2009(B). To the extent the State seeks special items of damages, including, but not limited to, exemplary or punitive damages, the State fails to

specifically state their nature or provide detail sufficient to inform Teva USA of the nature of its claim. *Id.*, § 2009(G).

TWENTY-SEVENTH ADDITIONAL DEFENSE: STATEMENTS OF VALUE OR QUALITY

To the extent the State seeks to impose liability on Teva USA for broad, general statements regarding the value or quality of Teva USA's products which were made to and reasonably understood by providers as opinion, such statements cannot constitute false representations as a matter of law. *See Greene v. Humphrey*, 274 P.2d 535, 537 (Okla. 1960).

TWENTY-EIGHTH ADDITIONAL DEFENSE: INDEMNITY

Teva USA's liability, if any, will not result from its conduct, but will result solely from obligations imposed by law. Thus, Teva USA is entitled to complete indemnity, express or implied, by other parties.

TWENTY-NINTH ADDITIONAL DEFENSE: DOUBLE RECOVERY

The State's claims seek duplicate or double recovery on the same injury or damage, contrary to Oklahoma law.

THIRTIETH ADDITIONAL DEFENSE: INTEREST AND FEES

The State is not entitled to attorneys' fees, costs, pre-judgment interest, or post-judgment interest.

THIRTY-FIRST ADDITIONAL DEFENSE: STATUTORY PENALTIES AND PUNITIVE DAMAGES UNCONSTITUTIONAL

The State seeks the recovery of civil penalties and punitive damages from Teva USA for, *inter alia*, alleged violations of the Oklahoma Medicaid False Claims Act, the Oklahoma Medicaid Program Integrity Act, and the Oklahoma Consumer Protection Act, and common-law

fraud. Pet. ¶¶ 91, 101, 115, 127-29. The State's punitive damages or statutory penalties claims against Teva USA:

- a. have no basis in law or fact;
- b. are not recoverable because the Petition's allegations of fact are legally insufficient to support or allow the imposition of punitive damages or statutory penalties on Teva USA consistent with the United States Constitution or Oklahoma law;
- c. cannot be sustained because the laws setting forth the standard(s) for determining liability for, and the amount(s) of, punitive damages or statutory penalties fail to give Teva USA prior notice of the conduct for which punitive damages or statutory penalties may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Teva USA's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution;
- d. cannot be sustained because any award of punitive damages or statutory penalties exceeding the limits authorized by law would violate Teva USA's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and would be improper under the laws and common law of Oklahoma;
- e. cannot be sustained because an award of punitive damages or statutory penalties in this case, combined with any prior, contemporaneous, or subsequent judgments against Teva USA for punitive damages or statutory penalties arising from the distribution, supply, marketing, sale, promotion, or use of Teva USA's products

would constitute constitutionally impermissible multiple punishments for the same wrong and double jeopardy under the Fifth Amendment to the United States Constitution and Art. II, § 21 of the Oklahoma Constitution;

- f. cannot be sustained because any award of punitive damages or statutory penalties without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the percentage of the wrong(s) allegedly committed by each tortfeasor, would violate Teva USA's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and would be improper under the laws and common law of Oklahoma;
- g. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitutions because due process requires that any award of punitive damages bear a close relationship to appropriate civil fines or penalties established by the legislature, or by administrative agencies under authority delegated by the legislature, and Oklahoma law fails to incorporate this due process requirement, and therefore no award of punitive damages may be constitutionally made under Oklahoma law;
- h. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitutions by the Commerce Clause of the United States Constitution and by

principles of federalism embodied in the Constitution, to the extent that any claim is based on any conduct by Teva USA that occurred outside Oklahoma;

- i. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitutions, because Oklahoma law permits the introduction of evidence of a defendant's financial condition or "net worth" with respect to the quantum of punitive damages and the introduction of such evidence violates Due Process by inviting the jury to award an arbitrary amount of punitive damages based on Teva USA's status as an industrial enterprise;
- j. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitutions because the conduct that is alleged to warrant punitive damages is unrelated to the claimant's harm. Punitive damages may not be awarded to punish and deter conduct that bears no relation to the claimant's harm; and
- k. cannot be sustained because subjecting Teva USA to punitive damages or statutory damages that are penal in nature without the same protections accorded to criminal defendants would violate Teva USA's rights guaranteed without limitation by the Fourth, Fifth, Sixth, and Fourteenth Amendments to the United States Constitution and would be improper under the laws and common law of Oklahoma.

THIRTY-SECOND ADDITIONAL DEFENSE: JURY-AWARDED PUNITIVE DAMAGES UNCONSTITUTIONAL

The State seeks the recovery of punitive damages from Teva USA for common-law fraud. Pet. ¶ 129. The State's claims for punitive damages against Teva USA cannot be

sustained and would violate Teva USA's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and would be improper under the laws and common law of Oklahoma to the extent punitive damages are awarded by a jury that:

- a. is not provided constitutionally adequate standards of sufficient clarity for determining whether to impose, and the appropriate size of, any punitive damages;
- b. is not adequately instructed on the limits of punitive damages set by the applicable principles of deference and punishment;
- c. is not required to make specific findings of fact establishing constitutionally permissible factors;
- d. is not expressly prohibited from awarding or calculating punitive damages based, in whole or in part, on invidiously discriminatory characteristics, including without limitation the residence, financial condition, and corporate state of Teva USA;
- e. is permitted to award punitive damages under a standard that is vague and arbitrary or does not define with sufficient clarity the conduct or mental state permitting the imposition of punitive damages;
- f. is not instructed upon, and required to make specific findings of fact with respect to the constitutional factors that govern permissible ratio of punitive damages to compensatory damages;

- g. is not instructed upon, and required to make specific findings of fact with respect to the comparable civil fine that could be imposed on Teva USA for the conduct in question;
- h. is not instructed upon, and required to make specific findings of fact with respect to the direct relationship between the conduct and the specific injury suffered by the State;
- i. is not properly instructed regarding the State's burden of proof with respect to each and every element of a claim for punitive damages; or
- j. is not subject to judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards.

THIRTY-THIRD ADDITIONAL DEFENSE: UNREASONABLE DAMAGES

The State's damages, if any, are limited to reasonable damages, and exclude unconscionable and grossly oppressive damages contrary to substantial justice. *See* 23 Okla. Stat. § 97. Further, the State cannot recover damages in excess of those allowed by the applicable statutory law.

**THIRTY-FOURTH ADDITIONAL DEFENSE:
ECONOMIC LOSS RULE**

The State's claims against Teva USA are barred or limited by the economic loss rule. The State alleges purely economic losses in the form of increased spending on opioid prescriptions allegedly resulting from Teva USA's challenged conduct. The State nonetheless seeks to recover these losses in tort. The economic loss rule bars any such recovery.

THIRTY-FIFTH ADDITIONAL DEFENSE: ADMINISTRATIVE DEFERENCE

_____The State's claims, including, but not limited to, any claims inconsistent with discretionary actions by the FDA under the FDCA, are barred, in whole or in part, under the common law doctrine of deference to administrative discretion.

THIRTY-SIXTH ADDITIONAL DEFENSE: ALLEGED VIOLATIONS OF FEDERAL LAW

To the extent the State asserts claims dependent solely on alleged violations of federal law, including any claims of a "fraud on the FDA" with respect to Teva USA's disclosure of information related to the safety of its products, such claims are barred and should be dismissed. *See Buckman v. Plaintiffs' Legal Claim*, 531 U.S. 341 (2001).

THIRTY-SEVENTH ADDITIONAL DEFENSE: CONFORMITY WITH APPLICABLE LAW, REGULATIONS, AND INDUSTRY STANDARDS

At all times relevant to the State's claims, and based upon the state of Teva USA's knowledge at those times, Teva USA's conduct conformed with the FDCA and the requirements of the FDA, the Controlled Substances Act, and the requirements of the DEA, as well as with all applicable state and federal statutes, regulations, and industry standards. Further, Teva USA's methods, standards, and techniques were in conformity with the generally recognized state of the art at the time.

**THIRTY-EIGHTH ADDITIONAL DEFENSE:
LACK OF ALLEGATIONS SPECIFIC TO TEVA USA**

The State fails to plead that it reimbursed any prescriptions written for an opioid product promoted, sold, or manufactured by Teva USA that harmed patients and should not have been written, or that Teva USA's allegedly improper conduct caused any provider to write any ineffective or harmful opioid prescriptions. To the extent the State's claims seek to impose liability on Teva USA solely on the basis of its proportionate participation in Oklahoma's market

for opioid products, and without establishing a causative link between Teva USA's specific conduct and the State's alleged injuries, such claims are barred under Oklahoma law. *See Case v. Fibreboard*, 743 P.2d 1062, 1064-67 (Okla. 1987).

THIRTY-NINTH ADDITIONAL DEFENSE: MEDICALLY REASONABLE AND NECESSARY USES OF TEVA USA'S PRODUCTS UNDER MEDICAID

The State's claims under the Oklahoma Medicaid False Claims Act are barred to the extent they seek to recover Medicaid reimbursements for treatment involving Teva USA products prescribed by providers for any on-label, FDA-approved use, or for any medically reasonable and necessary use under Medicaid standards, even if off-label. Medicaid coverage cannot be denied for such treatment as a matter of law. *See, e.g., In re Plavix Marketing, Sales Practices and Prods. Liability Litigation*, 123 F.Supp.3d 584, 604 (D.N.J. 2015); *United States ex rel. Petratos v. Genentech, Inc.*, 141 F.Supp.3d 311, 319-20 (D.N.J. 2015). Similarly, statements in Teva USA's branded or unbranded materials comporting with FDA-approved uses are not misleading as a matter of law or otherwise actionable.

**FORTIETH ADDITIONAL DEFENSE:
TEVA USA DID NOT MAKE OR AUTHORIZE MEDICAID CLAIMS**

Teva USA cannot be deemed to have made or caused to be made a claim, statement, or representation subject to the Oklahoma Medicaid Program Integrity Act because Teva USA had no authority or responsibility to make the Medicaid claims for which the State seeks recovery, or to supervise or authorize those who made such claims. *See* 56 Okla. Stat. § 1005(B).

FORTY-FIRST ADDITIONAL DEFENSE: RES JUDICATA

The State's claims are barred, in whole or in part, by the doctrines of res judicata, collateral estoppel, and/or issue or claim preclusion.

FORTY-SECOND ADDITIONAL DEFENSE: APPLICABLE CONSENT JUDGMENTS

The State's claims are barred, in whole or in part, by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of res judicata, collateral estoppel, issue or claim preclusion, failure to fulfill conditions precedent, failure to provide requisite notice, accord and satisfaction, and compromise and settlement.

FORTY-THIRD ADDITIONAL DEFENSE: NO RETROACTIVITY

To the extent the State seeks relief for Teva USA's conduct occurring before the enactment date of any statutes under which it brings a claim, such claims fail because the statutes do not apply retroactively.

FORTY-FOURTH ADDITIONAL DEFENSE: NO RECEIPT OF BENEFIT

The State's claim of unjust enrichment is barred, in whole or in part, because Teva USA did not receive and retain any alleged benefit from the State.

FORTY-FIFTH ADDITIONAL DEFENSE: NO STANDING

The State's claims are barred, in whole or in part, for lack of standing.

FORTY-SIXTH ADDITIONAL DEFENSE: FAILURE TO IDENTIFY SUBROGATION INTERESTS

The State's claims are barred, in whole or in part, by the State's failure to comply with the requirement that it identify each patient in whose claim(s) the State has a subrogation interest.

FORTY-SEVENTH ADDITIONAL DEFENSE: CONFLICT PREEMPTION

The State's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466 (2013), and related federal precedent.

FORTY-EIGHTH ADDITIONAL DEFENSE: SEPARATION OF POWERS

The State's claims are barred, in whole or in part, under the constitutional principles of separation of powers.

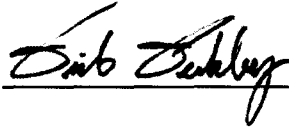
DEFENSES RESERVED

Teva USA hereby gives notice it intends to rely upon any other defenses that may become available or apparent during discovery or investigation in this matter and hereby reserves its right to amend its Answer and to assert any such additional defenses.

BIFURCATED TRIAL DEMAND

If the State is permitted to proceed upon claims for punitive damages, exemplary damages, or penalties, such claims must be bifurcated from the remaining issues for trial.

Dated: August 31, 2018



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was emailed this 31st day of August, 2018, to the following:

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