

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, INC.:
- (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 S.S. FILED

JAN 05 2018

In the office of the Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816

Honorable Thad Balkman

JURY TRIAL DEMANDED

<u>DEFENDANTS JANSSEN PHARMACEUTICALS, INC.'S</u> AND JOHNSON AND JOHNSON'S ANSWER TO PLAINTIFF'S PETITION

ANSWER

Defendant Janssen Pharmaceuticals, Inc., its predecessor companies Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. (jointly, "Janssen"), and its parent company Johnson & Johnson ("J&J") hereby respond to the Petition filed by the State of Oklahoma ("Plaintiff" or the "State"). To the extent that Plaintiff has included headings or impertinent material that are inappropriate, no response is necessary and any such inappropriate material should be stricken. In any event, to the extent any headings or inappropriate material are deemed to require a response, J&J and Janssen deny them. Except as expressly addressed below, J&J and Janssen deny each and every allegation in the Petition, including, without limitation, any allegations contained in the headings or Section VII (Prayer) of the Petition. J&J and Janssen further state as follows:

- 1. To the extent the references to "opioids" or "opium-based drugs" in Paragraph 1 pertain to Duragesic, Nucynta ER, and Nucynta, J&J and Janssen admit that Duragesic, Nucynta ER, and Nucynta expose users to risks of addiction, as disclosed in these drugs' FDA-approved labeling. Except as specifically admitted, J&J and Janssen aver that the allegations in Paragraph 1 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of those allegations, and, on that basis, deny them.
- 2. To the extent the references to "Defendants" in Paragraph 2 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 and, on that basis, deny the allegations. To the extent Paragraph 2's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen admit only that they manufacture and sell or previously sold opioids, and deny the remaining allegations in Paragraph 2. Except as specifically admitted, J&J and

Janssen aver that the allegations in Paragraph 2 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of those allegations, and, on that basis, deny them.

- 3. To the extent the reference to "Defendants" in Paragraph 3 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 and, on that basis, deny the allegations. To the extent Paragraph 3's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 3.
- 4. To the extent the references to "Defendants" in Paragraph 4 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 and, on that basis, deny the allegations. To the extent Paragraph 4's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 4.
- 5. To the extent the reference to "Defendants" in Paragraph 5 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief of the truth of the allegations in Paragraph 5 and, on that basis, deny the allegations. To the extent the reference to "Defendants" in Paragraph 5 pertains to J&J and/or Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, deny the allegations. In particular, J&J and Janssen lack knowledge or information sufficient to form a belief as to the statistics referenced in Paragraph 5.
- 6. To the extent the references to "Defendants" in Paragraph 6 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief of the truth of the allegations in Paragraph 6 and, on that basis, deny the allegations. To the

extent the references to "Defendants" in Paragraph 6 pertain to J&J and/or Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, deny the allegations. J&J and Janssen also aver that the document referenced in Paragraph 6 speaks for itself and deny any characterization of that document that is inconsistent with its meaning when it is read in its entirety.

- 7. The allegations contained in Paragraph 7 consist of argument and legal conclusions to which no response is required.
- 8. No response is necessary to Paragraph 8 as it contains no allegations against J&J or Janssen, or any other Defendant, and consists of argument and legal conclusions.
- 9. To the extent the references to "Defendants" in Paragraph 9 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9 and, on that basis, deny the allegations. To the extent Paragraph 9's references to "Defendants" pertain to J&J and/or Janssen, Janssen admits that it conducts business in Cleveland County and Oklahoma; Johnson & Johnson denies that it does business in Cleveland County or in Oklahoma. The remaining allegations contained in Paragraph 9 consist of argument and legal conclusions to which no response is required.
- 10. The allegations contained in Paragraph 10 consist of argument and legal conclusions to which no response is required.
- 11. The allegations contained in Paragraph 11 consist of argument and legal conclusions to which no response is required.
- 12. No response is necessary to Paragraph 12 as it contains no allegations against J&J or Janssen, or any other Defendant.

- 13. No response is necessary to Paragraph 13 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 13 and, on that basis, deny those allegations.
- 14. No response is necessary to Paragraph 14 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 14 and, on that basis, deny those allegations.
- 15. No response is necessary to Paragraph 15 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 15 and, on that basis, deny those allegations.
- 16. No response is necessary to Paragraph 16 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 16 and, on that basis, deny those allegations.
- 17. No response is necessary to Paragraph 17 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 17 and, on that basis, deny those allegations.
- 18. No response is necessary to Paragraph 18 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta

ER, or Nucynta contained in Paragraph 18 and, on that basis, deny those allegations.

- 19. With respect to Paragraph 19, J&J and Janssen aver that the allegations that J&J and Janssen "acted in concert with one another and acted as agents and/or principals of one another" consist of argument and legal conclusions to which no response is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 19, except that Janssen admits that it is a Pennsylvania corporation with its principal place of business in New Jersey, and is a wholly owned subsidiary of J&J, a New Jersey corporation with its principal place of business in New Jersey.
- 20. Janssen admits the allegations contained in Paragraph 20, except that Janssen denies that it currently promotes or markets its opioids in the State of Oklahoma.
- 21. To the extent the references to "Defendants" in Paragraph 21 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21 and, on that basis, deny those allegations. To the extent the references to "Defendants" in Paragraph 21 pertain to J&J and/or Janssen, J&J and Janssen aver that the allegations in Paragraph 21 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of those allegations, and, on that basis, deny them.
- 22. No response is necessary to Paragraph 22 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that the allegations in Paragraph 22 appear to refer to unspecified documents from the Centers for Disease Control and Prevention (the "CDC") and that such documents speak for themselves. J&J and Janssen deny any characterization of those documents that is inconsistent with their meaning when they are read in their entirety. J&J and Janssen further aver that they lack

knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 and, on that basis, deny them.

- 23. To the extent the reference to "Defendants" in Paragraph 23 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief of the truth of the allegations in Paragraph 23 and, on that basis, deny the allegations. To the extent the reference to "Defendants" in Paragraph 23 pertains to J&J and/or Janssen, J&J and Janssen aver that the allegations in Paragraph 23 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, deny the allegations. In particular, J&J and Janssen lack knowledge or information sufficient to form a belief as to the meaning of the references to the unidentified "prescription painkiller[s]," "[d]rug overdose deaths," and "unintentional poisoning death rate." J&J and Janssen further aver that they lack knowledge or information sufficient to form a belief as to the statistics referenced in Paragraph 23.
- 24. No response is necessary to Paragraph 24 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 and, on that basis, deny them.
- 25. No response is necessary to Paragraph 25 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 and, on that basis, deny them. J&J and Janssen further aver that they lack knowledge or information sufficient to form a belief as to the statistics referenced in Paragraph 25.

- 26. No response is necessary to Paragraph 26 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 and, on that basis, deny them.
- 27. No response is necessary to Paragraph 27 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 and, on that basis, deny them. J&J and Janssen further aver that the document referenced in Paragraph 27 speaks for itself and deny any characterization of the document that is inconsistent with its meaning when it is read in its entirety.
- 28. No response is necessary to Paragraph 28 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that the allegations in Paragraph 28 appear to refer to unspecified documents from the CDC and that such documents speak for themselves. J&J and Janssen deny any characterization of those documents that is inconsistent with their meaning when they are read in their entirety. J&J and Janssen further aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 and, on that basis, deny them.
- 29. No response is necessary to Paragraph 29 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 and, on that basis, deny them.
- 30. To the extent the reference to "Defendants" in Paragraph 30 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a

belief as to the truth of the allegations contained in Paragraph 30 and, on that basis, deny those allegations. To the extent Paragraph 30's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 30.

- 31. To the extent the reference to "Defendants" in Paragraph 31 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 and, on that basis, deny those allegations. To the extent Paragraph 31's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 31.
- 32. To the extent the reference to "Defendants" in Paragraph 32 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 and, on that basis, deny those allegations. To the extent Paragraph 32's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 32.
- 33. No response is necessary to Paragraph 33 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 33 and, on that basis, deny them. J&J and Janssen further aver that the document referenced in Paragraph 33 speaks for itself and deny any characterization of the document that is inconsistent with its meaning when it is read in its entirety.
- 34. To the extent the reference to "Defendants" in Paragraph 34 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 34 and, on that basis, deny those allegations. To the extent Paragraph 34's reference to "Defendants" pertains to J&J and/or

Janssen, J&J and Janssen deny the allegations in Paragraph 34.

- 35. No response is necessary to Paragraph 35 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 35 and, on that basis, deny those allegations.
- 36. No response is necessary to Paragraph 36 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 36 and, on that basis, deny those allegations.
- 37. No response is necessary to Paragraph 37 as it contains no allegations against J&J or Janssen. J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning other parties or medications other than Duragesic, Nucynta ER, or Nucynta contained in Paragraph 37 and, on that basis, deny those allegations.
- 38. J&J and Janssen deny the allegations contained in Paragraph 38, except that J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the number of prescriptions submitted to or amounts paid by the Oklahoma Health Care Authority and, on that basis, deny those allegations.
- 39. To the extent the references to "Defendants" in Paragraph 39 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 39 and, on that basis, deny those allegations. To the extent Paragraph 39's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 39.
 - 40. To the extent the reference to "Defendants" in Paragraph 40 pertains to parties

other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 40 and, on that basis, deny those allegations. To the extent Paragraph 40's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 40.

- 41. To the extent the reference to "Defendants" in Paragraph 41 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 41 and, on that basis, deny those allegations. To the extent Paragraph 41's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 41.
- 42. To the extent the reference to "Defendants" in Paragraph 42 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 42 and, on that basis, deny those allegations. To the extent Paragraph 42's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 42.
- 43. To the extent the reference to "Defendants" in Paragraph 43 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 43 and, on that basis, deny those allegations. To the extent Paragraph 43's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 43.
- 44. No response is necessary to Paragraph 44 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that the allegations in Paragraph 44 appear to refer to unspecified documents from the CDC and that such documents speak for themselves. J&J and Janssen deny any characterization of those

documents that is inconsistent with their meaning when they are read in their entirety. J&J and Janssen further aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 and, on that basis, deny them.

- 45. To the extent the reference to "Defendants" in Paragraph 45 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 45 and, on that basis, deny those allegations. To the extent Paragraph 45's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen aver that the allegations in Paragraph 45 appear to refer to unspecified documents from the CDC and that such documents speak for themselves. J&J and Janssen deny any characterization of those documents that is inconsistent with their meaning when they are read in their entirety. J&J and Janssen specifically deny that that they caused a public health crisis.
- 46. To the extent the reference to "Defendants" in Paragraph 46 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 46 and, on that basis, deny those allegations. To the extent Paragraph 46's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 46.
- 47. No response is necessary to Paragraph 47 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 and, on that basis, deny them.
- 48. No response is necessary to Paragraph 48 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver

that they lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 and, on that basis, deny them.

- 49. To the extent the reference to "Defendants" in Paragraph 49 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 49 and, on that basis, deny those allegations. To the extent Paragraph 49's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 49.
- 50. To the extent the reference to "Defendants" in Paragraph 50 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 50 and, on that basis, deny those allegations. To the extent Paragraph 50's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 50.
- 51. To the extent the references to "Defendants" in Paragraph 51 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 and, on that basis, deny those allegations. To the extent Paragraph 51's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 51.
- 52. To the extent the references to "Defendants" in Paragraph 52 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52 and, on that basis, deny those allegations. To the extent Paragraph 52's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 52.
 - 53. To the extent the references to "Defendants" in Paragraph 53 pertain to parties

other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53 and, on that basis, deny those allegations. To the extent Paragraph 53's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 53. J&J and Janssen further deny that they made any "unsubstantiated representations" regarding Nucynta or that they made any representations regarding Nucynta that were not in accordance with its FDA-approved labeling.

- 54. To the extent the references to "Defendants" in Paragraph 54 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 54 and, on that basis, deny those allegations. To the extent Paragraph 54's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 54.
- 55. To the extent the reference to "Defendants" in Paragraph 55 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 55 and, on that basis, deny those allegations. J&J and Janssen do not respond to the State's allegations concerning Defendant Purdue and its products. To the extent Paragraph 55's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen aver that the allegations in Paragraph 55 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of those allegations, and, on that basis, deny them.
- 56. To the extent the references to "Defendants" in Paragraph 56 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 56 and, on that basis, deny those allegations. To the extent Paragraph 56's references to "Defendants" pertain to J&J and/or

Janssen, J&J and Janssen deny the allegations in Paragraph 56.

- 57. To the extent the reference to "Defendants" in Paragraph 57 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 57 and, on that basis, deny those allegations. To the extent Paragraph 57's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 57.
- 58. To the extent the references to "Defendants" in Paragraph 58 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 58 and, on that basis, deny those allegations. To the extent Paragraph 58's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 58.
- 59. To the extent the references to "Defendants" in Paragraph 59 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 59 and, on that basis, deny those allegations. To the extent Paragraph 59's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen admit that Janssen lawfully sponsored CME presentations that involved the participation of independent physicians; but deny that the remaining allegations in Paragraph 59 accurately characterize their marketing practices. J&J and Janssen specifically deny that they made any false or misleading statements or in any way deceptively marketed opioids.
- 60. To the extent the reference to "Defendants" in Paragraph 60 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 60 and, on that basis, deny those

allegations. To the extent Paragraph 60's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen aver that the allegations in Paragraph 60 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of those allegations, and, on that basis, deny them.

- 61. To the extent the references to "Defendants" in Paragraph 61 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 61 and, on that basis, deny those allegations. To the extent Paragraph 61's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny those allegations. With respect to the allegations concerning Dr. Portenoy, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, deny those allegations.
- 62. To the extent the references to "Defendants" in Paragraph 62 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 62 and, on that basis, deny those allegations. To the extent Paragraph 62's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny those allegations. With respect to the allegations concerning Dr. Webster, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, deny those allegations.
- 63. To the extent the references to "Defendants" in Paragraph 63 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 63 and, on that basis, deny those allegations. To the extent Paragraph 63's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 63.

- 64. To the extent the references to "Defendants" in Paragraph 64 pertain to Defendants Purdue and Cephalon or parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 64 and, on that basis, deny those allegations. To the extent Paragraph 64's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 64.
- 65. To the extent the references to "Defendants" in Paragraph 65 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 65 and, on that basis, deny those allegations. To the extent Paragraph 65's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 65.
- 66. To the extent the references to "Defendants" in Paragraph 66 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 66 and, on that basis, deny those allegations. To the extent Paragraph 66's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 66.
- 67. To the extent the references to "Defendants" in Paragraph 67 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 67 and, on that basis, deny those allegations. To the extent Paragraph 67's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 67.
- 68. To the extent the references to "Defendants" in Paragraph 68 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a

belief as to the truth of the allegations contained in Paragraph 68 and, on that basis, deny those allegations. To the extent Paragraph 68's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 68. J&J and Janssen specifically deny that they made any false or misleading statements or in any way deceptively marketed opioids. With respect to the State's allegations concerning the alleged actions of the unidentified "KOLs," Dr. Portenoy, and Dr. Webster, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, deny those allegations. With respect to the reference to unidentified "studies" in Paragraph 68, J&J and Janssen aver that the allegations in Paragraph 68 are so vague and overbroad that they lack knowledge or information sufficient to form a belief as to the truth of those allegations, and, on that basis, deny them.

- 69. No response is necessary to Paragraph 69 as it contains no allegations against J&J or Janssen, or any other Defendant. To the extent a response is required, J&J and Janssen aver that the document referenced and quoted in Paragraph 69 speaks for itself and deny any characterization of the document that is inconsistent with its meaning when it is read in its entirety.
- 70. To the extent the references to "Defendants" in Paragraph 70 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 70 and, on that basis, deny those allegations. To the extent Paragraph 70's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 70.
- 71. To the extent the reference to "Defendants" in Paragraph 71 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a

belief as to the truth of the allegations contained in Paragraph 71 and, on that basis, deny those allegations. To the extent Paragraph 71's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 71.

- 72. To the extent the references to "Defendants" in Paragraph 72 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 72 and, on that basis, deny those allegations. To the extent Paragraph 72's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations in Paragraph 72.
- 73. With respect to the allegations contained in Paragraph 73, J&J and Janssen repeat and reallege every admission, denial, averment, and statement in Paragraphs 1 through 72 of this Answer with the same force and effect as though set forth in full here.
- 74. The allegations contained in Paragraph 74 consist of argument and legal conclusions to which no response is required.
- 75. To the extent the reference to "Defendant" in Paragraph 75 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 75 and, on that basis, deny those allegations. To the extent Paragraph 75's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 75.
- 76. To the extent the reference to "Defendant" in Paragraph 76 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 76 and, on that basis, deny those allegations. To the extent Paragraph 76's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 76.

- 77. To the extent the reference to "Defendant" in Paragraph 77 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 77 and, on that basis, deny those allegations. To the extent Paragraph 77's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 77.
- 78. To the extent the reference to "Defendant" in Paragraph 78 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 78 and, on that basis, deny those allegations. To the extent Paragraph 78's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 78.
- 79. To the extent the reference to "Defendant" in Paragraph 79 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 79 and, on that basis, deny those allegations. To the extent Paragraph 79's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 79.
- 80. To the extent the references to "Defendant" in Paragraph 80 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 80 and, on that basis, deny those allegations. To the extent Paragraph 80's references to "Defendant" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 80.
- 81. To the extent the references to "Defendant" in Paragraph 81 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 81 and, on that basis, deny those

allegations. To the extent a response is required, and to the extent Paragraph 81's references to "Defendant" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 81.

- 82. To the extent the reference to "Defendants" in Paragraph 82 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 82 and, on that basis, deny those allegations. To the extent Paragraph 82's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 82.
- 83. To the extent the references to "Defendant" in Paragraph 83 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 83 and, on that basis, deny those allegations. To the extent Paragraph 83's references to "Defendant" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 83.
- 84. To the extent the reference to "Defendant" in Paragraph 84 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 84 and, on that basis, deny those allegations. To the extent Paragraph 84's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 84.
- 85. To the extent the reference to "Defendant" in Paragraph 85 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 85 and, on that basis, deny those allegations. To the extent Paragraph 85's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 85.

- 86. To the extent the reference to "Defendant" in Paragraph 86 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 86 and, on that basis, deny those allegations. To the extent Paragraph 86's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 86.
- 87. To the extent the reference to "Defendant" in Paragraph 87 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 87 and, on that basis, deny those allegations. To the extent Paragraph 87's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 87.
- 88. To the extent the references to "Defendants" in Paragraph 88 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 88 and, on that basis, deny those allegations. To the extent Paragraph 88's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 88.
- 89. To the extent the reference to "Defendants" in Paragraph 89 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 89 and, on that basis, deny those allegations. To the extent Paragraph 89's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 89.
- 90. To the extent the reference to "Defendants" in Paragraph 90 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 90 and, on that basis, deny those

allegations. To the extent Paragraph 90's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 90.

- 91. The allegations contained in Paragraph 91 consist of argument and legal conclusions to which no response is required.
- 92. With respect to the allegations contained in Paragraph 92, J&J and Janssen repeat and reallege every admission, denial, averment, and statement in Paragraphs 1 through 91 of this Answer with the same force and effect as though set forth in full here.
- 93. The allegations contained in Paragraph 93 consist of argument and legal conclusions to which no response is required.
- 94. To the extent the reference to "Defendant" in Paragraph 94 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 94 and, on that basis, deny those allegations. To the extent Paragraph 94's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 94.
- 95. To the extent the reference to "Defendants" in Paragraph 95 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 95 and, on that basis, deny those allegations. To the extent Paragraph 95's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 95.
- 96. To the extent the reference to "Defendant" in Paragraph 96 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 96 and, on that basis, deny those allegations. To the extent Paragraph 96's reference to "Defendant" pertains to J&J and/or

Janssen, J&J and Janssen deny the allegations contained in Paragraph 96.

- 97. To the extent the references to "Defendant" in Paragraph 97 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 97 and, on that basis, deny those allegations. To the extent Paragraph 97's references to "Defendant" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 97.
- 98. To the extent the reference to "Defendant" in Paragraph 98 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 98 and, on that basis, deny those allegations. To the extent Paragraph 98's reference to "Defendant" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 98.
- 99. To the extent the reference to "Defendants" in Paragraph 99 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 99 and, on that basis, deny those allegations. To the extent Paragraph 99's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 99.
- 100. To the extent the references to "Defendants" in Paragraph 100 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 100 and, on that basis, deny those allegations. To the extent Paragraph 100's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 100.
- 101. To the extent the reference to "Defendants" in Paragraph 101 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a

belief as to the truth of the allegations contained in Paragraph 101 and, on that basis, deny those allegations. To the extent Paragraph 101's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 101.

- 102. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 102 is required. To the extent a response to the allegations contained in Paragraph 102 is required, J&J and Janssen repeat and reallege every admission, denial, averment, and statement in Paragraphs 1 through 101 of this Answer with the same force and effect as though set forth in full here.
- 103. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 103 is required. In any event, the allegations contained in Paragraph 103 consist of argument and legal conclusions to which no response is required.
- 104. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 104 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 104.
- 105. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 105 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 105.
- 106. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 106 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 106.
- 107. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 107 is required. To the

extent a response is required, J&J and Janssen deny the allegations in Paragraph 107.

- 108. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 108 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 108.
- 109. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 109 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 109.
- 110. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 110 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 110.
- 111. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 111 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 111.
- 112. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 112 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 112.
- 113. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 113 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 113.
- 114. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma Consumer Protection Act claim. Accordingly, no response to Paragraph 114 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 114.
 - 115. By Order entered December 6, 2017, the Court dismissed Plaintiff's Oklahoma

Consumer Protection Act claim. Accordingly, no response to Paragraph 115 is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 115. Moreoever, the allegations contained in Paragraph 115 consist of argument and legal conclusions to which no response is required.

- 116. With respect to the allegations contained in Paragraph 116, J&J and Janssen repeat and reallege every admission, denial, averment, and statement in Paragraphs 1 through 115 of this Answer with the same force and effect as though set forth in full here.
- 117. To the extent the reference to "Defendants" in Paragraph 117 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 117 and, on that basis, deny those allegations. To the extent Paragraph 117's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 117.
- 118. To the extent the references to "Defendants" in Paragraph 118 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 118 and, on that basis, deny those allegations. To the extent Paragraph 118's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 118.
- 119. To the extent the references to "Defendants" in Paragraph 119 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 119 and, on that basis, deny those allegations. To the extent Paragraph 119's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 119.
 - 120. To the extent the reference to "Defendants" in Paragraph 120 pertains to parties

other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 120 and, on that basis, deny those allegations. To the extent Paragraph 120's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 120.

- 121. With respect to the allegations contained in Paragraph 121, J&J and Janssen repeat and reallege every admission, denial, averment, and statement in Paragraphs 1 through 120 of this Answer with the same force and effect as though set forth in full here.
- 122. To the extent the references to "Defendants" in Paragraph 122 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 122 and, on that basis, deny those allegations. To the extent Paragraph 122's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 122.
- 123. To the extent the references to "Defendants" in Paragraph 123 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 123 and, on that basis, deny those allegations. To the extent Paragraph 123's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 123.
- 124. To the extent the references to "Defendants" in Paragraph 124 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 124 and, on that basis, deny those allegations. To the extent Paragraph 124's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 124.

- 125. To the extent the reference to "Defendants" in Paragraph 125 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 125 and, on that basis, deny those allegations. To the extent Paragraph 125's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 125.
- 126. To the extent the references to "Defendants" in Paragraph 126 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 126 and, on that basis, deny those allegations. To the extent Paragraph 126's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 126.
- 127. The allegations contained in Paragraph 127 consist of argument and legal conclusions to which no response is required.
- 128. To the extent the reference to "Defendants" in Paragraph 128 pertains to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 128 and, on that basis, deny those allegations. To the extent Paragraph 128's reference to "Defendants" pertains to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 128.
- 129. To the extent the references to "Defendants" in Paragraph 129 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 129 and, on that basis, deny those allegations. To the extent Paragraph 129's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 129.

- 130. To the extent the references to "Defendants" in Paragraph 130 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 130 and, on that basis, deny those allegations. To the extent Paragraph 130's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 130.
- 131. To the extent the references to "Defendants" in Paragraph 131 pertain to parties other than J&J and Janssen, J&J and Janssen lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 131 and, on that basis, deny those allegations. To the extent Paragraph 131's references to "Defendants" pertain to J&J and/or Janssen, J&J and Janssen deny the allegations contained in Paragraph 131.
- 132. The allegations contained in Paragraph 132 consist of argument and legal conclusions to which no response is required.
- 133. The allegations contained in Paragraph 133 consist of argument and legal conclusions to which no response is required. To the extent a response is required, J&J and Janssen deny the allegations in Paragraph 133.
- 134. The allegations contained in Paragraph 134 consist of argument and legal conclusions to which no response is required.

Defendants deny that Plaintiff is entitled to any of the relief requested in Section VII ("PRAYER") of the Petition.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE (Failure to State a Claim)

Plaintiff's claims are barred because the Petition fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE (Statute of Limitations)

Plaintiff's claims are barred, in whole or in part, by the applicable statute(s) of limitations and/or statute(s) of repose.

THIRD AFFIRMATIVE DEFENSE (Primary Jurisdiction)

Plaintiff's claims are barred and/or this Court should defer this matter to FDA, in whole or in part, pursuant to the doctrine of primary jurisdiction. An agency has primary jurisdiction over issues that, via a regulatory scheme, have been placed in that agency's special competence such that there is a paramount need for specialized agency fact-finding expertise. Plaintiff's claims are premised on the allegation that J&J and/or Janssen falsely represented that the opioid products they promoted for long-term treatment of chronic, non-cancer pain were safe and effective for that indication. Plaintiff's allegations necessarily implicate medical and scientific issues that are outside the conventional experience of judges and particularly within the FDA's expertise, discretion, and regulatory authority. Also, because the FDA is actively examining the issue of whether opioids are safe and effective for the long-term treatment of chronic, non-cancer pain, there is a danger of the Court issuing rulings on Plaintiff's claims inconsistent with the FDA's forthcoming findings.

FOURTH AFFIRMATIVE DEFENSE (Federal Preemption)

Plaintiff's claims are expressly and/or impliedly preempted by federal law because Janssen's conduct was authorized by FDA. The granting of the relief prayed for in the Petition would impede, impair, frustrate, or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution. Conflict in enforcement technique can be fully as disruptive to the system Congress enacted for FDA

regulation as conflict in overt policy. Imposition of liability and/or civil penalties or injunctive relief would impermissibly intrude upon and disrupt FDA's regulatory prerogatives by, among other things, conflicting with FDA's guidance and regulatory decision-making. Plaintiff's claims are premised on the allegation that J&J and Janssen falsely represented that the opioid products they promoted for long-term treatment of chronic, non-cancer pain were safe and effective for that indication. But the FDA has approved these products as safe and effective for that use and separately has rejected a citizen's petition to exclude long-term use for chronic, non-cancer pain from the labeling of such products. Further, federal law authorized J&J and Janssen to promote opioid products for their FDA-approved indications. To the extent Plaintiff's claims seek to hold J&J and Janssen 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.

FIFTH AFFIRMATIVE DEFENSE (No Fraud on the FDA)

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

SIXTH AFFIRMATIVE DEFENSE (Laches)

Plaintiff's claims are barred by the doctrines of laches. Plaintiff knew or reasonably should have known of the facts underlying its claims years ago and failed to file suit for years thereafter. J&J and Janssen have been prejudiced by Plaintiff's unreasonable delay. As a result, Plaintiff's claims are barred by laches.

SEVENTH AFFIRMATIVE DEFENSE (Waiver)

The Petition is barred, in whole or in part, based on the doctrine of waiver. Plaintiff's claims are, according to the Petition, based on marketing materials and product labeling developed as early as the 1990's. Plaintiff knew or reasonably should have known of the facts underlying its claims years ago and failed to file suit for years thereafter. Plaintiff voluntarily relinquished and/or abandoned these claims and is barred from asserting them here.

EIGHTH AFFIRMATIVE DEFENSE (Equity)

Plaintiff's claims for relief in the Petition are barred, in whole or in part, based on principles of equity. Numerous facts would render the imposition of injunctive relief, civil penalties, or other remedies inequitable here, including but not limited to J&J's and Janssen's good faith reliance on and interpretation of clinical data and medical literature, the absence of any intentionally unlawful conduct, the course of Plaintiff's investigation and pursuit of these claims, and J&J and Janssen's good faith reliance on guidance for product communications published by FDA.

NINTH AFFIRMATIVE DEFENSE (Adequate Remedy at Law)

Plaintiff is not entitled to equitable relief, in whole or in part, because an adequate remedy at law exists.

TENTH AFFIRMATIVE DEFENSE (Good Faith/Reasonable Belief as to Accuracy and Validity)

Any representations or statements alleged to have been made by J&J and/or Janssen were true and accurate at the time made and/or otherwise were made in good faith, with a reasonable belief as to their validity and accuracy and with a reasonable belief that all of J&J and Janssen's

conduct was lawful. J&J and Janssen's good faith and reasonable belief should be considered as a mitigating factor when assessing the amount of any civil penalties, in the event that any civil penalties are awarded.

ELEVENTH AFFIRMATIVE DEFENSE (Unclean Hands)

Plaintiff is barred from recovering, in whole or in part, by the doctrine of unclean hands. Should discovery show that Plaintiff, the chief law enforcement officer of the State of Oklahoma, acted inequitably during the course of its investigation or during this litigation, such conduct should be taken into account in assessing Plaintiff's claims and whether, and to what extent, Plaintiff is entitled to relief in this action.

TWELFTH AFFIRMATIVE DEFENSE (Estoppel)

The Petition is barred, in whole or in part, based on the doctrine of estoppel. Oklahoma institutions or agencies use and/or reimburse Janssen's opioids, and are aware of the inherent dangers of prescribing opioid medications. Oklahoma knew or should have known of the facts underlying Plaintiff's allegations here. As a result of these actions, and other actions, statements, and conduct, the State has taken a position that is contrary to Plaintiff's position here, and Plaintiff should be equitably estopped from asserting its claims.

THIRTEENTH AFFIRMATIVE DEFENSE (Learned Intermediary Doctrine)

Plaintiff's claims are barred in whole or in part by the learned intermediary doctrine.¹

The learned intermediary doctrine provides that, with respect to claims attacking the adequacy

¹ The learned intermediary doctrine defines the scope of a prescription drug manufacturer's duty to warn, and by raising this defense, J&J and Janssen do not waive any argument regarding Plaintiff's burden of proof in this action.

of prescription medical device labeling, the duty to warn runs only from the manufacturer to prescribing physicians, because only physicians can recommend and prescribe the device for patients. Under the doctrine, there is no liability for a failure to warn patients about potential risks or complications, because the duty to warn does not run from a manufacturer of a prescription-only product to patients. A manufacturer fulfills its duty to warn when it provides an adequate warning to prescribing physicians, who then engage in informed consent discussions of risks and benefits with their patients.

FOURTEENTH AFFIRMATIVE DEFENSE (Sophisticated User)

Some or all of Plaintiff's claims are barred by the sophisticated user doctrine. Because of their training and experience, doctors who prescribe opioids know or reasonably should know of the potential risks. Under the sophisticated user doctrine, J&J and Janssen have no duty to warn—and thus cannot be held liable for failing to warn—of risks and complications of which members of the relevant medical community knew or should have known.

FIFTEENTH AFFIRMATIVE DEFENSE (Informed Consent)

The doctors who prescribe Janssen's opioid medications have a duty to provide patients with material information so they can make informed decisions about a proposed treatment or operation. J&J and Janssen are entitled to rely on this duty—and doctors' professional education, training, and experience with respect to potential risks and complications associated with Janssen's opioid medications—and allege that patients who used the products were fully informed of the risks of using opioid medications. Accordingly, because Janssen provided

adequate warnings to doctors, Plaintiff's claims are barred by patients' provision of informed consent.

SIXTEENTH AFFIRMATIVE DEFENSE (Failure to Join Indispensable Parties)

Plaintiff has failed to join one or more necessary and indispensable parties, including without limitation health care providers, prescribers, patients, and other third parties whom Plaintiff alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Oklahoma.

SEVENTEENTH AFFIRMATIVE DEFENSE (Misjoinder and Severance)

J&J and Janssen have been improperly joined as Defendants in this action.

EIGHTEENTH AFFIRMATIVE DEFENSE (Ratification)

Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation, if any, was caused in whole or in part by Plaintiff's ratification of J&J's and Janssen's allegedly deceptive or misleading conduct.

NINETEENTH AFFIRMATIVE DEFENSE (Third-Party Actions)

Plaintiff's claims against J&J and Janssen are barred to the extent that any rely on or implicate the negligent, intentional, malicious, criminal, and/or otherwise unlawful acts or omissions of third parties that are not subject to J&J's and Janssen's control or authority and for which J&J and Janssen are not responsible and cannot be held liable.

TWENTIETH AFFIRMATIVE DEFENSE (Protected Speech)

Plaintiff's claims are barred by, in whole or in part, the applicable provisions of the United States Constitution and similar provisions in 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.

TWENTY-FIRST AFFIRMATIVE DEFENSE (Lack of Proximate Cause)

Plaintiff's claims or, at a minimum, Plaintiff's requests for relief are barred because J&J's and Janssen's alleged misrepresentations were not the proximate or legal cause of the purported injuries or damages incurred by Plaintiff or any other party.

TWENTY-SECOND AFFIRMATIVE DEFENSE (Due Process)

The imposition of civil monetary penalties or punitive damages in this action would violate the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, and similar provisions in the Oklahoma Constitution. Due process requires that J&J and Janssen have fair notice that specific conduct may subject them to substantial penalties or punitive damages awards. Given the malleable nature of Plaintiff's claims, the scope of the Attorney General's allegations, and the indeterminate and ad hoc nature of some of its theories of liability, any award of civil penalties or punitive damages would violate due process. Moreover, to the extent liability is based on the supposed inapplicability of the learned intermediary doctrine, due process bars Plaintiff's claims because J&J and Janssen are entitled to reasonable reliance on the law as it stands.

TWENTY-THIRD AFFIRMATIVE DEFENSE (Excessive Fines)

The imposition of civil monetary penalties in this action would violate the Excessive Fines Clause of the Eighth Amendment of the United States Constitution, and similar provisions in the Oklahoma Constitution. As contemplated by the Petition, the civil penalties sought by Plaintiff could be grossly disproportional to the gravity of J&J and Janssen's purported conduct

and thereby unconstitutional. Even civil penalties imposed at the statutory minimum can be unconstitutional if they are excessive in the aggregate.

TWENTY- FOURTH AFFIRMATIVE DEFENSE (Economic Loss Rule)

Plaintiff's claims against J&J and Janssen are barred or limited by the economic loss rule.

TWENTY-FIFTH AFFIRMATIVE DEFENSES (Conduct Predating Enactment of OMFCA)

To the extent Plaintiff seeks relief under the Oklahoma Medicaid False Claims Act ("OMFCA") for J&J's and/or Janssen's conduct occurring before the enactment date of the ordinance on November 1, 2007, the claim fails because the statute does not apply retroactively. See CNA Ins. Co. v. Ellis, 2006 OK 81, ¶ 13, 148 P.3d 874, 877.

TWENTY-SIXTH AFFIRMATIVE DEFENSE (Violation of Due Process and Statutory Rights Based On Contingent Fee Counsel)

J&J's and Janssen's rights under the Due Process Clause of the U.S. 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).

* * * * *

J&J and Janssen reserve the right to assert other defenses, cross-claims and third-party claims when and if they become appropriate in this action.

WHEREFORE, having fully answered, J&J and Janssen pray that Plaintiff takes nothing by way of its Petition and that they be dismissed with prejudice, together with any other relief to which the Court deems them entitled.

Dated: January 5, 2018

Respectfully submitted,

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CERTIFICATE OF MAILING

Pursuant to Okla. Stat. tit. 12, § 2005(D), this is to certify on January 5, 2018, a true and correct copy of the above and foregoing has been served via the United State Postal Service, First Class postage prepaid, to the following:

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