# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	) ) ) MDL No. 2740
	) ) SECTION "N" (5)
	) HON. KURT D. ENGELHARDT
	) This Document Relates to All Actions )

# ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS HOSPIRA, INC., HOSPIRA WORLDWIDE LLC, AND PFIZER INC. TO PLAINTIFFS' FIRST AMENDED MASTER LONG FORM COMPLAINT

Defendants Hospira, Inc. and Hospira Worldwide, LLC, formerly doing business as Hospira Worldwide, Inc. (collectively, "the Hospira Defendants"), and Pfizer Inc. ("Pfizer") (together, "the Hospira and Pfizer Defendants"), by their attorneys, hereby set forth their Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint [Doc. 689] and Demand for Jury Trial ("Complaint"). Certain allegations of the Complaint are made as to all or several defendants without differentiation or specification as to the extent of reference to the Hospira Defendants, Pfizer or the other defendants or entities. For the purpose of clarity, the Hospira and Pfizer Defendants respond herein to the allegations of the Complaint only insofar as such allegations pertain to the Hospira Defendants, Pfizer, or docetaxel manufactured or sold by either the Hospira Defendants or Pfizer. Except as otherwise expressly set forth below, the Hospira and Pfizer Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint to the extent that such allegations refer or relate to other defendants or entities other than the Hospira Defendants or

Pfizer. Any allegation, averment, contention or statement in the Complaint not specifically and unequivocally admitted is denied.

#### PRELIMINARY STATEMENT

To the extent that the titles and headings of the Complaint are intended to be allegations directed to the Hospira and Pfizer Defendants, they are, unless specifically admitted, denied.

- 1. Paragraph 1 is denied, except that the Hospira and Pfizer Defendants admit only that Hospira, Inc. has manufactured and sold a docetaxel product, which the Food and Drug Administration ("FDA") approved pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and that Pfizer also manufactured and sold a docetaxel product, which the FDA approved in March 2014, pursuant to Section 505(b)(2) of the FDCA. Responding further, the Hospira and Pfizer Defendants admit that Plaintiffs purport to assert certain claims against them but deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries and further deny that they are liable to Plaintiffs for damages or any other relief sought in the Complaint.
- 2. Paragraph 2 does not set forth any allegation susceptible to admission or denial, and therefore, no answer is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries and further deny that they are liable to Plaintiffs for damages or any other relief sought in the Complaint.
- 3. Paragraph 3 does not set forth any allegation susceptible to admission or denial and therefore, no answer is required. To the extent Paragraph 3 purports to refer to any Short Form Complaint, such document speaks for itself, and the Hospira and Pfizer Defendants deny any allegations with respect to waiver and/or claims not asserted.

### AS TO SECTION ENTITLED "INTRODUCTION"

- 4. The Hospira and Pfizer Defendants admit only that Taxotere® which is a medicine that was invented, developed, marketed, and sold by a company other the Hospira or Pfizer Defendants, is an FDA-approved chemotherapy medication approved for the treatment of certain cancers, including breast cancer. The Hospira and Pfizer Defendants deny all remaining allegations and specifically deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries or that they are liable to Plaintiffs for damages or any other relief sought in the Complaint.
- 5. In response to paragraph 3, the Hospira and Pfizer Defendants deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries and further deny that they are liable to Plaintiffs for damages or any other relief sought in the Complaint. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth relating to Plaintiffs' remaining allegations and therefore deny same.
  - 6. Paragraph 6 is denied.
- 7. Paragraph 7 is denied except the Hospira and Pfizer Defendants admit that Plaintiffs seek certain relief in this Complaint but the Hospira and Pfizer Defendants deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries and further deny that they are liable to Plaintiffs for damages or any other relief sought in the Complaint.

# AS TO SECTION ENTITLED "THE PARTIES" AS TO SUBSECTION A. ENTITLED "Plaintiffs"

8. Paragraph 8 is denied, except that the Hospira and Pfizer Defendants admit only that Plaintiffs have filed their Master Complaint on behalf of themselves and possible others and that Plaintiffs make the allegations set forth in the Complaint, but the Hospira and Pfizer

Defendants deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries.

- 9. Paragraph 9 is denied.
- 10. Paragraph 10 is denied.
- 11. Paragraph 11 is denied.

#### AS TO SUBSECTION B. ENTITLED "Sanofi-Related Entities"

- 12. The allegations in paragraph 12 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 and for that reason deny each of them.
- 13. The allegations in paragraph 13 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 and for that reason deny each of them.
- 14. The allegations in paragraph 14 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 and for that reason deny each of them.
- 15. The allegations in paragraph 15 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 15 and for that reason deny each of them.

- 16. The allegations in paragraph 16 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 and for that reason deny each of them.
- 17. The allegations in paragraph 17 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 and for that reason deny each of them.
- 18. The allegations in paragraph 18 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 and for that reason deny each of them.
- 19. The allegations in paragraph 19 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and for that reason deny each of them.

- 20. The allegations in paragraph 20 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 and for that reason deny each of them.
- 21. The allegations in paragraph 21 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 and for that reason deny each of them.
- 22. The allegations in paragraph 22 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 and for that reason deny each of them.
- 23. The allegations in paragraph 23 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 and for that reason deny each of them.
- 24. The allegations in paragraph 24 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 24 and for that reason deny each of them.

- 25. The allegations in paragraph 25 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 and for that reason deny each of them.
- 26. The allegations in paragraph 26 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 and for that reason deny each of them.
- 27. The allegations in paragraph 27 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 and for that reason deny each of them.
- 28. The allegations in paragraph 28 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28 and for that reason deny each of them.

- 29. The allegations in paragraph 29 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 and for that reason deny each of them.
- 30. The allegations in paragraph 30 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 and for that reason deny each of them.
- 31. The allegations in paragraph 31 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 and for that reason deny each of them.

# AS TO SUBSECTION C. ENTITLED "Other Brand Name Drug Sponsors, Manufacturers, Labelers, and Distributors"

32. In response to paragraph 32, the Hospira and Pfizer Defendants admit only that Hospira, Inc. received FDA approval to manufacture and sell a docetaxel product pursuant to Section 505(b)(2) of the FDCA, and Pfizer received FDA approval to manufacture and sell a docetaxel product pursuant to 505(b)(2) of the FDCA. To the extent that the allegations in paragraph 32 are directed at defendants other than the Hospira and Pfizer Defendants, they are without knowledge or information sufficient to form a belief as to the truth of those allegations and for that reason deny each of them.

- 33. Paragraph 33 purports to state legal conclusions, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 33 purports to refer to or characterize federal statutes, which speak for themselves, and Plaintiffs' attempts to characterize those statutes is denied.
- 34. Paragraph 34 purports to state legal conclusions, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 34 purports to refer to or characterize federal statutes, which speak for themselves, and Plaintiffs' attempts to characterize those statutes is denied.
- 35. Paragraph 35 purports to state legal conclusions, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 35 purports to refer to or characterize federal statutes, which speak for themselves, and Plaintiffs' attempts to characterize those statutes is denied.
- 36. Paragraph 36 purports to state legal conclusions, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 36 purports to refer to or characterize federal statutes, which speak for themselves, and Plaintiffs' attempts to characterize those statutes is denied.

# AS TO SUBSECTION C.1. ENTITLED "Sandoz"

- 37. The allegations in paragraph 37 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 and for that reason deny each of them.
- 38. The allegations in paragraph 38 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a

response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 and for that reason deny each of them.

- 39. The allegations in paragraph 39 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39 and for that reason deny each of them.
- 40. The allegations in paragraph 40 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 and for that reason deny each of them.
- 41. The allegations in paragraph 41 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 and for that reason deny each of them.
- 42. The allegations in paragraph 42 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 and for that reason deny each of them.

- 43. The allegations in paragraph 43 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 and for that reason deny each of them.
- 44. The allegations in paragraph 44 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 and for that reason deny each of them.
- 45. The allegations in paragraph 45 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 and for that reason deny each of them.
- 46. The allegations in paragraph 46 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46 and for that reason deny each of them.
- 47. The allegations in paragraph 47 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 47 and for that reason deny each of them.

- 48. The allegations in paragraph 48 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 and for that reason deny each of them.
- 49. The allegations in paragraph 49 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 and for that reason deny each of them.
- 50. The allegations in paragraph 50 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50 and for that reason deny each of them.

### AS TO SUBSECTION C.2. ENTITLED "Accord Healthcare & McKesson"

51. The allegations in paragraph 51 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 and for that reason deny each of them.

- 52. The allegations in paragraph 52 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52 and for that reason deny each of them.
- 53. The allegations in paragraph 53 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53 and for that reason deny each of them.
- 54. The allegations in paragraph 54 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54 and for that reason deny each of them.
- 55. The allegations in paragraph 55 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55 and for that reason deny each of them.
- 56. The allegations in paragraph 56 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 56 and for that reason deny each of them.

- 57. The allegations in paragraph 57 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 and for that reason deny each of them.
- 58. The allegations in paragraph 58 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 and for that reason deny each of them.
- 59. The allegations in paragraph 59 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 59 and for that reason deny each of them.
- 60. The allegations in paragraph 60 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 and for that reason deny each of them.

- 61. The allegations in paragraph 61 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 61 and for that reason deny each of them.
- 62. The allegations in paragraph 62 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62 and for that reason deny each of them.
- 63. The allegations in paragraph 63 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 63 and for that reason deny each of them.

### AS TO SUBSECTION C.4. ENTITLED "Hospira Entities" 1

- 64. In response to paragraph 64, the Hospira and Pfizer Defendants admit only that Hospira, Inc. is a Delaware corporation company located in Lake Forest, Illinois, and that it is involved in the manufacturing and sale of certain pharmaceutical products.
- 65. In response to paragraph 65, the Hospira and Pfizer Defendants admit only that Hospira Worldwide, LLC, formerly doing business as Hospira Worldwide, Inc., is a Delaware

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The Complaint does not contain a subsection C(3). The Hospira and Pfizer Defendants repeat this numbering error so the numbering is consistent with the Complaint.

limited liability company located in Lake Forest, Illinois, and that it has been involved in the manufacturing and sale of certain pharmaceutical products.

- 66. Paragraph 66 is admitted.
- 67. Paragraph 67 is denied, except that the Hospira and Pfizer Defendants admit only that the Hospira Defendants have been involved in the manufacturing and sale of certain pharmaceutical products, and have conducted business throughout the United States.
- 68. Paragraph 68 is denied, except that the Hospira and Pfizer Defendants admit only that they have been involved in the manufacturing, labeling, and sale of certain docetaxel products, which were approved by the FDA pursuant to New Drug Application number 022234.
- 69. Paragraph 69 is denied, except that the Hospira and Pfizer Defendants admit only that Hospira, Inc. submitted New Drug Application number 022234 pursuant to Section 505(b)(2) of the FDCA on July 11, 2007, and that the application listed Taxotere as the Reference Listed Drug.
- 70. In response to paragraph 70, the Hospira and Pfizer Defendants admit that Hospira, Inc.'s docetaxel products have been approved as a one-vial formulation and in different strengths and formulations, and that Hospira, Inc.'s docetaxel contains certain ingredients that are listed in its FDA-approved labeling, which speaks for itself. To the extent this paragraph also purports to refer to the labeling for Taxotere, such labeling speaks for itself, and the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of these allegations and for that reason deny each of them.
- 71. In response to paragraph 71, the Hospira and Pfizer Defendants admit that the FDA approved Hospira, Inc.'s New Drug Application number 022234 on or about March 8,

2011, and the Hospira Defendants started selling certain docetaxel products in the United States on or about March 17, 2011.

- 72. In response to paragraph 72, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to and quote portions of the FDA-approved Patient Information for Hospira, Inc.'s docetaxel products, which speaks for itself, and Plaintiffs' attempt to quote, paraphrase, or construe the information is denied.
- 73. In response to paragraph 73, the Hospira and Pfizer Defendants admit that Hospira, Inc. submitted a Supplemental New Drug Application ("sNDA") to the FDA on or about September 11, 2013, and that the FDA approved the sNDA on or about July 10, 2014. This sNDA and the FDA's approval speak for themselves and Plaintiffs' attempt to paraphrase or construe the application and related communications is denied. The remaining allegations in paragraph 73 are denied, except that the Hospira and Pfizer Defendants admit only that paragraph 73 purports to refer to an FDA letter dated April 21, 2014, which speaks for itself.
- 74. Paragraph 74 is denied, except that the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to the FDA-approved labeling for Hospira, Inc.'s docetaxel products, which speaks for itself, and the Hospira and Pfizer Defendants deny any attempt by Plaintiffs to characterize or paraphrase such labeling.

## AS TO SUBSECTION C.5. ENTITLED "Sun Pharma Entities & Caraco Labs"

75. The allegations in paragraph 75 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 75 and for that reason deny each of them.

- 76. The allegations in paragraph 76 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 76 and for that reason deny each of them.
- 77. The allegations in paragraph 77 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 77 and for that reason deny each of them.
- 78. The allegations in paragraph 78 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 and for that reason deny each of them.
- 79. The allegations in paragraph 79 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 and for that reason deny each of them.
- 80. The allegations in paragraph 80 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 80 and for that reason deny each of them.

- 81. The allegations in paragraph 81 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81 and for that reason deny each of them.
- 82. The allegations in paragraph 82 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 and for that reason deny each of them.
- 83. The allegations in paragraph 83 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 and for that reason deny each of them.
- 84. The allegations in paragraph 84 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 84 and for that reason deny each of them.

85. The allegations in paragraph 85 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 and for that reason deny each of them.

### AS TO SUBSECTION C.6. ENTITLED "Pfizer"

- 86. Paragraph 86 is denied, except that Pfizer admits only that it is incorporated under the laws of Delaware and maintains its principal place of business in New York, and that it has been involved in the manufacturing and sale of certain pharmaceuticals.
  - 87. Paragraph 87 is admitted.
- 88. Paragraph 88 is denied, except that Pfizer admits only that it has been involved in the and sale of certain docetaxel products and has conducted business throughout the United States.
- 89. Paragraph 89 is denied, except that Pfizer admits only that it was involved in the manufacturing, labeling, and sale of certain docetaxel products, which were approved by the FDA pursuant to New Drug Application number 202356, but Pfizer states that it discontinued sale of its docetaxel products in 2016.
- 90. Paragraph 90 is denied, except that Pfizer admits only that it submitted New Drug Application number 202356 pursuant to Section 505(b)(2) of the FDCA on or about September 13, 2013, and that the application listed Taxotere as the Reference Listed Drug.
- 91. In response to paragraph 91, Pfizer admits only that its docetaxel products were available in a one-vial formulation and certain doses, and that Pfizer's docetaxel products contained certain ingredients that are listed in the FDA-approved labeling, which speaks for itself. To the extent this paragraph also purports to refer to the labeling for Taxotere, such

labeling speaks for itself, and Pfizer is without knowledge or information sufficient to form a belief as to the truth of these allegations and for that reason denies each of them.

- 92. In response to paragraph 92, Pfizer admits only that the FDA approved Pfizer's New Drug Application number 202356 on or about March 13, 2014, and that Pfizer started selling certain docetaxel products in the United States on or about June 23, 2014.
- 93. In response to paragraph 93, Pfizer admits only that this paragraph purports to refer to and quote portions of the FDA-approved Patient Information for Pfizer's docetaxel products, which speaks for itself, and Plaintiffs' attempt to quote, paraphrase, or construe the information is denied.
  - 94. Paragraph 94 is admitted.
  - 95. Paragraph 95 is denied.
- 96. Paragraph 96 is denied, except that Pfizer admits only that this paragraph purports to refer to the FDA-approved labeling for Pfizer's docetaxel products, which speaks for itself, and Pfizer denies any attempt by Plaintiffs to characterize or paraphrase such labeling.

# AS TO SUBSECTION C.7. ENTITLED "Actavis Entities"

- 97. The allegations in paragraph 97 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97 and for that reason deny each of them.
- 98. The allegations in paragraph 98 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 98 and for that reason deny each of them.

- 99. The allegations in paragraph 99 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 99 and for that reason deny each of them.
- 100. The allegations in paragraph 100 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 100 and for that reason deny each of them.
- 101. The allegations in paragraph 101 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 101 and for that reason deny each of them.
- 102. The allegations in paragraph 102 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 102 and for that reason deny each of them.

- 103. The allegations in paragraph 103 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 103 and for that reason deny each of them.
- 104. The allegations in paragraph 104 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 104 and for that reason deny each of them.
- 105. The allegations in paragraph 105 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 105 and for that reason deny each of them.
- 106. The allegations in paragraph 106 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106 and for that reason deny each of them.
- 107. The allegations in paragraph 107 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 107 and for that reason deny each of them.

## AS TO SECTION ENTITLED "JURISDICTION AND VENUE"

- 108. Paragraph 108 purports to state a legal conclusion, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 108 relating to the citizenship of other parties, and for that reason deny same and deny the remaining allegations of paragraph 108.
- 109. Paragraph 109 purports to state a legal conclusion, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 109 and for that reason deny each of them.
- 110. Paragraph 110 purports to state a legal conclusion, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 110 purports to refer to and characterize Transfer Orders of the Judicial Panel on Multidistrict Litigation, which speak for themselves.
- 111. Paragraph 111 purports to state a legal conclusion, as to which no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 111 that are directed at other Defendants and for that reason deny same and deny all remaining allegations of paragraph 111.

### AS TO SECTION ENTITLED "FACTUAL ALLEGATIONS"

#### AS TO SUBSECTION I. ENTITLED

# "Development, Approval, and Labeling Changes for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez"

- 112. In response to paragraph 112, the Hospira and Pfizer Defendants admit only that Taxotere, which is a medicine marketed, manufactured, and sold by a company other than Pfizer and the Hospira Defendants, is an FDA-approved chemotherapy medication that is approved for treatment of certain cancers, including breast cancers, and is a member of a class of medicines known as taxanes.
- 113. Paragraph 113 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit that the class of medicines known as taxanes were originally derived from the yew tree and inhibit the multiplication of cancer cells and that taxanes have been used as chemotherapy agents.
- 114. Paragraph 114 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 and for that reason deny each of them.
- 115. Paragraph 115 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 115 and for that reason deny each of them.

- 116. Paragraph 116 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 and for that reason deny each of them.
- 117. Paragraph 117 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 and for that reason deny each of them.
- 118. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118 and for that reason deny each of them.
- 119. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119 and for that reason deny each of them, except that the Hospira and Pfizer Defendants admit only that their docetaxel products are approved by FDA for use intravenously.
- 120. The allegations in paragraph 120 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 120 and for that reason deny each of them.

- 121. The allegations in paragraph 121 are directed at a defendant other than the Hospira Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira Defendants is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121 and for that reason deny each of them.
- 122. The allegations in paragraph 122 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122 and for that reason deny each of them.
- 123. Paragraph 123 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 and for that reason deny each of them.
- 124. The allegations in paragraph 124 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124 and for that reason deny each of them.
- 125. The allegations in paragraph 125 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 125 and for that reason deny each of them.

- 126. The allegations in paragraph 126 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 126 and for that reason deny each of them.
- 127. The allegations in paragraph 127 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 127 and for that reason deny each of them.
- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 128 purports to quote, paraphrase or construe portions of the Taxotere label, which speaks for itself, and Plaintiffs' attempt to quote, paraphrase or construe the labeling is denied. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 128 and for that reason deny each of them.
- 129. The allegations in paragraph 129 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 129 and for that reason deny each of them.

- 130. The allegations in paragraph 130 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 130 and for that reason deny each of them.
- 131. The allegations in paragraph 131 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 131 and for that reason deny each of them.
- 132. The allegations in paragraph 132 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 132 and for that reason deny each of them.
- 133. The allegations in paragraph 133 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 133 and for that reason deny each of them.

- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 134 purports to quote, paraphrase or construe portions of the 2010 and 2014 Taxotere Patient Counseling Information, which speak for themselves, and Plaintiffs' attempt to quote, paraphrase or characterize the labeling information is denied. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 134 and for that reason deny each of them.
- 135. The allegations in paragraph 135 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 135 and for that reason deny each of them.
- 136. The allegations in paragraph 136 are directed at a defendant other than the Hospira Defendants or Pfizer and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 136 and for that reason deny each of them.
- 137. Paragraph 137 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 137 purports to quote, paraphrase or construe portions of the Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to quote, paraphrase or characterize the

labeling is denied. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 137 and for that reason deny each of them.

# <u>AS TO SUBSECTION II. ENTITLED</u> "Defendants' Duties Under the FDCA and State Law"

- 138. Paragraph 138 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, paragraph 139 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
- 139. Paragraph 139 purports to state legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, paragraph 139 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
- 140. Paragraph 140 purports to state legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, paragraph 140 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
- 141. Paragraph 141 purports to state legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, paragraph 141 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
- 142. Paragraph 142 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to quote or paraphrase certain federal statutes, which

speak for themselves, and Plaintiffs' attempt to characterize those statutes is denied. Responding further, the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty and deny all remaining allegations of paragraph 142.

- 143. Paragraph 143 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to quote or paraphrase certain federal statutes, which speak for themselves, and Plaintiffs' attempt to characterize those statutes is denied. Responding further, the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty and deny all remaining allegations of paragraph 143.
- 144. Paragraph 144 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to quote or paraphrase certain federal statutes, which speak for themselves, and Plaintiffs' attempt to characterize those statutes is denied.

  Responding further, the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty and deny all remaining allegations of paragraph 144.
- 145. Paragraph 145 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to quote or paraphrase federal statutes, which speak for themselves, and Plaintiffs' attempt to characterize those statutes is denied. Responding further, the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty and deny all remaining allegations of paragraph 145.

- 146. Paragraph 146 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to quote or paraphrase federal statutes, which speak for themselves, and Plaintiffs' attempt to characterize those statutes is denied. Responding further, the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty and deny all remaining allegations of paragraph 146.
  - 147. Paragraph 147 is denied.

# AS TO SUBSECTION III. ENTITLED "Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia"

- 148. The allegations in paragraph 148 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 148 and for that reason deny each of them. Responding further, the Hospira and Pfizer Defendants admit only that paragraph 148 purports to refer to or construe information about a clinical study sponsored by another defendant, which speaks for itself, and Plaintiffs' attempt to characterize the study is denied.
- 149. Paragraph 149 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 149 purports to quote or construe a 2006 study, which speaks for itself, and Plaintiffs' attempt to characterize the study is denied.

- 150. The allegations in paragraph 150 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 150 and for that reason deny each of them. Responding further, the Hospira and Pfizer Defendants admit only that paragraph 150 purports to refer to or quote from a November 21, 2008 letter, which speak for itself, and Plaintiffs' attempt to characterize the letter is denied.
- 151. Paragraph 151 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 151 purports to quote or paraphrase a 2009 article, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- 152. Paragraph 152 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 152 purports to quote or paraphrase a 2010 article, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- 153. Paragraph 153 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 153 purports to quote or paraphrase the research and statements of a particular oncologist, which speaks for themselves, and Plaintiffs' attempt to characterize the oncologist's research and statements is denied.

- 154. Paragraph 154 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 154 purports to quote or paraphrase a 2010 news article, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- 155. Paragraph 155 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 155 purports to quote or paraphrase a 2010 news article, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- 156. Paragraph 156 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 156 purports to quote or paraphrase a 2010 article, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 157 purports to quote or paraphrase a 2011 article in the American Journal of Dermatopathology, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- 158. Paragraph 158 does not set forth any allegation directed to the Hospira

  Defendants or Pfizer that is susceptible to admission or denial and therefore no response is

required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 158 purports to quote or paraphrase a 2012 article in the Annals of Oncology, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.

- 159. Paragraph 159 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 159 purports to quote or paraphrase a presentation given at the Clatterbridge Cancer Centre in October 2013, which speaks for itself, and Plaintiffs' attempt to characterize the presentation is denied.
- 160. Paragraph 160 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 160 purports to refer to a 2014 publication at the San Antonio Breast Cancer Symposium, which speaks for itself.
- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 161 purports to quote or paraphrase a November 2015 article in the Journal of Clinical Oncology, which speaks for itself, and Plaintiffs' attempt to characterize the article is denied.
- 162. The allegations in paragraph 162 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 162

purports to refer to a 1999 Patient Information Letter issued by Sanofi, which speaks for itself, and Plaintiffs' attempt to characterize the letter is denied.

- 163. The allegations in paragraph 163 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 163 purports to refer to and quote from the Taxotere labeling approved by the European Medicines Agency in 2005, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.
- 164. Paragraph 164 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 164 purports to refer to a September 28, 2007 version of the Highlights of Prescribing Information, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.
- 165. The allegations in paragraph 165 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 165 purports to refer to and quote different versions of the Taxotere labeling, all of which speak for themselves, and Plaintiffs' attempt to characterize the labeling is denied.
- 166. The allegations in paragraph 166 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 166

purports to refer to and quote from the Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.

- 167. The allegations in paragraph 167 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 167 purports to refer to and quote from the 2015 Canadian Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.
- 168. The allegations in paragraph 168 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 168 purports to refer to and quote from the 2015 Australian Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.
- 169. The allegations in paragraph 169 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 169 purports to refer to a FDA regulatory request that Sanofi submitted on November 25, 2015, which speaks for itself, and Plaintiffs' attempt to characterize the request is denied.
- 170. Paragraph 170 does not set forth any allegation directed to the Hospira and Pfizer Defendants that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 170 purports to refer to and quote from certain Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.
  - 171. Paragraph 171 is denied.

172. Paragraph 172 states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to certain FDA regulations, which speak for themselves, and Plaintiffs' attempt to characterize the regulations is denied. Responding further, the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty and deny all remaining allegations of paragraph 172.

# AS TO SUBSECTION IV. ENTITLED "Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate Caused Permanent Alopecia in Many Breast Cancer Patients"

- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel, that Plaintiffs' allegations concerning hair loss in paragraph 173 will be appropriately addressed through expert and medical testimony, and the Hospira and Pfizer Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173 and for that reason deny each of them.
- 174. Paragraph 174 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel, that Plaintiffs' allegations concerning hair loss in paragraph 174 will be appropriately addressed through expert and medical testimony, and the

Hospira and Pfizer Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174 and for that reason deny each of them.

- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel, that Plaintiffs' allegations concerning hair loss in paragraph 175 will be appropriately addressed through expert and medical testimony, and the Hospira and Pfizer Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 175 and for that reason deny each of them.
- Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel, that Plaintiffs' allegations concerning hair loss in paragraph 176 will be appropriately addressed through expert and medical testimony, and the Hospira and Pfizer Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 176 and for that reason deny each of them.
- 177. Paragraph 177 does not set forth any allegation directed to the Hospira

  Defendants or Pfizer that is susceptible to admission or denial and therefore no response is

required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel, that Plaintiffs' allegations concerning hair loss in paragraph 177 will be appropriately addressed through expert and medical testimony, and the Hospira and Pfizer Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177 and for that reason deny each of them.

- Defendants that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel, that Plaintiffs' allegations concerning hair loss in paragraph 178 will be appropriately addressed through expert and medical testimony, and the Hospira and Pfizer Defendants are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 178 and for that reason deny each of them.
- 179. Paragraph 179 does not set forth any allegation directed to the Hospira and Pfizer Defendants that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to statements by the Mayo Clinic and Dr. Ralph M. Trueb, which speak for themselves, and Plaintiffs' attempt to characterize those statements is denied.
- 180. Paragraph 180 is denied except that the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of those products.

- 181. Paragraph 181 is denied, except that the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to certain statements by an unidentified oncologist, which speak for themselves, and Plaintiffs' attempt to characterize those statements is denied.
- 182. The allegations in paragraph 182 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 182 purports to refer to a Sanofi clinical study, which speaks for itself, and Plaintiffs' attempt to characterize the study is denied.
- 183. Paragraph 183 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to a 2006 study, which speaks for itself, and Plaintiffs' attempt to characterize the study is denied.
- 184. Paragraph 184 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to a 2010 article, which speaks for itself, and Plaintiffs' attempt to characterize the study is denied.
- 185. Paragraph 185 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to a 2012 study, which speaks for itself, and Plaintiffs' attempt to characterize the study is denied.

- 186. Paragraph 186 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that this paragraph purports to refer to a 2014 presentation, which speaks for itself, and Plaintiffs' attempt to characterize the presentation is denied.
- 187. To the extent allegations in paragraph 187 are directed at the Hospira or Pfizer Defendants, they are denied. Responding further, the Hospira and Pfizer Defendants state only that other aspects of this paragraph purport to refer to and quote Sanofi's 2015 Taxotere label, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.
- 188. Paragraph 188 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 188 purports to refer to and quote a report issued by the European Medicines Agency in May 2016, which speaks for itself, and Plaintiffs' attempt to characterize the report is denied.
- 189. Paragraph 189 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.

# <u>AS TO SUBSECTION V. ENTITLED</u> "Sanofi Marketed & Promoted Taxotere Despite Knowing It Caused Permanent Alopecia"

190. The allegations in paragraph 190 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 190 and for that reason deny each of them.

- 191. The allegations in paragraph 191 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 191 and for that reason deny each of them.
- 192. The allegations in paragraph 192 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 192 and for that reason deny each of them.
- 193. The allegations in paragraph 193 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 193 and for that reason deny each of them.
- 194. The allegations in paragraph 194 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 194 and for that reason deny each of them.
- 195. The allegations in paragraph 195 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 195 and for that reason deny each of them.

- 196. The allegations in paragraph 196 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 196 and for that reason deny each of them.
- 197. The allegations in paragraph 197 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 197 and for that reason deny each of them.
- 198. The allegations in paragraph 198 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 198 and for that reason deny each of them.
- 199. The allegations in paragraph 199 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 199 and for that reason deny each of them.

- 200. The allegations in paragraph 200 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 200 and for that reason deny each of them.
- 201. The allegations in paragraph 201 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 201 and for that reason deny each of them.
- 202. The allegations in paragraph 202 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 202 and for that reason deny each of them.
- 203. The allegations in paragraph 203 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 203 and for that reason deny each of them.
- 204. The allegations in paragraph 204 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or

information sufficient to form a belief as to the truth of the allegations in paragraph 204 and for that reason deny each of them.

- 205. The allegations in paragraph 205 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 205 and for that reason deny each of them.
- 206. The allegations in paragraph 206 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 206 and for that reason deny each of them.
- 207. The allegations in paragraph 207 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 207 and for that reason deny each of them.
- 208. The allegations in paragraph 208 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 208 and for that reason deny each of them.

- 209. The allegations in paragraph 209 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 209 and for that reason deny each of them.
- 210. Paragraph 210 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 210 purports to refer to a 2007 and a 2008 study, which speaks for themselves, and Plaintiffs' attempt to characterize the studies is denied.
- 211. The allegations in paragraph 211 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that paragraph 211 purports to quote from an FDA letter in 2009, which speaks for itself, and Plaintiffs' attempt to characterize the letter is denied.
- 212. The allegations in paragraph 212 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 212 and for that reason deny each of them.

### AS TO SUBSECTION VI. ENTITLED "Permanent Alopecia is Devastating for Plaintiffs"

213. Paragraph 213 does not set forth any allegation directed to the Hospira

Defendants or Pfizer that is susceptible to admission or denial and therefore no response is

required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants admit only that the paragraph purports to refer to unidentified research, which speaks for itself, and Plaintiffs' attempt to characterize the research is denied.

- 214. Paragraph 214 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 214 and for that reason deny each of them.
- 215. Paragraph 215 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 215 and for that reason deny each of them.
- 216. Paragraph 216 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 216 and for that reason deny each of them.
- 217. Paragraph 217 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 217 and for that reason deny each of them except that the Hospira and Pfizer

Defendants admit only that the third sentence of paragraph 217 purports to refer to an unidentified study, which speaks for itself, and Plaintiffs' attempt to characterize the results of the study is denied.

- 218. Paragraph 218 does not set forth any allegation directed to the Hospira Defendants or Pfizer that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 218 and for that reason deny each of them
- 219. To the extent any allegations in paragraph 219 are directed to the Hospira and Pfizer Defendants, they are denied. The Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 219 and for that reason deny each of them.

### AS TO PLAINTIFFS' FIRST CLAIM FOR RELIEF (Strict Products Liability – Failure to Warn – Against All Defendants)

- 220. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
- 221. Responding to paragraph 221, the Hospira and Pfizer Defendants admit only that they have been involved in the manufacturing and sale of certain docetaxel products but are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 221 relating to the other defendants or Plaintiffs' docetaxel use and for that reason deny each of them.
  - 222. Paragraph 222 is denied.

- 223. The allegations in paragraph 223 are directed at a defendant other than the Hospira and Pfizer Defendants and therefore, no responsive pleading is required. To the extent a response is deemed necessary, the Hospira and Pfizer Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 223 and for that reason deny each of them.
  - 224. Paragraph 224 is denied.
  - 225. Paragraph 225 is denied.
  - 226. Paragraph 226 is denied.
  - 227. Paragraph 227 is denied.
- 228. Paragraph 228 calls for a legal conclusion, to which no response is required. To the extent a response is required, the Hospira and Pfizer Defendants deny the allegations in paragraph 228.
  - 229. Paragraph 229 is denied.
  - 230. Paragraph 230 is denied.

# AS TO PLAINTIFFS' SECOND CLAIM FOR RELIEF (Strict Products Liability For Misrepresentation - Against All Defendants)

- 231. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
- 232. The allegations contained in paragraph 232 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.

- 233. The allegations contained in paragraph 233 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 234. The allegations contained in paragraph 234 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 235. The allegations contained in paragraph 235 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 236. The allegations contained in paragraph 236 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 237. The allegations contained in paragraph 237 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61. Therefore, no response is required.
- 238. The allegations contained in paragraph 238 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.

# AS TO PLAINTIFFS' THIRD CLAIM FOR RELIEF (Negligence – Against All Defendants)

239. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.

- 240. To the extent the allegations in paragraph 240 are directed at the Hospira and Pfizer Defendants, they are denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
  - 241. Paragraph 241 is denied.
  - 242. Paragraph 242 is denied, including all subparts.
  - 243. Paragraph 243 is denied.
  - 244. Paragraph 244 is denied.
  - 245. Paragraph 245 is denied.
  - 246. Paragraph 246 is denied.

# AS TO PLAINTIFFS' FOURTH CLAIM FOR RELIEF (Negligent Misrepresentation – Against All Defendants)

- 247. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
- 248. Paragraph 248 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
  - 249. Paragraph 249 is denied.
  - 250. Paragraph 250 is denied.
  - 251. Paragraph 251 is denied.
  - 252. Paragraph 252 is denied.
  - 253. Paragraph 253 is denied.
  - 254. Paragraph 254 is denied.
- 255. Paragraph 255 is denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.

- 256. Paragraph 256 denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
  - 257. Paragraph 257 is denied.

### AS TO PLAINTIFFS' FIFTH CLAIM FOR RELIEF (Fraudulent Misrepresentation – Against All Defendants)

- 258. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
- 259. Paragraph 259 is denied, except the Hospira and Pfizer Defendants state only that the FDA-approved labeling for their docetaxel products accurately presented the potential risks and benefits of docetaxel.
  - 260. Paragraph 260 is denied.
  - 261. Paragraph 261 is denied.
  - 262. Paragraph 262 is denied, including all subparts.
  - 263. Paragraph 263 is denied.
  - 264. Paragraph 264 is denied.
  - 265. Paragraph 265 is denied.

### <u>AS TO PLAINTIFFS' SIXTH CLAIM FOR RELIEF</u> (Fraudulent Concealment – Against All Defendants)

- 266. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
  - 267. Paragraph 267 is denied.
  - 268. Paragraph 268 is denied.
  - 269. Paragraph 269 is denied, including all subparts.

- 270. Paragraph 270 denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
  - 271. Paragraph 271 is denied.
  - 272. Paragraph 272 is denied.
  - 273. Paragraph 273 is denied.
  - 274. Paragraph 274 is denied.
  - 275. Paragraph 275 is denied.

### AS TO PLAINTIFFS' SEVENTH CLAIM FOR RELIEF (Fraud and Deceit – Against All Defendants)

- 276. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
  - 277. Paragraph 277 is denied.
  - 278. Paragraph 278 is denied.
  - 279. Paragraph 279 is denied.
  - 280. Paragraph 280 is denied.
- 281. Paragraph 281 denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
- 282. Paragraph 282 denied, except that the Hospira and Pfizer Defendants admit only those duties imposed by law, but expressly deny the breach of any applicable duty.
  - 283. Paragraph 283 is denied.
  - 284. Paragraph 284 is denied.
  - 285. Paragraph 285 is denied.
  - 286. Paragraph 286 is denied.

- 287. Paragraph 287 is denied.
- 288. Paragraph 288 is denied.
- 289. Paragraph 289 is denied.
- 290. Paragraph 290 is denied.
- 291. Paragraph 291 is denied.
- 292. Paragraph 292 is denied.
- 293. Paragraph 293 is denied.
- 294. Paragraph 294 is denied.
- 295. Paragraph 295 is denied.
- 296. Paragraph 296 is denied.
- 297. Paragraph 297 is denied.
- 298. Paragraph 298 is denied.
- 299. Paragraph 299 is denied.
- 300. Paragraph 300 is denied.
- 301. Paragraph 301 is denied.
- 302. Paragraph 302 is denied.
- 303. Paragraph 303 is denied.
- 304. Paragraph 304 is denied.
- 305. Paragraph 305 is denied.
- 306. Paragraph 306 is denied.
- 307. Paragraph 307 is denied.
- 308. Paragraph 308 is denied.
- 309. Paragraph 309 is denied.

310. Paragraph 310 is denied.

# AS TO PLAINTIFFS' EIGHTH CLAIM FOR RELIEF (Breach of Express Warranty – Against Sanofi-Related Entities Only)

- 311. The Hospira and Pfizer Defendants incorporate by reference their responses to the preceding paragraphs of the Complaint with the same legal force and effect as if fully set forth at length herein.
- 312. The allegations contained in paragraph 312 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 313. The allegations contained in paragraph 313 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 314. The allegations contained in paragraph 314 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 315. The allegations contained in paragraph 315 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 316. The allegations contained in paragraph 316 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.
- 317. The allegations contained in paragraph 317 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.

318. The allegations contained in paragraph 318 pertain to claims that were dismissed by this Court on September 27, 2017, pursuant to Pretrial Order No. 61 and therefore, no response is required.

#### AS TO PLAINTIFFS' "PRAYER FOR RELIEF"

319. Responding to paragraph 319 of the Complaint, the Hospira and Pfizer

Defendants deny that their conduct or docetaxel caused or contributed to Plaintiffs' alleged injuries and deny that they are liable to Plaintiffs for alleged damages or any other relief sought in the Complaint.

### AS TO SECTION ENTITLED "JURY DEMAND"

320. Responding to paragraph 320 of the Complaint, the Hospira and Pfizer Defendants admit that Plaintiffs demand a jury trial and the Hospira and Pfizer Defendants also demand a jury trial.

#### AFFIRMATIVE AND OTHER DEFENSES

By asserting the matters set forth below, the Hospira and Pfizer Defendants do not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters. The Hospira and Pfizer Defendants assert as follows:

**<u>FIRST</u>**. The Complaint and each claim contained therein fails to state a claim upon which relief can be granted.

**SECOND**. The claims asserted in the Complaint are barred, in whole or in part, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

<u>**THIRD**</u>. The claims asserted in the Complaint are preempted by federal law, including (without limitation) the federal Food, Drug, and Cosmetic Act.

**FOURTH**. Plaintiffs' claims are barred, in whole or in part, by the learned intermediary doctrine because adequate warnings were given to learned intermediaries.

**<u>FIFTH.</u>** The claims asserted in the Complaint are barred, in whole or in part, by Restatement (Second) of Torts § 402A, Comment k, and Restatement (Third) of Torts: Products Liability § 6.

**SIXTH**. Plaintiffs assumed the risks alleged in the Complaint.

**SEVENTH**. Plaintiffs' claims are barred because the risks, if any, associated with the use of docetaxel are outweighed by its utility.

**EIGHTH**. Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

<u>NINTH</u>. If Plaintiffs have sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences or conditions, which were in no way caused by the Hospira or Pfizer Defendants and for which they are not liable.

**TENTH**. Plaintiffs may not recover from the Hospira and Pfizer Defendants because the methods, standards, or techniques of designing, manufacturing, and labeling of docetaxel complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, and labeled.

**ELEVENTH**. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and of repose.

**TWELFTH**. Plaintiffs' claims are barred, in whole or in part, by doctrines of laches, waiver, unclean hands, estoppel and/or ratification.

**THIRTEENTH**. Plaintiffs' warranty-based claims are barred by Plaintiffs' failure to give proper or timely notice of any alleged defect or breach of warranty.

**FOURTEENTH**. To the extent that Plaintiffs' claims relate to the Hospira and Pfizer Defendants' advertising, public statements, lobbying, or other activities protected by the First

Amendment to the Constitution of the United States or by the Constitution of the State of Louisiana or that of any other state whose laws may apply, such claims are barred.

**<u>FIFTEENTH</u>**. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate any damages allegedly sustained.

**SIXTEENTH**. Plaintiffs' damages, if any, were the direct result of Plaintiffs' preexisting medical conditions, and/or occurred by operation of nature or as a result of circumstances over which the Hospira and Pfizer Defendants had and continue to have no control.

**SEVENTEENTH**. Any verdict or judgment that might be recovered by Plaintiffs must be reduced by those amounts that have already or will in the future, with reasonable certainty, indemnify Plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program.

**EIGHTEENTH**. Plaintiffs' injuries and damages, if any, are barred in whole or in part by the actions, omissions, and/or conduct of third parties over whom the Hospira and Pfizer Defendants had no control or authority and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

<u>NINETEENTH</u>. Plaintiffs' claims are barred and/or reduced by Plaintiffs' contributory or comparative negligence and Plaintiffs' contributory or comparative fault.

**TWENTIETH**. Plaintiffs' claims are barred, in whole or in part, by the alteration, modification, or misuse by Plaintiffs or third parties of the docetaxel administered to Plaintiffs.

TWENTY-FIRST. Plaintiffs' claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit

Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Louisiana or that of any other state whose laws may apply. Any law, statute or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on harms to third parties, outof-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to the Hospira and Pfizer Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; (8) would unconstitutionally impose a penalty, criminal in nature, without according to the Hospira and Pfizer Defendants the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, Louisiana, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific* Mut. Life Ins. Co. v. Haslip, 499 U.S. 1 (1991); TXO Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of N. Am. v. Gore, 517 U.S. 559 (1996); State Farm Ins. Co. v. Campbell, 538 U.S. 408 (2003); and Philip Morris USA v. Williams, 549 U.S. 346 (2007).

**TWENTY-SECOND.** Plaintiffs' warranty-based claims are barred because Plaintiffs were not in privity with the Hospira Defendants or Pfizer, and are further barred and/or limited by any and all express conditions or disclaimers given by the Hospira Defendants or Pfizer, and by Plaintiffs' lack of reliance upon such warranties.

**TWENTY-THIRD**. If Plaintiffs used docetaxel, they used it after learning of its alleged risks.

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

**TWENTY-FIFTH**. The Hospira and Pfizer Defendants' liability, if any, will not result from their conduct but is solely the result of an obligation imposed by law, and thus the Hospira and Pfizer Defendants are entitled to complete indemnity, express or implied, by other parties.

<u>TWENTY-SIXTH</u>. Plaintiffs' injuries and damages, if any, were due to Plaintiffs' preexisting condition or idiosyncratic reaction to docetaxel, for which the Hospira and Pfizer Defendants cannot be held responsible.

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

**TWENTY-EIGHTH.** The Hospira and Pfizer Defendants are liable only for damages found by the trier of fact equal to their percentage of responsibility, if any. Pursuant to Louisiana Civil Code article 2323, and any similar provisions under any applicable state law deemed to apply to the individual Plaintiffs' claims, if a person suffers injury, death, or loss as the result partly of her own negligence and partly as a result of the fault of another person or persons,

the amount of damages recoverable shall be reduced in proportion to the degree or percentage of negligence attributable to the person suffering the injury, death, or loss. Furthermore, liability for damages caused by two or more persons shall be a joint and divisible obligation. *See*, *e.g.*, La. C.C. art. 2324. The Hospira and Pfizer Defendants shall not be solely liable with any other person for damages attributable to the fault of such other person, including the person suffering injury, death, or loss, regardless of such other person's insolvency, ability to pay, degree of fault, immunity by statute, or otherwise. *See*, *e.g.*, *id*.

TWENTY-NINTH. The Hospira and Pfizer Defendants affirmatively plead the applicability of the Louisiana Products Liability Act, La. Rev. Stat. § 9:2800.51 et seq. ("LPLA") and specifically aver that Plaintiffs are not entitled to recovery under any of the exclusive theories of liability set forth in the Act.

**THIRTIETH.** Venue may be improper or inconvenient in this action.

THIRTY-FIRST. Plaintiffs are not entitled to exemplary damages, as courts uniformly dismiss these claims as falling outside the LPLA's provisions. See *Cheeks v. Bayer Corp.*, No. 03-132, 2003 WL 1748460 (E.D. La. March 28, 2003); *Bladen v. C.B. Fleet Holding*, No. 06-0973, 2007 WL 1237799 (W.D. La. April 23, 2007); *Ross v. Conoco, Inc.*, No. 02-C-0299, 828 So. 2d. 546 (La. 2002); *Ricard v. State*, 390 So. 2d. 882 (La. 1980).

**THIRTY-SECOND**. The Hospira and Pfizer Defendants are entitled to, and claim the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of the State of Louisiana or any other state whose substantive law might control the action.

**THIRTY-THIRD.** Plaintiffs' claims may be subject to dismissal due to lack of personal jurisdiction under the Due Process clause and any potentially applicable state law.

**THIRTY-FOURTH.** Plaintiffs' 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).

**THIRTY-FIFTH.** Plaintiffs' claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

**THIRTY-SIXTH.** Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs did not rely to their detriment upon any statement by the Hospira or Pfizer Defendants in determining to use docetaxel.

**THIRTY-SEVENTH.** Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA.

THIRTY-EIGHTH. To the extent Plaintiffs assert claims that depend solely on violations of federal law, including any claims of a "fraud on the FDA" with respect to the Hospira or Pfizer Defendants' disclosure of information related to the safety of docetaxel, such claims are barred and should be dismissed. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

THIRTY-NINTH. The conduct of the Hospira and Pfizer Defendants, as well as Defendants' docetaxel, conformed with the FDCA and the requirements of the FDA. Moreover, the activities of the Hospira and Pfizer Defendants alleged in the Complaint conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s) alleged in the Complaint.

**FORTIETH**. Plaintiffs' causes of action are or may be barred, in whole or in part, by lack of standing.

**FORTY-FIRST**. Plaintiffs' claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

**FORTY-SECOND.** Any recovery by Plaintiffs for medical or healthcare expenses should be limited to the amount actually paid or incurred. Specifically, Plaintiffs are not entitled to an award of damages for medical bills for which an obligation to pay never existed, nor are they entitled to an award of damages for future medical bills.

**FORTY-THIRD.** Any finding against the Hospira or Pfizer Defendants may not be based solely on evidence of a bad result to Plaintiffs, and the Hospira and Pfizer Defendants assert their right to instructions to the fact finder in this regard.

**FORTY-FOURTH.** The Hospira and Pfizer Defendants expressly invoke the procedural provisions authorized by the Louisiana Code of Civil Procedure Chapter 5, and any similar provisions under any applicable state law deemed to apply to the individual Plaintiffs' claims.

**FORTY-FIFTH.** Plaintiffs' causes of action are barred because Plaintiffs' medical providers owed a nondelegable duty to obtain their informed consent for all medical procedures and treatment, and the Hospira and Pfizer Defendants could not assume or comply with this duty because they are not medical providers.

**FORTY-SIXTH**. Liability may not be imposed as to a properly manufactured prescription drug distributed with information regarding the risks of which the manufacturer knew at the time of the manufacture, and liability may not be imposed for untold risks not known at the time of such design, manufacture, and sale of the subject prescription drug.

**FORTY-SEVENTH**. No act or omission of the Hospira or Pfizer Defendants was due to malice, oppression, or fraud or due to an evil motive or a reckless indifference to the rights of others; therefore, any award of punitive damages is barred. *Molzof v. United States*, 502 U.S. 301 (1992); *Smith v. Wade*, 461 U.S. 30 (1983).

**FORTY-EIGHTH.** Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

**FORTY-NINTH**. Plaintiffs' inadequate warning claims are barred because the alleged risk upon which Plaintiffs' claim is based is open, obvious, and/or a matter of common knowledge.

**<u>FIFTIETH</u>**. Plaintiffs' claims are barred, in whole or in part, because the Hospira and Pfizer Defendants acted reasonably and in good faith.

**<u>FIFTY-FIRST.</u>** Plaintiffs' claims are barred in whole or in part because the drug at issue was at all times properly tested, manufactured, labeled, marketed, sold, and/or distributed, and was not defective or unreasonably dangerous.

**FIFTY-SECOND**. Plaintiffs' claims are barred in whole or in part because the drug at issue provided a benefit to users of such drugs and greatly outweighed any risk created by using such drugs, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

#### **DEFENSES RESERVED**

The Hospira and Pfizer Defendants hereby give notice that they intend to rely upon any other defenses that may become available or apparent during the discovery proceedings in this matter, and hereby reserve their right to amend their Answer and to assert any such defenses.

### **DEMAND FOR JURY TRIAL**

The Hospira and Pfizer Defendants hereby demand a trial by jury of all issues so triable.

WHEREFORE, the Hospira and Pfizer Defendants demand judgment dismissing
Plaintiffs' Complaint in its entirety, together with costs and disbursements. The Hospira and
Pfizer Defendants further demand such other relief, both general and specific, at law or in equity,
to which they are justly entitled.

Dated: October 16, 2017 Respectfully submitted,

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Attorneys for Defendants Hospira, Inc., Hospira Worldwide, LLC, formerly doing business as Hospira Worldwide, Inc., and Pfizer Inc.

### **CERTIFICATE OF SERVICE**

I hereby certify that, this 16th day of October, 2017, I electronically filed a copy of the above and foregoing with Clerk of the Court using the ECF system, which sent notification of such filing to counsel of record.

/s/ Mara Cusker Gonzalez\_\_\_\_\_