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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES – CENTRAL DISTRICT

MARINA GOLDEN, an individual,

Plaintiff,

vs.

SANOFI-AVENTIS U.S., LLC, a Delaware Corporation; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., a Delaware Corporation; GLAXOSMITHKLINE, LLC, a Delaware Limited Liability Company; PFIZER, INC., a Delaware Corporation; AMERISOURCE HEALTH SERVICES, LLC, a Delaware Corporation; MYLAN PHARMACEUTICALS, INC., a West Virginia Corporation; PAR PHARMACEUTICAL, INC., a New York Corporation; L. PERRIGO COMPANY, a Michigan Corporation; TARO PHARMACEUTICALS U.S.A., INC., a New York Corporation; TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation; WOCKHARDT USA, LLC, a Delaware Limited Liability Company; ZYDUS PHARMACEUTICALS (USA), Inc., a New Jersey Corporation; CVS PHARMACY, INC., a Delaware Corporation; THE KROGER CO., an Ohio Corporation; WALGREEN CO., an Illinois Corporation; WALMART INC., an Arkansas Corporation, ALBERTSONS COMPANIES, INC., a Delaware Corporation; RITE AID CORPORATION, a Pennsylvania Corporation; and DOES 1-10, inclusive.

Defendants.

CASE NO. 21STCV14674

COMPLAINT

JURY TRIAL DEMANDED

Table of Contents

Plaintiff, Ms. Marina Golden ("Plaintiff"), alleges the following based on information and belief:

I. INTRODUCTION

1. This case concerns personal injuries suffered by Plaintiff as a result of ranitidine, the active ingredient in both Zantac and its generic forms ("Ranitidine-Containing Drugs"), which had been used to treat heartburn, upset stomach and ulcers since the early 1980's until April 1, 2020 when the U.S. Food and Drug Administration ("FDA") recalled all Ranitidine-Containing Drugs based on scientific evidence of a contaminant known as N-Nitrosodimethylamine (or "NDMA"), a human carcinogen, in the Ranitidine-Containing Drugs.

2. Plaintiff has been diagnosed with breast cancer because of ingesting carcinogenic Ranitidine-Containing Drugs due to Defendants' willful misconduct and gross dereliction of duty.

3. Had she known that Ranitidine-Containing Drugs would wreak such havoc to her body, Plaintiff would not have purchased or ingested any Ranitidine-Containing Drug.

4. Plaintiff seeks redress to compensate her for her injuries and to strongly deter the type of misconduct that caused to the damages she has and will continue to suffer.

II. PARTIES

A. Plaintiff

5. Plaintiff is a citizen of California and has resided in Los Angeles County, California at all relevant times.

6. Plaintiff took prescription generic ranitidine (300 mg) from approximately 1981 to the late 1980's. Plaintiff was prescribed generic ranitidine (300 mg) by a various physicians, including ones practicing at Axminster Medical Group.

7. Plaintiff consumed over-the-counter Zantac (150 mg) from approximately the mid-1980's through 2017 to treat upset stomach and acid reflex on an as-needed basis. More specifically, from 2014 – 2017, Plaintiff consumed over-the-counter Zantac (150 mg) to treat severe stomach issues during her cancer chemotherapy treatments.

8. Plaintiff purchased her Ranitidine-Containing Drugs from various retailers in and

around Los Angeles County, California, including Albertson's, CVS Pharmacy, Rite Aid, Kroger, Walmart, and Walgreens.

9. As a direct and proximate result of ingesting carcinogenic Ranitidine-Containing Drugs due to Defendants' willful misconduct and gross dereliction of duty, Plaintiff was diagnosed with breast cancer in 2014.

10. Plaintiff would not have purchased, nor ingested Ranitidine-Containing Drugs had she known of the hazards associated with the human consumption of Ranitidine-Containing Drugs.

11. Plaintiff is informed and believes that as a direct and proximate result of Plaintiff's ingestion and/or exposure to Ranitidine-Containing Drugs distributed and supplied by Defendants, Plaintiff experienced conscious pain and suffering and bodily impairment, including, but not limited to breast cancer. To address the adverse physical effects and damage from Plaintiff's exposure to Ranitidine-Containing Drugs, Plaintiff required hospitalizations, in-patient surgeries, and other medical treatment.

12. Plaintiff suffered special damages including, but not limited to, medical expenses and loss of earnings. Additionally, Plaintiff suffered general damages including, but not limited to, pain and suffering, mental anguish, and loss of enjoyment of life.

B. Manufacturer Defendants (Brand-Named)

13. Defendants are collectively composed of entities that designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Drugs under the brand name Zantac or a generic equivalent by either prescription or over the counter. Defendants sold or otherwise made available ranitidine in the following forms: injection, syrup, granules, tablets and/or capsules.

14. Each defendant below regularly conducts business in the state of California, and its Ranitidine-Containing Drugs have been placed in the stream of commerce to be sold in California retail locations, including those located in Los Angeles.

15. Plaintiff ingested and/or was exposed to Ranitidine-Containing Drugs under the brand name Zantac from each of the manufacturers identified below.

1. Defendant Sanofi

16. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC's sole member is Sanofi U.S. Services, Inc., a Delaware corporation with its principal place of business in New Jersey. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

17. Sanofi US Services Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is a citizen of Delaware and New Jersey.

18. Sanofi S.A. is a corporation formed and existing under the laws of France, having a principal place of business at 54 Rue La Boetie, 8th Arrondissement, Paris, France 75008. Sanofi S.A. is a citizen of France.

19. Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are subsidiaries of Sanofi S.A.

34. Chattem, Inc. is a Tennessee corporation with its principal place of business located at 1715 West 38th Street Chattanooga, Tennessee 37409. Chattem is a citizen of Tennessee. Chattem is a wholly owned subsidiary of French corporation Sanofi S.A.

2. Defendant Boehringer

20. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a citizen of Delaware and Connecticut.

21. Boehringer Ingelheim Corporation is a Nevada corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Corporation is a citizen of Nevada and Connecticut.

22. Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Rd., Ridgebury, Connecticut 06877. Boehringer Ingelheim USA Corporation is a citizen of Delaware and Connecticut.

23. Boehringer Ingelheim International GmbH is a limited liability company formed and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim AM Rhein, Rheinland-Phalz, Germany. Boehringer Ingelheim International GmbH is a citizen of Germany.

24. Boehringer Ingelheim Pharmaceuticals, Inc. is a direct or indirect subsidiary of Boehringer Ingelheim Corporation and Boehringer Ingelheim USA Corporation, which are wholly owned, directly, or indirectly, by Boehringer Ingelheim International GmbH. Collectively, these entities shall be referred to as "Boehringer Ingelheim."

25. Boehringer Ingelheim Promeco, S.A. de C.V. is a foreign corporation organized and existing under the laws of Mexico with its principal place of business located at Maiz No. 49, Barrio Xaltocan, Xochimilco, Ciudad de Mexico, 16090 Mexico. Boehringer Ingelheim Promeco, S.A. de C.V. is a citizen of Mexico.

3. Defendant GSK

26. Defendant GlaxoSmithKline LLC, a Delaware limited liability company, has its principal place of business at Five Crescent Drive, Philadelphia, Pennsylvania, 19112. GlaxoSmithKline LLC's sole member is GlaxoSmithKline (America) Inc., a Delaware corporation with its principal place of business in that state. GlaxoSmithKline LLC is a citizen of Delaware.

27. Defendant GlaxoSmithKline (America) Inc. is a Delaware corporation with its principal place of business located at 1105 N. Market Street, Suite 622, Wilmington, Delaware 19801. Defendant GlaxoSmithKline (America) Inc. is a citizen of Delaware.

28. GlaxoSmithKline plc is a public limited company formed and existing under the laws of the United Kingdom, having a principal place of business at 980 Great West Road, Brentford Middlesex XO, TW8 9GS, United Kingdom. GlaxoSmithKline plc is a citizen of the United Kingdom.

29. GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are subsidiaries of GlaxoSmithKline plc.

30. Ranitidine's origins trace to Allen & Hanbury's Ltd., who was awarded a patent that

covered the ranitidine molecule from the U.S. Patent and Trademark Office in December 1978. Allen & Hanbury, Ltd. was a subsidiary of Glaxo Labs, Ltd. during this period. The FDA granted approval to Glaxo Holdings, Ltd. in 1983 to sell Zantac to the United States.

4. Defendant Pfizer

31. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer is a citizen of Delaware and New York.

32. Boehringer Ingelheim, GSK, Pfizer, and Sanofi are referred to collectively as the "Brand-Name Manufacturer Defendants."

33. At all relevant times, the Brand-Name Manufacturer Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Zantac within each of the States and Territories of the United States, and the District of Columbia. Every Brand-Named Manufacturer Defendant has conducted business and derived revenue in the state of California.

34. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to Zantac manufactured by each of the Brand-Name Manufacturers in California.

C. Manufacturer Defendants (Generic)

1. Amerisource Bergen

35. Defendant Amerisource Health Services, LLC d/b/a American Health Packaging, is a Delaware limited liability company with its principal place of business located at 2550 John Glenn Avenue, Suite A, Columbus, Ohio 43217. Amerisource Health Services, LLC's sole member is AmerisourceBergen Corporation, a Delaware corporation with its principal place of business in Pennsylvania. Amerisource Health Services, LLC is a citizen of Delaware and Pennsylvania.

36. AmerisourceBergen Corporation is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. AmerisourceBergen Corp. is a citizen of Delaware and Pennsylvania.

37. AmerisourceBergen Corporation handles about 20% of all pharmaceuticals sold and distributed throughout the United States. The company has three distribution centers in California. These centers are located in Valencia, Corona, and Sacramento.

38. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs distributed from these distribution centers in California.

2. Mylan

39. Defendant Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan Pharmaceuticals, Inc. is a citizen of West Virginia.

40. Mylan Institutional LLC is a Delaware limited liability company with its principal place of business located at 1718 Northrock Court, Rockford, Illinois 61103. The sole member of Mylan Institutional LLC is Mylan, Inc., a Pennsylvania corporation with is principal place of business in that state. Mylan Institutional LLC is a citizen of Pennsylvania.

41. Mylan, Inc. is a Pennsylvania corporation with its principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan, Inc. is a citizen of Pennsylvania.

42. Mylan Laboratories Ltd., a non-party, is a corporation organized and existing under the laws of India with its principal place of business located at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500 034, Hyderabad, India. Mylan Laboratories Ltd. is a citizen of India.

43. Mylan Pharmaceuticals, Inc., Mylan Institutional LLC, Mylan Laboratories Ltd., and Mylan, Inc. are subsidiaries of non-party Mylan N.V.

44. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs from customer retail locations in California that sell products from Mylan Pharmaceuticals Inc. and other subsidiaries of Mylan N.V.

3. Par Pharmaceutical

45. Defendant Par Pharmaceutical Inc. is a New York corporation with its principal place of business located at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical Inc. is a citizen of New York.

46. Par Pharmaceutical Inc. is a subsidiary of Endo International PLC, a non-party.

47. Par Pharmaceutical Inc.'s products are distributed throughout the United States, including California. The company's distribution center locations include Irvine, California. The company has three distribution centers in California.

48. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs distributed and sold in California from Par Pharmaceutical Inc.'s distribution centers.

4. Perrigo

49. Defendant L. Perrigo Co. is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. L. Perrigo Co. is a citizen of Michigan.

50. Perrigo Research & Development Company is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Research & Development Company is a citizen of Michigan.

51. L. Perrigo Co. and Perrigo Research & Development Company are subsidiaries of Perrigo Company, PLC, a non-party.

52. Perrigo Co. is the largest manufacturer of OTC pharmaceuticals in the United States and is estimated to hold more than 50 percent of the store brand market.

53. Based on information and belief, Plaintiff has purchased, ingested and/or has been exposed to generic Ranitidine-Containing Drugs from customer retail locations in California that sell products manufactured by Perrigo Co., including CVS and Walgreens.

5. Taro Pharmaceutical

54. Defendant Taro Pharmaceuticals U.S.A., Inc. is a New York corporation with its principal place of business located at Three Skyline Drive, Hawthorne, New York 10532. Taro Pharmaceuticals U.S.A., Inc. is a citizen of New York.

55. Ranbaxy Inc. is a Texas corporation with its principal place of business located at 2 Independence Way, Princeton, New Jersey 08540. Ranbaxy Inc. is a citizen of Texas and New Jersey.

56. Sun Pharmaceutical Industries, Inc., f/k/a Ranbaxy Pharmaceuticals Inc., is a Delaware corporation with is principal place of business located at 2 Independence Way, Princeton, New Jersey 08540. Sun Pharmaceutical Industries, Inc. is a citizen of Delaware and New Jersey.

57. Sun Pharmaceutical Industries Ltd., a non-party, is corporation organized and existing under the laws of India with its principal place of business located at Western Express Highway Sun House, CTS No 201 B/1 Goregaon East, Mumbai, 400 063 India. Sun Pharmaceutical Industries Ltd. is a citizen of India.

58. Taro Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel with its principal place of business located at 14 Hakitor Street, Haifa Bay 2624761, Israel. Taro Pharmaceutical Industries Ltd. is a citizen of Israel.

59. Taro Pharmaceuticals U.S.A., Inc., Ranbaxy Inc., Sun Pharmaceutical Industries, Inc. (f/k/a Ranbaxy Pharmaceuticals Inc.), and Sun Pharmaceutical Industries Ltd. are subsidiaries of Taro Pharmaceutical Industries Ltd., a non-party.

60. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs from customer retail locations in California that sell products from Taro Pharmaceuticals U.S.A. and other subsidiaries of Taro Pharmaceutical Industries Ltd.

6. Teva

61. Defendant Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business in Pennsylvania. Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business located at 1877 Kawai Rd., Lincolnton, North Carolina

28092. The membership interest of Actavis Mid Atlantic LLC is owned by Teva Pharmaceuticals U.S.A., Inc., either directly or through an intervening limited liability company. Actavis Mid Atlantic LLC is a citizen of Delaware and Pennsylvania.

62. Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business located at 400 1090 Horsham Road, North Wales, Pennsylvania 19454.

63. Teva Pharmaceuticals U.S.A., Inc. is a citizen of Delaware and Pennsylvania.

64. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business located at 400 Interpace Parkway, Building A, Parsippany, New Jersey 07054. Watson Laboratories, Inc. is a citizen of Nevada and New Jersey.

65. Teva Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel with its principal place of business located at 5 Basel Street, Petach Tikva, Israel, 4951033. Teva Pharmaceutical Industries Ltd is a citizen of Israel.

66. Actavis Mid Atlantic LLC, Teva Pharmaceuticals U.S.A., Inc., and Watson Laboratories, Inc. are subsidiaries of Teva Pharmaceutical Industries Ltd., a non-party.

67. Teva Pharmaceutical U.S.A., Inc., is the largest manufacturer of generic drugs in the U.S. It has 130 offices located throughout the U.S., including one in Irvine, California.

68. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs from customer retail locations in California that sell products manufactured by Teva Pharmaceutical U.S.A., Inc., including CVS and Walgreens.

7. Wockhardt

69. Defendant Wockhardt USA LLC is a Delaware limited liability company with its principal place of business located at 20 Waterview Boulevard, Parsippany, New Jersey 07054. Upon information and belief, the sole member of Wokhardt USA LLC is Wockhardt USA, Inc., a Delaware corporation with its principal place of business in New Jersey. Wockhardt USA LLC is a citizen of Delaware and New Jersey.

70. Wockhardt USA, Inc. is a Delaware corporation with its principal place of business located at 135 Route 202/206, Bedminster, New Jersey 07921. Wockhardt USA, Inc. is a citizen of Delaware and New Jersey.

71. Wockhardt, Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India. Wockhardt, Ltd. is a citizen of India.

72. Wockhardt USA LLC and Wockhardt USA, Inc. are subsidiaries of Wockhardt, Ltd.

73. Wockhardt USA LLC distributes its products throughout the United States. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs distributed by Wockhardt USA LLC in California.

8. Zydus-Cadila

74. Defendant Zydus Pharmaceuticals (USA) Inc. is a New Jersey corporation with its principal place of business located at 73 Route 31 North, Pennington, New Jersey 08534. Zydus Pharmaceuticals (USA) Inc. is a citizen of New Jersey.

75. Cadila Healthcare Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Zydus Tower, Satellite Crossroads, Sarkhej-Gandhinagar Highway, Amedabad 380 015, India. Cadila Healthcare Ltd. is a citizen of India.

76. Zydus Pharmaceuticals (USA) Inc. is a subsidiary of Cadila Healthcare Ltd. These entities operate under the trade name of, and shall be referred to as, "Zydus-Cadilla."

77. Zydus Pharmaceuticals (USA) Inc distributes its products throughout the United States. Based on information and belief, Plaintiff has purchased, ingested, and/or has been exposed to generic Ranitidine-Containing Drugs manufactured and distributed by Zydus Pharmaceuticals in California.

D. Retailers Defendants

1. CVS

78. Defendant CVS Pharmacy, Inc. ("CVS") is a Delaware corporation with its principal places of business located at One CVS Drive, Woonsocket, Rhode Island 02895. Defendant CVS is

a citizen of Delaware and Rhode Island.

79. In 2015, CVS Health Corporation acquired Target Corporation's pharmacies and clinics. CVS defined herein includes any current or former Target Corporation pharmacy.

80. On November 28, 2018, CVS Health completed the acquisition of Aetna.

81. CVS/pharmacy acquired Longs Drugs Stores Corporation in 2008. Longs Drug Stores Corporation was incorporated in Maryland on May 24, 1985 as successor to Longs Stores. Longs Stores was incorporated in 1946 in California, and its principal place of business was 141 North Civic Drive, Walnut Creek, California 94596.

82. Longs Drugs Stores Corporation's principal subsidiaries were Longs Drugs Stores California, Inc. and RXAmerica, LLC.

83. RXAmerica, LLC provides pharmacy benefit management services. CVS acquired RxAmerica, LLC on October 20, 2008.

84. At all relevant times, Plaintiff regularly purchased and ingested Ranitidine-Containing Drugs from CVS and Longs Drugs Stores locations in California, including stores in Los Angeles.

2. Kroger

85. Defendant the Kroger Co. is an Ohio corporation with its principal place of business located at 1014 Vine Street, Cincinnati, Ohio 45202. The Kroger Co. is a citizen of Ohio.

86. Smith's Food and Drug Centers, Inc. is an Ohio corporation with its principal place of business located at 1014 Vine Street, Cincinnati, Ohio 45202. Smith's Food and Drug Centers, Inc. is a citizen of Ohio.

87. Fred Meyer Stores, Inc. is an Ohio corporation with its principal place of business located at 3800 SE 22nd Avenue, Portland, Oregon 97202. Fred Meyer Stores, Inc. is a citizen of Ohio and Oregon.

88. Smith's Food and Drug Centers, Inc. and Fred Meyer Stores, Inc. are subsidiaries of the Kroger Co.

89. At all relevant times, Plaintiff purchased and ingested, or was otherwise exposed, to Ranitidine-Containing Drugs from Kroger Co. and/or its subsidiaries' locations in California, including stores in Los Angeles.

3. Walgreens

90. Defendant Walgreen Co. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreen Co. is a citizen of Delaware and Illinois.

91. Defendant Duane Reade, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Duane Reade, Inc. is a citizen of Delaware and Illinois.

92. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreens Boots Alliance is a citizen of Delaware and Illinois.

93. Walgreen Co. and Duane Reade, Inc. are subsidiaries of Walgreens Boots Alliance.

94. Plaintiff purchased and ingested Ranitidine-Containing Drugs from Walgreen Co. and/or its subsidiaries in California, including stores in Los Angeles at all relevant times.

4. Walmart

95. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business located at 702 SW 8th Street, Bentonville, Arkansas 72716. Walmart Inc. is a citizen of Delaware and Arkansas.

96. At all relevant times, Plaintiff purchased and ingested Ranitidine-Containing Drugs from pharmacies at Walmart locations in California, including stores in Los Angeles.

5. Albertson's

97. Defendant Albertson's Companies, Inc. is a Delaware corporation with its principal place of business located at 132 E. Lake Street, McCall, Idaho 83638. Albertson's is a citizen of Delaware and Idaho.

98. Safeway, Inc. is a Delaware corporation with its principal place of business located at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway, Inc. is a citizen of Delaware and California.

99. Safeway, Inc. is a subsidiary of Albertson's.

100. At all relevant times, Plaintiff purchased, purchased, ingested, or was otherwise exposed to Ranitidine-Containing Drugs from Albertson's or Safeway locations in California, including stores in Los Angeles.

6. Rite Aid

101. Defendant Rite Aid Corporation ("Rite Aid") is a Delaware corporation with its principal place of business located at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid is a citizen of Delaware and Pennsylvania.

102. At all relevant times, Plaintiff purchased, ingested, or was otherwise exposed to Ranitidine-Containing Drugs from Rite Aid locations in California, including stores in Los Angeles.

103. The true names or capacities, whether individual, corporate, associate or otherwise of defendants, DOES 1 through 10, inclusive, are unknown to Plaintiff who therefore sues said DOE defendants by such fictitious names.

104. Plaintiff is informed and believes, and thereon alleges that each of the defendants designated herein as a DOE is responsible for the unlawful acts as herein alleged, and Plaintiff will request leave of the Court to amend this complaint to show its true names and capacities when the same have been ascertained.

105. Plaintiff is informed and believes, and thereon alleges that at all times herein

mentioned, Defendants, and each of them, were the agents, servants, and employees each of the other, acting within the course and scope of said agency and employment, with the full knowledge and consent of each of the Defendants. Each of the acts and/or omissions alleged herein were made known to and ratified by each of the Defendants (including any DOE defendant).

106. Defendant and each and every DOE Defendant shall be referred to collectively as "Defendants" hereafter.

III. JURISDICTION AND VENUE

107. This Court has jurisdiction over all causes of action asserted herein, and the amount in controversy exceeds the jurisdictional minimum of this Court.

108. Defendants caused tortious injury by acts and omissions in this judicial jurisdiction and caused tortious injury in this jurisdiction by acts and omissions outside this jurisdiction while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this jurisdiction.

109. Defendants, and each of them, are subject to the jurisdiction of this Court by virtue of their dealings and transactions in Los Angeles County and by having caused injuries through their acts and omissions within this County to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

110. Venue is proper in this Court because the injury and damage to Plaintiff occurred within Los Angeles County. California Code of Civ. Proc. § 395(a).

111. Plaintiff seeks relief that is in the jurisdictional limits of the Court.

IV. FACTUAL BACKGROUND

A. Brief History of Ranitidine and Zantac

112. Scientist John Bradshaw originally discovered and developed Zantac (ranitidine) on behalf of GSK in 1976.

113. Zantac has been sold to consumers since the early 1980's, first by prescription and later as an over-the-counter ("OTC") medication.

114. The drug is in a class of medications called histamine H2-receptor antagonists (or H2 blockers). H2 blockers decrease the amount of acid produced by cells in the lining of the stomach.

115. Cimetidine (Tagamet), discovered and developed by Smith, Kline and French2, was the first H2 blocker to be developed and is the prototypical histamine H2 receptor antagonist. The later members of the class were developed from Tagamet. Specifically, Zantac was developed by GSK in response to the success of cimetidine.

116. In 1983, the FDA approved the sale of prescription Zantac, (NDA 18-703), and Zantac quickly became one of GSK's most successful products. Zantac was the first prescription drug in history to reach $1 billion in sales.

117. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac.

118. GSK's patent on the original prescription Zantac product expired in 1997, allowing generic manufacturers to sell prescription ranitidine to consumers.

119. The FDA approved numerous generic manufacturers for the sale of prescription and OTC ranitidine.

120. Even after the entry of generic competition, brand name manufacturers continued to sell prescription and OTC Zantac.

121. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States.

122. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States.

123. The right to sell OTC Zantac in the United States later passed to Defendant Boehringer Ingelheim Pharmaceuticals and then to Sanofi.

124. In 2017, Boehringer Ingelheim sold the rights to OTC Zantac to Sanofi pursuant to a Sales Purchase Agreement. As part of this deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. However, Boehringer Ingelheim continued to manufacture all drugs subject to the SPA, including

Zantac.

125. When GSK's and Pfizer's patent on the original OTC Zantac product expired, generic manufacturers could sell OTC ranitidine to consumers.

126. Sanofi controlled the NDAs for OTC Zantac and marketed, distributed, and sold Zantac in the United States from January 2017, until the FDA issued a recall in 2019.

B. The FDA Recall

127. On April 1, 2020, the FDA requested the voluntary withdrawal of all Ranitidine-Containing Drugs from the market after it began reviewing the safety of ranitidine, with specific focus on the presence of NDMA.

C. The Dangers of NDMA

128. The U.S. Department of Health and Human Services ("DHHS") that NDMA is reasonably anticipated to be a human carcinogen.[1]

129. The high levels of NDMA produced by Zantac are inherent to the molecular structure of ranitidine, the active ingredient in Zantac. The ranitidine molecule contains both a nitrite and DMA group which are well known to combine to form NDMA. Ranitidine produces NDMA by "react[ing] with itself," such that every dosage of ranitidine exposes consumers to NDMA.

130. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes[.]"[2] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health.

131. Both the EPA and the IARC classify NDMA as a probable human carcinogen.[3] Further, in 1978, IARC stated that NDMA "should be regarded for practical purposes as if it were

[1] U.S. Envtl Prot. Agency, Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA) (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[2] *Id.*

[3] *Id.*; International Agency for Research on Cancer (IARC) - Summaries & Evaluations, N-NITROSODIMETHYLAMINE (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

carcinogenic to humans."[4]

132. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[5]

D. How Ranitidine Transforms into NDMA Within the Human Body

133. The ranitidine molecule itself contains the constituent molecules to form NDMA.

134. Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H3C-N-CH3 (DMA) on the other side to form NDMA.

135. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply. In 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.

136. Ranitidine leads to NDMA exposure in four ways: (a) formation of NDMA in the human digestive system; (b) formation of NDMA due to an enzymatic reaction throughout the human body; (c) formation of NDMA over time under normal storage conditions and that increases significantly when exposed to heat; and (d) formation of NDMA during manufacture.

1. NDMA Forms in The Human Stomach

137. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (O=N) and the DMA molecule (H3C-N-CH3) break off and reform as NDMA.

138. In 1981, two years before the FDA approved Zantac, Dr. Silvio de Flora published the results of experiments he conducted on ranitidine in the well-known journal, The Lancet. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed

[4] IARC, Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds, Vol. 17, 151-152 (May 1978) (Emphasis added.).

[5] WHO, Guidelines for Drinking-Water Quality, N-Nitrosodimethylamine (NDMA) (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf. (Emphasis added.).

"toxic and mutagenic effects[.]"[6] Dr. Flora formed the hypothesis that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id*. Dr. Flora cautioned that, concerning ranitidine ingestion, "it would seem prudent to ... suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals[.]" *Id.*

139. Notwithstanding Dr. Flora's findings in 1981, GSK told the FDA in the early 1980's that the nitrite would not likely be formed in the stomach because an unrealistically large amount of the nitrate needs to be present to form and maintain the nitrosamine. GSK even applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal."

140. Additionally, before Zantac was approved by the FDA, GSK admitted to the FDA that its own studies evidenced that ranitidine use caused the proliferation of bacteria in the human stomach known to convert nitrates to nitrites and elevated levels of nitrite in the stomach. While GSK did acknowledge that this could increase the risk of developing cancer, the risk was dismissed based on assumptions about human eating habits at that time.

141. Summarily, GSK knew—before Zantac hit the market —that ranitidine could react with nitrite in the human stomach to form NDMA, and that long-term use of ranitidine could result in elevated levels of nitrite in the human stomach.

142. In response to Dr. Flora's findings, GSK conducted a clinical study in 1982 (republished in 1987) that purportedly tested for NDMA. However, the gold-standard mass spectrometry to test for NDMA was not utilized to support GSK's findings. Instead, GSK used a process that inefficiently measured N-nitrosamines. Even more telling, GSK failed to test the gastric samples that included ranitidine in them.

143. In 1983, Dr. Flora, along with four other researchers, published their complete findings

[6] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, 318 THE LANCET 8253, 993¬94 (Oct. 31, 1981).

regarding the genotoxicity of ranitidine.[7] Dr. Flora's team "confirm[ed] our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine[,]" emphasizing "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." *Id*.

144. The high instability of the ranitidine molecule was elucidated in multiple scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[8] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water treatment plants which supply many American cities with water.

145. In 2016, researchers at Stanford University conducted an experiment by measuring the NDMA in urine of healthy individuals over the course of 24 hours and administering one dose of ranitidine, then measuring the NDMA in the urine of the same volunteers for another 24 hours.[9] The study found that the level of NDMA generally increased by a staggering 400 times.

146. The Stanford study clearly proved that unsafe levels of NDMA are formed in the human body as a result of ranitidine ingestion.

147. On September 9, 2019, Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition calling for the recall of all Ranitidine-Containing Drugs due to scientific studies demonstrating that ranitidine can transform into the cancer-causing NDMA.

148. The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, as shown below in Table 1.

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[7] Silvio de Flora, *et al., Genotoxicity of nitrosated ranitidine,* 4 CARCINOGENESIS 3, 255-60 (1983).

[8] Le Roux, et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 Environ. Sci. Technol 20, 11095-103 (2012).

[9] Zeng, et al., *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37 CARCINOGENESIS 625-34 (2016).

Table 1 — Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)
Reference Powder*	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L80081 9A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

149. Valisure's testing shows, on average, 2,692,291 ng of NDMA in one 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at 28,000 times the legal limit. Smoking at least 6,200 cigarettes achieves the same levels of NDMA found in one 150 mg dose of Zantac.

150. On September 26, 2019, Walgreens, Walmart, Rite-Aid, and Apotex Corp.—makers of generic OTC ranitidine—voluntarily recalled all Ranitidine-Containing Drugs and removed the drugs from the shelves.

151. On September 28, 2019, CVS Health Corp. announced that it would terminate the sale of Zantac and its own generic Ranitidine-Containing Drugs due to concerns that it might contain a carcinogen.

152. Sanofi voluntarily recalled all brand-name OTC Zantac on October 18, 2019.

153. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions illustrate significant NDMA formation under simulated gastric conditions with nitrite present.

154. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the

FDA's permissible limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 nanogram level (over 7,000 for the 50 nanogram level).

155. Assessed overall, the scientific data in literature demonstrates that the ingestion of ranitidine in the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine molecule breaks down into levels of NDMA that would dramatically increase a person's risk of developing cancer

2. Formation of NDMA in the Other Organs of Human Body

156. Valisure's findings also identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

157. Computational modelling demonstrates that ranitidine can readily bind to the DDAH-1enzyme in a manner comparable to the natural substrate of DDAH-1 known as asymmetric dimethylarginine.

158. This is an indicator that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

159. While DDAH-1 is most strongly expressed in the kidneys, it is broadly distributed throughout the body, including the liver, prostate, stomach, bladder, brain, colon, and prostate. This distribution offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically causes concern for NDMA's effects on numerous organs, such as the bladder.

160. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body - ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When the ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA, as validated by the Stanford Study.

3. Formation of NDMA by Exposure to Heat and/or Time

161. As indicated in Valisure's September 2019 Citizen Petition to the FDA, the risk of creating NDMA by exposing ranitidine to heat is generally known and documented in the scientific community from the early 1980's.

162. In response to Valisure's Petition, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the contemporaneous "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

163. In or about early 2020, Emery Pharma ran a series of tests on ranitidine using the FDA-recommended LC-HRMS protocol. During these tests, the researchers exposed ranitidine to 70 °C at different periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. The researchers cautioned (emphasis added):

> **NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures**, **which would be routinely reached during shipment and during storage**. More importantly, these conditions occur post-lot release by the manufacturer. Hence, **while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer**.

164. Given these facts, in conjunction with the historical data from the 1980s, it is evident that during normal transport and storage, and especially when exposed to heat, the ranitidine molecule systematically breaks down into cancer causing NDMA, accumulating over time in the finished product.

165. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility, and even likelihood, of the drug accumulating dangerously high levels of NDMA prior to consumption is unreasonably high.

4. Ranitidine Exposure Is Directly Linked to Cancer

166. In addition to studies examining how NDMA causes cancer in humans, researchers have also specifically linked ranitidine with cancer.

167. One epidemiology study, published in 2004, showed that men taking either ranitidine

or cimetidine (Tagamet) experienced increased risks of bladder cancer.[10]

168. In another comprehensive epidemiological study that examined various cancer risks and H2 blockers, including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer. Notably, the study also indicated that people under the age of 60 that took ranitidine were five times more likely to contract prostate cancer.

169. A study published in 2018 demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other histamine type 2 receptor antagonists (H2RAs) in the class.[11]

170. Another study in 2018 found an increased risk in hepatocellular carcinoma associated with use of H2RAs.[12] The authors evaluated the risk of cancer in association with proton pump inhibitors and looked at H2RAs as a confounder. Even narrowed to consideration of use of H2RAs within one year of cancer diagnosis, the study showed an increased odds ratio associated with use of H2RAs and hepatocellular carcinoma, a type of liver cancer.

E. Defendants Knew or Should Have Known of the NDMA Risk

171. Between 2014 and 2017, when Plaintiff purchased and ingested Ranitidine-Containing Drugs, Defendants knew or should have known that the weight of scientific evidence showed that Ranitidine-Containing Drugs exposed consumers to dangerous levels of NDMA.

172. Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and Defendants failed to report these risks to the FDA.

173. As early as 1981, scientific research was available that evidenced elevated rates of NDMA. This was known or should have been known by the Defendants when they began marketing, promoting, labelling, and selling Ranitidine-Containing Drugs.

174. Defendants concealed the dangerous hazards of ingesting Zantac and Ranitidine-

[10] D. Michaud, et al, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPI. BIOMARK. & PREV. 250-54, 252 (Feb. 2004).

[11] Kim Tu Tran,, et al., *Proton pump inhibitor and histamine-2 receptor antagonist use and risk of liver cancer in two population-based studies,* 48 ALIMENTARY PHARMA & THERAP 1, 55-64 (2018).

[12] Shao, Y-HJ, et al., *Association between proton pump inhibitors and the risk of hepatocellular carcinoma,* 48 ALIMENTARY PHARMA & THERAP 4, 460-68 (2018).

Containing Drugs from consumers by neglecting to report it to the FDA, which in turn relies on manufacturers (and testing laboratories) to bring new information about approved drugs.

175. Manufacturers of an approved drug are required by regulations to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

176. 21 C.F.R. § 314.81(b)(2)(v) provides:

> The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

177. Defendants ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine-Containing Drugs.

178. Knowledge regarding the risk of NDMA in ranitidine was sufficiently accessible in publicly available scientific literature that any maker or distributor, consistent with their heightened obligations to ensure the safety of their products, should have known about the potential NDMA risks associated with ranitidine consumption.

179. Defendants failed to warn the public and failed to conduct and/or publish and share relevant studies or testing with the FDA and scientific community concerning the link between NDMA and Ranitidine-Containing Drugs.

180. Defendants also knew that they are required by federal law to store, warehouse, and distribute pharmaceutical drugs in accordance with current "Good Manufacturing Practices" ("GMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

181. 21 C.F.R. § 211.142(b) states that the GMPs required that warehousing of drug

products shall be performed to ensure "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." Stated differently, Defendants had a duty and were obligated to safely store, handle, and warehouse Ranitidine-Containing Drugs.

182. The FDA's own testing demonstrated the following rudimentary facts that would have helped reduce the hazards of Ranitidine-Containing Drugs had Defendants invested their profits into testing and research: (a) improper storage of Ranitidine-Containing Drugs has resulted in extremely high levels of NDMA; (b) NDMA can increase in Ranitidine-Containing Drugs even under normal storage conditions; (c) NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers; and (d) Ranitidine-Containing Drugs age the level of NDMA in the product increases.

183. Based on these facts, other findings, and scientific research, the FDA concluded that these defects raised the level of NDMA in Ranitidine-Containing Drugs well above the safe daily intake limit to the point that Ranitidine-Containing Drugs had to be banned as of April 2020.

184. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

185. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[13]

186. In 1981, Dr. Silvio de Flora published the results of his experiments showing that ranitidine was converting into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly found in food and in the body, including foods that consumers were informed that they could consume shortly before or after

[13] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, GLOBE & MAIL (CANADA), Oct. 11, 1979 (emphasis added); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, GLOBE & MAIL (CANADA), Jan. 6, 1990 (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); S.A. Kyrtopoulos, *DNA Adducts in Humans after Exposure to Methylating Agents*, 405 MUTATION RES. 2, 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

ingesting ranitidine.[14]

187. In a 2011 epidemiological study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women."[15]

188. At all relevant times, Defendants failed to disclose to Plaintiff or her physicians the scientific link between ranitidine and NDMA. More generally, Defendants also failed to disclose the scientific link to prescribing physicians of Ranitidine-Containing Drugs or the FDA.

F. Equitable Tolling

189. The nature of Plaintiff's injuries in relation to Defendants' conduct was not discovered, and through reasonable care and due diligence, could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

190. Within the period of any applicable statutes of limitation, Plaintiff was unaware and could not have discovered through the exercise of reasonable diligence that Defendants were not disclosing the dangerous levels of the carcinogen NDMA produced by Ranitidine-Containing Drugs, including Zantac.

191. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rules, and/or fraudulent concealment.

192. At all relevant times, Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Ranitidine-Containing Drugs, including Zantac, and never disclosed this risk to the FDA or the consuming public.

193. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to Plaintiff's claims.

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[14] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, 318 LANCET 8253, 993-94 (Oct. 31, 1981).

[15] Yet Hua Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)-Norfolk Study*, 93 AM. J. CLINICAL NUTRITION 5, 1053-61 (May 2011).

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

STRICT LIABILITY – DESIGN DEFECT

(AGAINST ALL DEFENDANTS)

194. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated herein.

195. At all relevant times, Defendants have been in the business of designing, manufacturing, labeling, marketing and promoting, selling, inspecting, handling, storing and distributing defective Ranitidine-Containing Drugs to consumers.

196. At all relevant times, Defendants' Ranitidine-Containing Drugs have contained unreasonably dangerous design defects, including, but not limited to, grave risks that may follow the foreseeable use of Ranitidine-Containing Drugs.

197. At all relevant times, Defendants had a duty to ensure that Ranitidine-Containing Drugs did not pose unreasonable and dangerous risks to consumers.

198. Ranitidine-Containing Drugs did not perform as safely as an ordinary consumer would have expected when used in an intended and foreseeable manner.

199. Plaintiff was harmed by ingesting defective and unreasonably dangerous Ranitidine-Containing Drugs without knowledge of the grave risks of cancer and other serious illnesses.

200. The Ranitidine-Containing Drugs' failure to operate safely was a substantial factor in causing Plaintiff's harm. Plaintiff ingested these drugs, which caused Plaintiff's conscious pain, suffering, and bodily impairment, including breast cancer.

SECOND CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

(AGAINST MANUFACTURER-DEFENDANTS)

201. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated herein.

202. Defendants manufactured Ranitidine-Containing Drugs.

203. At all relevant times, Defendants' Zantac products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

204. The Ranitidine-Containing Drugs had potential risks that Defendants knew or were knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of manufacture.

205. The potential risk of cancer presented a substantial danger when Ranitidine-Containing Drugs are used in an intended and/or reasonably foreseeable way.

206. Ordinary consumers would not have been able to recognize the potential risks of cancer as a result of ingesting Ranitidine-Containing Drugs.

207. Defendants failed to adequately warn of potential risks from Ranitidine-Containing Drugs. During the time period Plaintiff ingested and/or was exposed to Ranitidine-Containing Drugs, the warnings associated with the product were incomplete, vague, or otherwise inadequate and failed to notify consumers to the health risks, including risks of cancer, stemming from the use of such Ranitidine-Containing Drugs.

208. Defendants failed to warn Plaintiff's prescribing physician and failed to provide Plaintiff's physicians with the potential risks that may follow the foreseeable use of Ranitidine-Containing Drugs.

209. The lack of sufficient warning was a substantial factor in causing Plaintiff's harm. As a result of the lack of sufficient warning, Plaintiff chose to ingest these drugs, which caused Plaintiff's conscious pain, suffering, and bodily impairment, including breast cancer.

THIRD CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(AGAINST MANUFACTURER-DEFENDANTS)

210. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated herein.

211. While representing carcinogenic Ranitidine-Containing Drugs as safe, Manufacturer-Defendants failed to employ manufacturing methods that ensured Ranitidine-Containing Drugs met the quality and purity characteristics they purported to possess.

212. As early as 1981, scientific research was available that evidenced elevated rates of NDMA. This was known or should have been known by the Defendants when they began marketing, promoting, labelling, and selling Ranitidine-Containing Drugs.

213. Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and Defendants failed to report these risks to the FDA.

214. The public, including Plaintiff, justifiably relies on information from the FDA and drug labels, as well as medical providers, to communicate potentially life-altering risks of exposure and/or ingestion of medications.

215. As a result of Defendants' representation of the safety of Ranitidine-Containing Drugs, Plaintiff chose to ingest these drugs, which caused Plaintiff's conscious pain, suffering, and bodily impairment, including breast cancer.

FOURTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(AGAINST MANUFACTURER-DEFENDANTS)

216. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated therein.

217. Despite the available scientific evidence of elevated rates of NDMA in Ranitidine-Containing Drugs, Defendants concealed the dangerous hazards of ingesting Zantac and Ranitidine-Containing Drugs from consumers by failing to report it to the FDA. The FDA relies on manufacturers to present new and updated information regarding approved drugs. The public, including Plaintiff, in turn depends on the FDA to make this information accessible to them.

218. Manufacturers of an approved drug are required by regulations to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to C.F.R. § 314.81(b)(2) and 21 C.F.R. § 314.81(b)(2)(v).

219. In addition to failing to report these significant risks to the FDA, the Manufacturer-Defendants deliberately concealed grave risks when marketing and promoting Ranitidine-Containing Drugs that were known to the Defendant-Manufacturers but unknown to Plaintiff. These concealments were motivated by Manufacturers' desire to profit from Ranitidine-Containing Drugs by representing to consumers that they were safe. Defendants were aware that full disclosure of the true life-threatening risks would likely cause the FDA recall long before April 1, 2020.

220. Plaintiff would not have ingested neither the prescription nor OTC form of Ranitidine-Containing Drugs had she been aware of the severity of these risks.

221. As a direct result of ingesting these drugs, Plaintiff experienced conscious pain and suffering and bodily impairment, including,

but not limited to breast cancer, because of the ingestion and/or exposure to Ranitidine-Containing Drugs.

FIFTH CAUSE OF ACTION

NEGLIGENCE – MANUFACTURE

(AGAINST MANUFACTURER-DEFENDANTS)

222. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated herein.

223. Defendants distributed, marketed and/or sold Ranitidine-Containing Drugs to consumers within Los Angeles County.

224. At all relevant times, Defendants knew or, in the exercise of reasonable care, should

have known, that Ranitidine-Containing Drugs were dangerous when used in a reasonably foreseeable manner.

225. At all relevant times, Defendants knew or should have known that Ranitidine Containing Drugs had been contaminated with an industrial chemical known to cause cancer.

226. At all relevant times, Defendants had a duty to exercise reasonable care in providing both OTC and prescription users' healthcare providers with: (a) specific directions for safe use of Ranitidine-Containing Drugs; (b) accurate, true, and correct information concerning the known or foreseeable risks of using Ranitidine-Containing Drugs as directed; and (c) appropriate, complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Drugs when used as intended, including the drugs' ability to transform into a carcinogenic compound, NDMA – through a means that could reasonably be expected to reach foreseeable users and consumers. Defendants had a duty to provide adequate warnings while Ranitidine-Containing Drugs remained on the market.

227. At all relevant times, Defendants had a further duty to avoid tendering into the marketplace a product which Defendants knew, or should have known, posed risks outweighing its benefits or which they knew, or should have known, was dangerous and unfit for ingestion by anyone.

228. Defendants' duty included exercising reasonable care to cease marketing and to discontinue Ranitidine-Containing Drugs when Defendants knew, or had reason to know, that the product should not be used for any purpose considering its relative risks.

229. Defendants knew or reasonably should have known that consumers would not be aware of the danger or the carcinogenic properties of Ranitidine-Containing Drugs when ingested.

230. Defendants failed to adequately warn of the danger of the consumption of Ranitidine Containing Drugs.

231. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would have warned of the danger of the consumption of Ranitidine-Containing Drugs.

232. Defendants failed to warn Plaintiff's prescribing physician and failed to provide

Plaintiff's physician with the potential risks that may follow the foreseeable use of Ranitidine-Containing Drugs.

233. Defendant also breached their duty of care by failing to undertake sufficient studies and conduct necessary tests to determine whether Ranitidine-Containing Drugs were safe for their intended and foreseeable consumer use.

234. Defendants further breached their duty of care and were negligent in that while representing carcinogenic Ranitidine-Containing Drugs as safe, Defendants failed to employ manufacturing methods that ensured Ranitidine-Containing Drugs met the quality and purity characteristics they purported to possess.

235. Defendants' breach of duty to Plaintiff was a substantial factor in causing Plaintiff's harm.

SIXTH CAUSE OF ACTION

NEGLIGENCE - RETAILER

(AGAINST RETAILER-DEFENDANTS)

210. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated herein.

211. Defendants sold, handled, and stored Ranitidine-Containing Drugs within Los Angeles County.

236. At all relevant times, Defendants knew – or in the exercise of ordinary and reasonable care, should have known – of the hazards and dangers associated with Ranitidine-Containing Drugs' intended or foreseeable use.

237. At all relevant times, Defendants knew, or reasonably should have known, that Ranitidine-Containing Drugs' carcinogenic properties caused them to be so dangerous that they should not have been purchased or consumed by anyone.

238. At all relevant times, Defendants knew or should have known of the carcinogenic properties of NDMA when Ranitidine-Containing Drugs are ingested and/or the elevated levels of NDMA that result from the transport, handling, and storage of Ranitidine-Containing Drugs.

239. Defendants were charged with a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as storage and handling of Ranitidine-Containing Drugs.

240. Defendants had a duty to exercise ordinary care in storing ranitidine according to the temperature requirements on the label or otherwise informed of. Defendants breached their duty by failing to adhere to the established practices and procedures in storing Ranitidine-Containing Drugs. Ranitidine leads to NDMA exposure through the formation of NDMA over time under normal storage conditions and that increases significantly when exposed to heat. Defendants had a duty to exercise ordinary care in storing ranitidine in a way so as to avoid the formation of NDMA.

241. Defendants' breach of duty was a substantial factor in causing Plaintiff's harm.

PUNITIVE DAMAGES

(AGAINST MANUFACTURER-DEFENDANTS)

242. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully stated herein.

243. The Defendant-Manufacturers' conduct, as described above, was wanton, willful, and malicious, and carried out with conscious, reckless, and flagrant disregard for the rights, health, welfare, and safety of the consuming public, including Plaintiff.

244. Since introducing Ranitidine-Containing Drugs to the market, the Defendant Manufacturers made conscious decisions to not properly manufacture, warn, test, or inform consumers, including Plaintiff, of Ranitidine-Containing Drugs' unreasonably dangerous condition.

245. The Defendant-Manufacturers' officers, directors, and/or managing agents authorized and participated in the Defendant-Manufacturers' practice of concealing the known risks and exposing unsuspecting purchasers and users of Ranitidine-Containing Drugs to excessive levels of NDMA, a known carcinogen.

246. The Defendant-Manufacturers deliberately marketed and promoted dangerous Ranitidine-Containing Drugs to mislead consumers, concealing grave risks known to the Defendant-Manufacturers but unknown to Plaintiff. These concealments were motivated by Defendant-

Manufacturers' desire to profit from Ranitidine-Containing Drugs by representing to consumers that they were safe. Defendants were aware that full disclosure of the true life-threatening risks would likely cause the FDA recall long before April 1, 2020.

247. Thus, the Defendant-Manufacturers' willful, outrageous and malicious conduct warrants an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, as follows:

A. For an award of actual and compensatory damages in such amount to be determined at trial and as provided by applicable law;

B. For exemplary and punitive damages sufficient to punish and deter Defendants and others from future wrongful practices;

C. For pre-judgment and post-judgment interest;

D. For reasonable attorneys' fees, court costs, and other litigation expenses; and

E. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby respectfully requests a trial by jury on all appropriate issues raised in this Complaint.

DATED: April 19, 2021

BEVERLY HILLS TRIAL ATTORNEYS, P.C.

By: _____

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Attorneys for Plaintiff
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