IN THE FIRST JUDICIAL DISTRICT COURT, COUNTY OF SANTA FE
STATE OF NEW MEXICO

STATE OF NEW MEXICO, *ex rel.* HECTOR H. BALDERAS, Attorney General,

Plaintiff,

v.

No. D-101-CV-2020-01289

Case assigned to Biedscheid, Bryan

GLAXOSMITHKLINE LLC; PFIZER INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; CHATTEM, INC.; SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; PERRIGO RESEARCH & DEVELOPMENT COMPANY; LANNETT COMPANY, INC.; NOVITIUM PHARMA LLC; AUROBINDO PHARMA USA, INC.; AMNEAL PHARMACEUTICALS, LLC; GLENMARK PHARMACEUTICALS INC., USA; APPCO PHARMA LLC; ANI PHARMACEUTICALS, INC.; SANDOZ INC.; APOTEX CORP.; DR. REDDY'S LABORATORIES, INC.; STRIDES PHARMA, INC.; TELIGENT, INC.; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; THE KROGER CO.; SMITH'S FOOD & DRUG CENTERS, INC.; FRED MEYER, INC.; TARGET CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WALGREENS CO.; WALMART INC., AND COSTCO WHOLESALE CORP.,

Defendants.

COMPLAINT WITH JURY DEMAND

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SUMMARY OF THE ACTION

1. The State of New Mexico, by and through its Attorney General Hector Balderas ("Plaintiff," "New Mexico," or the "State"), brings this civil action against Defendants GlaxoSmithKline, LLC ("GSK"), Pfizer Inc. ("Pfizer"), Boehringer Ingelheim Pharmaceuticals, Inc. ("BI"), Chattem, Inc. ("Chattem"), Sanofi-Aventis U.S. LLC ("Sanofi-Aventis"), Sanofi US Services Inc. ("Sanofi US," and collectively with Chattem and Sanofi-Aventis, the "Sanofi Defendants"), Perrigo Research & Development Company ("Perrigo Research"), Lannett Company, Inc. ("Lannett"), Novitium Pharma LLC ("Novitium"), Aurobindo Pharma USA, Inc. ("Aurobindo USA"), Amneal Pharmaceuticals, LLC ("Amneal"), Glenmark Pharmaceuticals Inc., USA ("Glenmark USA"), Appco Pharma LLC ("Appco"), ANI Pharmaceuticals, Inc. ("ANI"), Sandoz Inc. ("Sandoz"), Apotex Corp. ("Apotex"), Dr. Reddy's Laboratories, Inc., Strides Pharma, Inc. ("Strides Pharma"), Teligent, Inc. ("Teligent"), CVS Health Corporation ("CVS HC"), CVS Pharmacy, Inc. ("CVS Pharmacy"), The Kroger Co. ("Kroger"), Smith's Food & Drug Centers, Inc. ("Smith's"), Fred Meyer, Inc. ("Fred Meyer"), Target Corporation ("Target"), Walgreens Boots Alliance, Inc., Walgreens Co., Walmart Inc. ("Walmart"), and Costco Wholesale Corp. ("Costco") (collectively, the "Defendants") to obtain declaratory and equitable relief, damages, restitution, disgorgement, and civil penalties for violations of New Mexico law in connection with Defendants' practices in manufacturing, designing, distributing, supplying, marketing, promoting, advertising, and/or selling

ranitidine and/or Zantac—dangerous, but extremely common pharmaceutical products—for decades to New Mexico residents.[1]

2. Defendants' Zantac/ranitidine products contain extremely unsafe levels of a toxic, carcinogenic substance known as N-Nitrosodimethylamine ("NDMA"), such that those products should never have been marketed or sold to anyone in the State of New Mexico.

3. Defendants withheld from the U.S. Food and Drug Administration ("FDA"), the State, and the New Mexico public the known dangers associated with their Zantac/ranitidine products. After FDA obtained data confirming the high level of NDMA in these products, in late 2019, it instructed all manufacturers and distributors of such products to recall them.

4. Most fundamentally, to comply with New Mexico law, no Defendant should ever have sold Zantac/ranitidine products in New Mexico.

5. In addition, however, the Brand Manufacturer Defendants' (as defined below) unlawful practices include, *inter alia*:

a. knowingly concealing from New Mexico and the citizens of New Mexico the dangerous carcinogenic effects of NDMA contained in Zantac and/or ranitidine even though the Brand Manufacturer Defendants knew or should reasonably have known of the dangerous carcinogenic effects of NDMA in Zantac (ranitidine);

[1] Plaintiff attaches as Exhibit A hereto a Glossary defining certain technical terms.

b. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that the benefits of such products in treating gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease could outweigh the adverse health risks even though Brand Manufacturer Defendants knew or should reasonably have known of the dangerous carcinogenic effects of NDMA in Zantac (ranitidine);

c. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that such products did not contain NDMA at levels higher than the FDA's recommended daily allowance even though Brand Manufacturer Defendants knew or should reasonably have known that a single dose of ranitidine and/or Zantac exceeds the FDA's recommended daily allowance of NDMA;

d. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that persons who consumed Zantac (ranitidine) would not be exposed to dangerous levels of NDMA even though Brand Manufacturer Defendants knew or should reasonably have known that the consumption of ranitidine and/or Zantac caused users to be exposed to dangerous amounts of NDMA;

e. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that such products were not highly likely to form NDMA when digested by the human body even though Brand Manufacturer Defendants knew or should reasonably have known that they were;

f. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that the NDMA in such products would not increase over time resulting in the consumption of unacceptable levels of NDMA even though Brand Manufacturer Defendants knew or should reasonably have known that they would;

g. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of

ranitidine and/or Zantac that NDMA in such products would not increase when stored at higher than room temperatures resulting in the consumption of unacceptable levels of NDMA even though Brand Manufacturer Defendants knew or should reasonably have known that they would;

h. knowingly concealing from New Mexico and the citizens of New Mexico that when ingested, Zantac and/or ranitidine metabolizes and forms high levels of NDMA in the body even though Brand Manufacturer Defendants knew or should reasonably have known that they would;

i. knowingly concealing from New Mexico and the citizens of New Mexico the connection between ranitidine and/or Zantac and NDMA formation even though Brand Manufacturer Defendants knew or should reasonably have known that (i) NDMA was highly likely to form in Zantac (ranitidine) when digested by the human body; (ii) the levels of NDMA in Zantac (ranitidine) would increase over time resulting in the consumption of unacceptable levels of NDMA; (iii) NDMA in Zantac (ranitidine) was likely to increase when stored at higher than room temperatures resulting in the consumption of unacceptable levels of NDMA; and (iv) when ingested, Zantac (ranitidine) metabolizes and forms high levels of NDMA in the body;

j. knowingly concealing from New Mexico and the citizens of New Mexico that the levels of NDMA to which Zantac (ranitidine) users would be exposed exceeds levels of NDMA assumed to be non-toxic by regulatory agencies, including the FDA and the EPA, even though Brand Manufacturer Defendants knew or should reasonably have known that it did;

k. representing to New Mexico and the citizens of New Mexico through the product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that ranitidine and/or Zantac was safe for human consumption even though Brand Manufacturer Defendants knew or should reasonably have known that Zantac (ranitidine) was not safe for human consumption and breaks down into NDMA and other harmful metabolites in the body;

l. manufacturing, designing, marketing, promoting, distributing and/or selling ranitidine and/or Zantac to New Mexico and the citizens of New

Mexico even though Brand Manufacturer Defendants knew or should reasonably have known that the ranitidine molecule would break down into NDMA and other harmful metabolites in the body;

m. packaging, marketing and promoting Zantac and/or ranitidine without disclosing to New Mexico and the citizens of New Mexico the safety risks of Zantac and/or ranitidine, particularly the carcinogenic potential of Zantac and/or ranitidine as it transforms into NDMA within the chemical environment of the human body even though the Brand Manufacturer Defendants knew or should reasonably have known of the safety risks of Zantac and/or ranitidine, particularity the carcinogenic potential of Zantac and/or ranitidine as it transforms into NDMA within the chemical environment of the human body; and

n. packaging, marketing and promoting Zantac and/or ranitidine without disclosing to New Mexico and the citizens of New Mexico that consumption of Zantac and/or ranitidine poses a material risk of adverse health effects, including cancer due to the presence of NDMA, even though Brand Manufacturer Defendants knew or should have known that it did.

6. As a result of the conduct alleged herein, all Defendants have created, maintained, and/or contributed to a public nuisance in violation in statutory public nuisance law, NMSA 1978, Sections 30-8-1 to -14 (1963, as amended through 2018) ("Public Nuisance Statute"); created, maintained, and/or contributed to a common law public nuisance; and breached their duties of care under New Mexico law. In addition, the Brand Manufacturer Defendants have violated the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 to -26(1967, as amended through 2018) (the "Unfair Practices Act" or "UPA"), and the New Mexico False Advertising Act, NMSA 1978, Sections 57-17-1 to -10 (1965, as amended through 1967) (the "False Advertising Act" or "FAA").

7. Consequently, the State seeks all available damages, including compensatory, consequential, and punitive damages; restitution; disgorgement of revenues; civil penalties; and all other available relief, including but not limited to a statewide medical monitoring program designed to detect, assess, and treat medical disorders associated with use of Zantac/ranitidine, to remedy Defendants' violations of law.

8. The State brings this action exclusively under the laws of the State of New Mexico. No federal claims are being asserted. No issue of federal Constitutional, statutory, or regulatory law is raised herein—not directly, indirectly, or by implication. All issues raised herein relate to the State of New Mexico, its laws, and its programs; therefore, this case does not have national systemic importance or impact, and no issue raised in this case affects the federal system as a whole. To the extent that any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, such federal claim is expressly and undeniably disavowed and disclaimed by the State.

9. The State of New Mexico does not bring this action on behalf of a class or any group of person that can be construed as a class. The claims asserted herein are brought solely by the State, and are wholly independent of any claims that the individual users of Zantac and/or ranitidine may have against Defendants.

I. PARTIES

A. PLAINTIFF

10. The State of New Mexico is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state.

11. The State of New Mexico, by the Honorable Hector H. Balderas, the Attorney General of the State of New Mexico, brings this suit on its own behalf and pursuant to its inherent *parens patriae* authority to remedy an injury to its quasi-sovereign interest in the physical and economic health and well-being of a substantial segment of its population.

12. The Attorney General is authorized to act on behalf of the State in all actions when the interests of the State require action in his judgment, and is further empowered to prosecute all actions and proceedings brought by any State officer or head of a State department, board, or commission, or any employee of the State in his official capacity. NMSA 1978, Sections 8-5-2(B)-(C) (1933, as amended through 1975).

13. Further, the Attorney General has the authority to enforce the Unfair Practices Act, the False Advertising Act, and the Public Nuisance Statute to ensure the protection of New Mexico residents and consumers.

B. DEFENDANTS

1. Brand Manufacturer Defendants

(a) GlaxoSmithKline LLC

14. Defendant GSK, formerly known as SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, is a Delaware limited liability company with its principal place of business located in Pennsylvania. The sole member of GSK is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in Wilmington, Delaware.

15. GSK is a large pharmaceutical company that is responsible for operating the U.S. division of GlaxoSmithKline plc, the British entity that is the "global head" of the GlaxoSmithKline group of companies. As described in more detail below, GSK was formed on October 27, 2009, when its predecessor – SmithKlineBeecham Corporation – was converted from a Pennsylvania corporation into a Delaware limited liability company.

16. After the combination of Glaxo Wellcome plc and SmithKline Beecham p.l.c. (now known as SmithKline Beecham Limited), on December 27, 2000, SmithKline Beecham Corporation, a Pennsylvania corporation, made a fictitious name filing in Pennsylvania on January 16, 2001 to be known as GlaxoSmithKline. SmithKlineBeecham Corporation converted from a Pennsylvania corporation to a Delaware corporation, and then subsequently converted to a Delaware limited liability company and changed its name to GlaxoSmithKline LLC, effective as of October 27, 2009.

17. GlaxoSmithKline plc is the successor-in-interest to the companies that initially developed, patented, and commercialized ranitidine. Specifically, Allen & Hanburys Ltd., a subsidiary of Glaxo Labs Ltd., developed ranitidine. On December 5, 1978, Allen & Hanburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office, which covered the ranitidine molecule. In 1983, Glaxo Holdings, Ltd. ("Glaxo") was awarded its first U.S. FDA approval to sell Zantac in the United States. Later, Glaxo was absorbed into Glaxo Wellcome plc.

18. On October 3, 1994, Glaxo filed for an over-the-counter ("OTC") indication for Zantac with the FDA, and Zantac became available without a prescription in 1996. On December 31, 1998, Warner-Lambert Co. ("Warner-Lambert") and certain of its affiliates and Glaxo Wellcome plc and certain of its affiliates entered into transactions in various countries whereby Glaxo Wellcome transferred to Warner Lambert rights to OTC Zantac products in the U.S. and Canada, and Warner-Lambert principally transferred to Glaxo Wellcome its rights to OTC Zantac products in all other markets, among other things. These OTC products were previously marketed through joint ventures between Warner-Lambert and Glaxo Wellcome that were formed to develop, seek approval of and market OTC versions of Glaxo Wellcome prescription drugs. The December 31, 1998 transaction ended the joint venture relationship between Warner-Lambert and Glaxo Wellcome.

19. GSK is authorized to conduct business in New Mexico, has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New

Mexico since at least 2002, and its registered agent for service of process in New Mexico is CSC of Lea County, Inc., MC-CSC1, 726 E., Michigan Drive, Suite 101, Hobbs, New Mexico 88240-3464. Its mailing address is Philadelphia Navy Yard, 5 Crescent Drive, Philadelphia, Pennsylvania 19112.

20. GSK, and its predecessors, developed, designed, manufactured, and commercialized Zantac (ranitidine) and controlled the prescription NDA for Zantac between 1983 and at least 2009.

21. Glaxo Group Ltd. has held NDA #019675 for Zantac syrup since December 30, 1988; NDA #018703 for Zantac 150 and Zantac 300 tablets since June 9, 1983; NDA #020251 for Zantac 150 effervescent tablets, Zantac 150 effervescent granule and Zantac 25 effervescent tablets since March 31, 1994.

22. GSK has held NDA #020095 for Zantac 150 capsules and Zantac 300 capsules since March 8, 1994.

(b) Pfizer Inc.

23. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer is authorized to conduct business in New Mexico, has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 1993, and its registered agent for service of process in New Mexico is C T Corporation System, 206 South Coronado Avenue, Espanola, New Mexico 87532-2792.

24. From 2000, when Pfizer completed its merger with Warner-Lambert Company and acquired the marketing rights to Zantac 75, and from January 2005, when Pfizer launched Zantac 150 as an OTC medication, Pfizer manufactured, developed and commercialized at least Zantac 75 and Zantac 150, respectively until December 2006.

25. In December 2006, BI acquired the U.S. rights to OTC Zantac from Pfizer and Johnson & Johnson ("JNJ"). Specifically, in order to obtain regulatory approval of JNJ's acquisition of Pfizer's Consumer Healthcare business, JNJ agreed, among other things, to divest Pfizer's Zantac H-2 blocker business to BI.

(c) Boehringer Ingelheim Pharmaceuticals, Inc.

26. Defendant BI is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Its registered agent for service of process in Delaware is The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801. BI has held active pharmacy wholesaler licenses in the State of New Mexico since at least 2006.

27. BI is the largest U.S. subsidiary of Boehringer Ingelheim Corporation, and a member of the Boehringer Ingelheim International GmbH ("Boehringer Ingelheim") group of companies. Boehringer Ingelheim is headquartered in Ingelheim, Germany, and operates globally. Boehringer describes itself as "a research-driven pharmaceutical company."

28. On or around December 20, 2006, BI acquired all assets related to Pfizer's Zantac H-2 blockers business when JNJ acquired Pfizer's Consumer Healthcare business. BI developed, designed, manufactured, distributed and commercialized OTC Zantac in the United States from approximately December 2006 until approximately January 2017.

29. Boehringer has held ANDA #074662 for ranitidine 150 mg and 300 mg tablets since August 29, 1997.

(d) The Sanofi Defendants

30. Defendant Sanofi US Services Inc. ("Sanofi U.S.") is a Delaware corporation with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi U.S.'s registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Sanofi U.S. is a wholly-owned subsidiary of the France-based global drug-maker, Sanofi. Sanofi U.S. is a healthcare company engaged in the research, development, and marketing of prescription drugs in the United States.

31. Sanofi U.S. has held NDA #021698 for Zantac 150 OTC tablets since August 31, 2004.

32. Defendant Chattem, Inc. is a Tennessee corporation with its principal place of business located at 1715 West 38th Street, Chattanooga, Tennessee 37409. Its registered agent for service of process in Tennessee is Corporation Service Company, 2908 Poston Avenue, Nashville, Tennessee 37203-1312, and it has held active pharmacy wholesaler

and/or controlled substance facility licenses in the State of New Mexico since at least 2011. Chattem is a wholly-owned subsidiary of the France-based global drug-maker, Sanofi.

33. Defendant Sanofi-Aventis U.S. LLC ("Sanofi-Aventis") is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis' registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, and Sanofi-Aventis has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 1996. Sanofi-Aventis is a wholly-owned subsidiary of the France-based global drug-maker, Sanofi. Sanofi-Aventis is a healthcare company engaged in the research, development, and marketing of prescription drugs in the United States.

34. Sanofi U.S., Chattem and Sanofi-Aventis are referred to herein as the "Sanofi Defendants."

35. The Sanofi Defendants controlled the U.S. rights to OTC Zantac from approximately January 2017, when its French parent (Sanofi) acquired it in a product swap with Germany-based Boehringer Ingelheim, until the present, and the Sanofi Defendants manufactured and distributed OTC Zantac until the Sanofi Defendants recalled OTC brand-name Zantac 150, 150 Cool Mint and Zantac 75 in the U.S. and Canada on or about October 18, 2019.

36. GSK, Pfizer, BI and the Sanofi Defendants are referred to herein as the "Brand Manufacturer Defendants."

2. Generic Manufacturer Defendants

(a) Perrigo Research & Development Company

37. Defendant Perrigo Research & Development Company ("Perrigo Research") is a Michigan corporation, with its principal place of business at 601 Abbot Road, East Lansing, Michigan 48823. Perrigo Research's registered agent for service of process in Michigan is CSC-Lawyers Incorporating Service (Company), 601 Abbot Road, East Lansing, Michigan 48823-3366. Upon information and belief, Perrigo Research is a wholly-owned subsidiary of Perrigo Company plc ("Perrigo Company"), a company incorporated under the laws of Ireland on June 28, 2013 that became the successor registrant to Perrigo Company, a Michigan corporation, on December 18, 2013, in connection with the acquisition of Elan Corporation, plc. Perrigo Company's principal place of business is located at The Sharp Building, Hogan Place, Dublin 2, Ireland D02 TY74.

38. Perrigo Company describes itself as "a leading provider of over-the-counter health and wellness solutions that enhance individual well-being by empowering consumers to proactively prevent or treat conditions that can be self-managed." Perrigo Company "sells its products primarily in North America and Europe, as well as in other markets."

39. Perrigo Company's North American base of operations is located at 515 Eastern Avenue, Allegan, Michigan 49010.

40. As of 2019, Perrigo Company had at least forty-eight facilities in the United States, more than in any other country. Perrigo Company does substantial business in New Mexico. Perrigo Company has been engaged in the manufacturing, distribution, and sale of defective ranitidine throughout the United States, including in the State of New Mexico. Perrigo has held active pharmaceutical wholesaler and controlled substance facility licenses in the State of New Mexico since at least 2012.

41. Walmart is Perrigo Company's largest customer. As of January 22, 2020, Walmart had 53 retail centers, 35 supercenters, 2 discount stores, 9 neighborhood markets, 7 Sam's Clubs and 1 distribution center in New Mexico. Perrigo Company also manufacturers ranitidine for, *inter alia*, Costco, CVS, Target, and Walgreens (defined below). On information and belief, Perrigo Company's ranitidine products were distributed in New Mexico by these authorized distributors, among others.

42. Perrigo Research has held ANDA #076195 since August 30, 2002 and ANDA #091429 since May 11, 2011 for OTC ranitidine 75 mg tablets and 150 mg tablets, respectively.

43. Perrigo Research also distributed at least GoodSense Ranitidine 75 mg and 150 mg tablets during the relevant time period.

44. Perrigo Company PLC and Perrigo Research are referred to herein as "Perrigo."

45. Perrigo's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

46. On or about October 23, 2019, Perrigo recalled all pack sizes of ranitidine worldwide.

(b) Lannett Company, Inc.

47. Defendant Lannett Company, Inc. ("Lannett") is a Delaware corporation with its principal place of business at 9000 State Road, Philadelphia, Pennsylvania 19136. Lannett's registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Lannett "primarily develop[s], manufacture[s], market[s], and distribute[s] generic versions of brand pharmaceutical products," and has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 2010.

48. Lannett has held ANDA #078890 for 15 mg/mL prescription ranitidine syrup and ANDA #091288 for 15 mg/mL prescription ranitidine syrup since July 1, 2010 and December 9, 2010, respectively.

49. Lannett's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

50. Lannett's authorized distributors include several retailers with New Mexico locations, such as, *inter alia*, Walgreens and CVS. On information and belief, Lannett's ranitidine products were sold in New Mexico by such authorized distributors.

51. On or about October 25, 2019, Lannett recalled all lots within expiry of its Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/mL to the consumer level that it sold. The affected Ranitidine Syrup was distributed nationwide to wholesalers/distributors.

(c) Novitium Pharma LLC

52. Defendant Novitium Pharma LLC ("Novitium") is a Delaware limited liability company that was formed in 2016 with its principal place of business at 70 Lake Drive, East Windsor, New Jersey 08520. Novitium's registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, and Novitium has held an active pharmacy wholesaler license in the State of New Mexico since at least 2017. Novitium "specializes in development, manufacturing, and distribution of niche generic products."

53. On or about November 23, 2018, Novitium received FDA approval on its ANDA #210681 for prescription ranitidine capsules 150 mg and 300 mg, and thereafter began distributing these products to customers. As Novitium explained in its press release: "Ranitidine is a therapeutic equivalent to the reference listed drug Zantac® of GlaxoSmithKline PLC. For the 12 months ended October 2018, total U.S. sales of

Ranitidine Capsules 150 mg and 300 mg was approximately $48 million according to IQVIA."

54. Novitium's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

55. Cardinal Health Inc. ("Cardinal Health") supplied Novitium's ranitidine products to distributors with locations in New Mexico, including, *inter alia*, CVS and Walgreens. On information and belief, Novitium's ranitidine product were distributed in New Mexico by such authorized distributors.

56. On or about October 25, 2019, Novitium recalled all quantities and lots, within expiry, of Ranitidine Hydrochloride Capsules 150 mg and 300 mg in the United States to the consumer level.

(d) Aurobindo Pharma USA, Inc.

57. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a New Jersey corporation with its principal place of business located at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Its registered agent for service of process in New Jersey is Gangadhara Rao Gorla, 6 Wheeling Road, Dayton, New Jersey, 08810. Aurobindo USA distributes "a broad line of generic pharmaceuticals," and has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 2011.

58. On July 28, 2010, Aurobindo Pharma Limited ("Aurobina Pharma"), Aurobindo USA's parent, received approval from the FDA to sell prescription ranitidine syrup 15 mg/ml in the United States market (ANDA #090623). On November 13, 2017, Aurobindo Pharma received FDA approval to sell OTC ranitidine 75 mg tablets (ANDA #207579) and ranitidine 150 mg tablets (ANDA #207578) in the United States market. On November 16, 2018, Aurobindo Pharma received FDA approval to sell prescription ranitidine 150 mg capsules and 300 mg capsules (ANDA #211058) in the United States market.

59. Aurobindo Pharma's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

60. Aurobindo Pharma's authorized distributors include several retailers with New Mexico locations, such as, *inter alia*, Costco, CVS, Kroger, Walgreens and Walmart. On information and belief, Aurobindo Pharma's ranitidine products were distributed in New Mexico by such authorized distributors.

61. On or about November 6, 2019, Aurobindo USA recalled one lot of Ranitidine Tablets 150 mg to the retail level and 37 lots of Ranitidine Capsules 150 mg, Ranitidine Capsules 300 mg and Ranitidine Syrup 15mg/mL to the consumer level. These recalled products were distributed nationwide to Aurobindo USA and AuroHealth wholesale and distributor customers September 28, 2018 through September 19, 2019.

(e) Amneal Pharmaceuticals, LLC

62. Defendant Amneal Pharmaceuticals, LLC ("Amneal") was founded in 2002 and has been a Delaware limited liability company since 2004, with its principal place of business at 400 Crossing Blvd., 3rd Floor, Bridgewater, New Jersey 08807. Its registered agent for service of process in Delaware is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and Amneal has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 2008

63. Amneal received FDA approval on its ANDA #078312 for ranitidine 15 mg/mL syrup on September 2, 2008.

64. Amneal manufactured and distributed at least 10 mL cups of ranitidine oral solution 150 mg/10 mL that were distributed by Precision Dose, Inc., and ranitidine tablets 150 mg and 300 mg.

65. Amneal's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

66. Cardinal Health supplied Amneal's ranitidine products to distributors with locations in New Mexico, including, *inter alia*, CVS and Walgreens. Amneal's authorized distributors also include several retailers with New Mexico locations, such as, *inter alia*, Kroger. On information and belief, Amneal's ranitidine products were distributed in New Mexico by such authorized distributors.

67. On or about November 8, 2019, Amneal recalled Ranitidine Tablets, 150 mg and 300 mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL to the consumer level. Amneal's affected ranitidine products were distributed directly to wholesalers, distributers, retailers and repackagers.

(f) Glenmark Pharmaceuticals Inc. USA

68. Defendant Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") was incorporated in New Jersey in 2003. Its registered agent for service of process in New Jersey is National Registered Agents Inc. of NJ, Registered Agent, P.O. Box 927, Princeton Junction, New Jersey 08550-0927, and Glenmark has held active pharmacy wholesaler licenses in the State of New Mexico since at least 2006. Glenmark USA's principal place of business is located at 750 Corporate Drive, Mahway, New Jersey 07430. Glenmark USA is a subsidiary of Glenmark Pharmaceuticals Ltd. ("Glenmark Pharmaceuticals"), a pharmaceutical company headquartered in Mumbai, India with its registered office located at B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai – 400 026, with its corporate office located at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (E), Mumbai - 400 099.

69. Glenmark Pharmaceuticals has held an ANDA for prescription ranitidine 150 mg and 300 mg tablets in the United States market since November 18, 2008.

70. Glenmark Pharmaceuticals and Glenmark USA are collectively referred to herein as "Glenmark."

71. Glenmark's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

72. Glenmark's authorized distributors include several retailers with New Mexico locations, such as, *inter alia*, Walmart, CVS, and Kroger. Cardinal Health also supplied Glenmark's products to distributors with locations in New Mexico, including, *inter alia*, CVS and Walgreens. On information and belief, Glenmark's ranitidine products were distributed in New Mexico by such authorized distributors.

73. On or about December 17, 2019, Glenmark USA recalled 928 unexpired lots of Ranitidine Tablets, 150 mg and 300 mg, to the consumer level. The affected Ranitidine Tablets were distributed directly to wholesalers, distributors, retailers and repackagers nationwide.

(g) Defendants Appco and ANI

74. Defendant Appco Pharma LLC ("Appco") is a New Jersey limited liability company with its principal place of business at 262 Old Newbrunswick Road, Suite N, Piscataway, New Jersey 08854. Appco's registered agent for service of process in New Jersey is Appalaneni Rajendra, 120 Belmont Drive, Somerset, New Jersey 08873-4243.

75. Established in 2012, Appco is a generic drug development and manufacturing company that operates through two US FDA approved manufacturing sites in Somerset, New Jersey and Piscataway, New Jersey.

76. Defendant ANI Pharmaceuticals, Inc. ("ANI") is a Delaware corporation with its principal place of business located at 210 Main Street West, Baudette, Minnesota 56623. ANI's registered agent for service of process in Delaware is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

77. In March 2018, ANI entered into an agreement with Appco, in which a potential generic product, ranitidine, was to be developed and marketed. Per the agreement, ANI paid Appco a series of licensing fees in conjunction with certain development milestones. Appco launched generic prescription ranitidine hydrochloride 150 mg and 300 mg capsules on or about April 5, 2019 after receiving FDA approval of its ANDA #21183, in collaboration with ANI.

78. ANI has held ANDA #074488 for ranitidine 150 mg and 300 mg tablets since July 31, 1997; ANDA #075212 and ANDA #075296 for OTC ranitidine 75 mg tablets since January 14, 2000; and ANDA #077426 for ranitidine 150 mg and 300 mg tablets since December 19, 2005.

79. Appco and ANI's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

80. Appco and ANI's products are sold by retailers with New Mexico locations, such as, *inter alia*, CVS, Walgreens and Walmart. Cardinal Health, AmerisourceBergen Corporation ("AmerisourceBergen"), and McKesson Corporation ("McKesson") supplied Appco and ANI's ranitidine products to distributors with locations in New Mexico,

including, *inter alia*, CVS, Walgreens and Walmart. On information and belief, Appco and ANI's ranitidine products were distributed in New Mexico by such authorized distributors.

81. On or about January 7, 2020, Appco recalled all unexpired quantities and lots of Ranitidine Hydrochloride Capsules 150 mg and 300 mg to the consumer level. Appco's Ranitidine Capsules 150 mg and Ranitidine Capsules 300 mg were distributed nationwide.

(h) Sandoz Inc.

82. Defendant Sandoz Inc. ("Sandoz") is a Colorado company, with its principal place of business at 100 College Road West, Princeton, New Jersey 08540. Its registered agent for service of process in Colorado is Corporation Service Company, 1900 West Littleton Boulevard, Littleton, Colorado 80120-2023, and Sandoz has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 1991. Sandoz is a subsidiary of Novartis AG, a global pharmaceutical company based in Basel, Switzerland.

83. Sandoz has held ANDA #074467 since August 29, 1997 for prescription ranitidine 150 mg and 300 mg tablets; ANDA #074655 since October 22, 1997 for prescription ranitidine 150 mg and 300 mg capsules; and ANDA #075519 for ranitidine 75 mg tablets since September 26, 2002.

84. Sandoz's ranitidine products were distributed nationwide to wholesalers, and sold in CVS pharmacies throughout the United States. On information and belief,

Sandoz's ranitidine products were distributed in New Mexico by CVS and other authorized distributors with locations in New Mexico.

85. Sandoz's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

86. On or about September 23, 2019, Sandoz recalled all quantities and lots within expiry of its ranitidine 150 mg and 300 mg capsules in the United States.

(i) Apotex Corp.

87. Defendant Apotex Corp. ("Apotex") is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Its registered agent for service of process in Delaware is Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810, and Apotex has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 2001.

88. Apotex manufactures and distributes generic medications, including ranitidine.

89. Apotex received ANDA #074680 for prescription ranitidine 150 mg and 300 mg tablets on September 12, 1997; ANDA #075167 for OTC ranitidine 75 mg tablets on May 4, 2000; ANDA #077602 for ranitidine 15 mg/ML syrup on September 17, 2007; and ANDA #200172 for OTC ranitidine 150 mg tablets on May 31, 2012.

90. Apotex's products were labeled and distributed by several retailers with New Mexico locations, such as, *inter alia*, Walgreens and Walmart. On information and belief, Apotex's ranitidine products were labeled and distributed in New Mexico by such authorized distributors.

91. Apotex's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

92. On or about September 25, 2019, Apotex recalled all pack sizes and formats of ranitidine tablets 75 mg and 150 mg to the retail level. The affected ranitidine tablets were distributed nationwide to warehousing chains.

(j) Dr. Reddy's Laboratories, Inc.

93. Defendant Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business located in Princeton, New Jersey. Its registered agent for service of process in New Jersey is Marc Kikuchi, 107 College Road East, Princeton, New Jersey 08540, and it held a pharmacy wholesaler license in the State of New Mexico in or around 2011. On information and belief, Dr. Reddy's Laboratories, Inc.'s parent is Dr. Reddy's Laboratories Ltd., a holding company with its principal place of business located at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, India.

94. Dr. Reddy's Laboratories Ltd. has held ANDA #075294 since March 28, 2000 for OTC ranitidine 75 mg tablets; ANDA #075742 since November 29, 2000 for prescription ranitidine 150 mg and 300 mg capsules; ANDA #076705 since July 27, 2005

for prescription ranitidine 150 mg and 300 mg tablets; and ANDA #078192 since August 31, 2007 for OTC ranitidine 150 mg tablets.

95. Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. are collectively referred to herein as "Dr. Reddy's."

96. Dr. Reddy's Laboratories, Inc. manufactured and distributed ranitidine capsules and tablets for various retailers including its retail locations, Sam's Club, Walgreens, Kroger, Walmart, CVS, CDMA, HCA, Target and GeriCare. On information and belief, Dr. Reddy's Laboratories, Inc.'s products were distributed in New Mexico by such authorized distributors.

97. Dr. Reddy's generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

98. On or about October 1, 2019, Dr. Reddy's recalled all of its ranitidine medications sold in the United States at the retail level for OTC products, and at the consumer level for prescription products with expiration dated September 2019 to March 2022.

(k) Strides Pharma, Inc.

99. Defendant Strides Pharma, Inc. ("Strides Pharma") is a New Jersey corporation with its principal place of business located at 2 Tower Center Blvd., Suite 1102, East Brunswick, New Jersey 08816. Its registered agent for service of process in New Jersey is Adam Levitt, 201 South Main Street Suite 3, Lambertville, New Jersey

08530-1859, and Strides has held active pharmacy wholesaler and/or controlled substance facility licenses in the State of New Mexico since at least 2014. On information and belief, Strides Pharma is a subsidiary of Strides Pharma Science Limited (formerly known as Strides Shasun) ("Strides Pharma Science"), a pharmaceutical company headquartered in India with its principal place of business located at Strides House, Bilekahalli, Bannerghatta Road, Bangalore – 560076, India.

100. Strides Pharma "is the front-end company with a clear vision of providing quality healthcare products to the market both in Prescription, OTC, and consumer health markets."

101. Strides Pharma Science received FDA approval for OTC ranitidine 150 mg tablets on June 28, 2011 (ANDA #200536), OTC ranitidine 75 mg on February 29, 2012 (ANDA #201745), prescription ranitidine 150 mg and 300 mg tablets on August 22, 2016 (ANDA #205512), OTC ranitidine 75 mg tablets on March 5, 2018 (ANDA #209169), OTC ranitidine 150 tablets on February 22, 2018, and ranitidine 150 mg and 300 mg tablets on August 1, 2018 (ANDA #210010).

102. Strides Pharma marketed Strides Pharma Science's ranitidine 75 mg, 150 mg, and 300 mg tablets in the United States, including in New Mexico, at all relevant times herein.

103. Strides Pharma Science and Strides Pharma are collectively referred to herein as "Strides."

104. Strides' generic versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

105. Strides Pharma manufactured 912 lots of ranitidine 150 mg and 300 mg tablets that were recalled by Glenmark on or about December 17, 2019.

106. Glenmark's authorized distributors include several retailers with New Mexico locations, such as, *inter alia*, Walmart, CVS, and Kroger. On information and belief, ranitidine products manufactured by Strides Pharma, were distributed in New Mexico by such authorized distributors.

(l) Teligent, Inc.

107. Defendant Teligent, Inc. ("Teligent") is a New Jersey corporation with its principal place of business located at 105 Lincoln Avenue, Buena, New Jersey 08310. Teligent is authorized to conduct business in New Mexico, and its registered agent for service of process in New Mexico is CT Corporation System, 123 East Marcy, Santa Fe, New Mexico 87501. Teligent has held an active pharmacy wholesaler facility license in the State of New Mexico since at least 2013. Teligent is a specialty generic pharmaceutical company that manufactures injectable prescription Zantac under license with the registered trademark owner of Zantac®.

108. Teligent has held NDA #019090 for prescription Zantac 25 mg/mL injectable solution since October 19, 1984 and NDA #019593 for Zantac in plastic container 50

mg/mL injectable since December 17, 1986. On October 28, 2019, Teligent announced that it filed a prior approval supplement for ranitidine injection.

109. Teligent's products were sold by retailers with New Mexico locations, such as, *inter alia*, Walgreens. Cardinal Health, AmerisourceBergen, and McKesson supplied Teligent's ranitidine products to distributors with locations in New Mexico, including, *inter alia*, Walgreens and CVS. On information and belief, Teligent's ranitidine products were distributed in New Mexico by such authorized distributors.

110. Teligent's versions of Zantac/ranitidine, as relevant to this action, were sold in New Mexico during the relevant period.

111. Perrigo Research, Lannett, Novitium, Aurobindo USA, Amneal, Glenmark USA, Appco, ANI, Sandoz, Apotex, Dr. Reddy's Laboratories, Inc., Strides Pharma, and Teligent are referred to herein as "Generic Manufacturer Defendants."

3. Store Brand Defendants

(a) The CVS Defendants

112. Defendant CVS Health Corporation ("CVS HC") is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. Its registered agent for service of process in Delaware is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

113. CVS HC is a licensed wholesale distributor that distributes products through its subsidiaries, including Defendant CVS Pharmacy, Inc.

114. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy"), is a Rhode Island corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Pharmacy is authorized to conduct business in New Mexico, and its registered agent for service of process in New Mexico is C T Corporation System, 206 South Coronado Avenue, Espanola, New Mexico 87532-2792. CVS Pharmacy is a subsidiary of CVS HC, and operates numerous licensed pharmacies throughout New Mexico.

115. CVS HC and CVS Pharmacy are collectively referred to herein as "CVS."

116. As relevant to this action, CVS Pharmacy sold CVS Heath brand ranitidine 75 mg and 150 mg tablets in New Mexico during the relevant period.

117. Dr. Reddy's Laboratories, Inc. manufactured ranitidine capsules and tablets for various retailers including CVS. On or about October 1, 2019, Dr. Reddy's recalled all of its ranitidine medications sold in the United States at the retail level for OTC products, and at the consumer level for prescription products with expiration dated September 2019 to March 2022.

118. On or about October 1, 2019, CVS Pharmacy suspended the sale of all Zantac brand and CVS Health brand ranitidine products.

(b) The Kroger Defendants

119. Defendant The Kroger Co. ("Kroger") is an Ohio corporation with its principal place of business located at 1014 Vine Street, Cincinnati Ohio 45202. Its

registered agent for service of process in Ohio is Corporation Service Company, 50 West Broad Street Suite 1330, Columbus, Ohio 43215-3301.

120. As of February 1, 2020, Kroger operated 2,757 supermarkets under a variety of local banner names in thirty-five states, including in New Mexico, of which 2,270 had pharmacies.

121. Defendant Smith's Food & Drug Centers, Inc. ("Smith's") is a Delaware corporation with its principal place of business located at 1550 S. Redwood Road, Salt Lake City, Utah 84104. Smith's registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Smith's is a subsidiary of Defendant Fred Meyer, Inc. ("Fred Meyer"), a Delaware corporation, with its principal place of business located at 3800 S.E. 22nd Avenue, Portland, Oregon 97202. Fred Meyer's registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. In New Mexico, Kroger operates under the name Smith's Food and Drug.

122. Dr. Reddy's manufactured ranitidine labeled by Kroger, including ranitidine tablets 150 mg 50-count bottle, 150 mg 24-count bottle, and 75 mg 30-count bottle.

123. As relevant to this action, Kroger sold its store brand ranitidine 75 mg and 150 mg products in New Mexico during the relevant period.

124. On or about October 1, 2019, Dr. Reddy's recalled all of its ranitidine medications sold in the United States at the retail level for OTC products, and at the

consumer level for prescription products with expiration dated September 2019 to March 2022.

(c) Target Corporation

125. Defendant Target Corporation ("Target") is a Minnesota corporation with its principal place of business located at 1000 Nicollet Mall, Minneapolis, Minnesota 55403. Target is authorized to conduct business in New Mexico, and its registered agent for service of process in New Mexico is C T Corporation System, 206 South Coronado Avenue, Espanola, New Mexico 87532-2792. In 2019, Target had at least 1,868 stores in the United States, including stores in New Mexico.

126. Dr. Reddy's Laboratories, Inc. manufactured ranitidine capsules and tablets for various retailers including Target.

127. As relevant to this action, Target sold its store brand ranitidine 75 mg and 150 mg products in New Mexico during the relevant period.

128. On or about October 1, 2019, Dr. Reddy's recalled all of its ranitidine medications sold in the United States at the retail level for OTC products, and at the consumer level for prescription products with expiration dated September 2019 to March 2022.

(d) The Walgreens Defendants

129. Defendant Walgreens Boots Alliance, Inc. ("Walgreens Boots") is a Delaware corporation with its principal place of business at 108 Wilmot Road, Deerfield,

Illinois 60015. Its registered agent for service of process in Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

130. Defendant Walgreen Co. (d/b/a Walgreens) is an Illinois company with its principal place of business at 108 Wilmot Road, Deerfield, Illinois 60015. Its registered agent for service of process in Illinois is Illinois Corporation Service C, 801 Adlai Stevenson Drive, Springfield, Illinois 62703-4261. Walgreens Co. is a subsidiary of Walgreens Boots.

131. Walgreens Co. operates a national pharmacy chain store in the United States.

132. As of May 16, 2020, Walgreens Co. had at least twenty-three pharmacies in New Mexico.

133. Walgreens Boots and Walgreens Co. are collectively referred to herein as "Walgreens."

134. As relevant to this action, Walgreens sold its store brand ranitidine products in New Mexico during the relevant period.

135. Dr. Reddy's Laboratories, Inc. manufactured ranitidine capsules and tablets for various retailers, including Walgreens. On or about October 1, 2019, Dr. Reddy's recalled all of its ranitidine medications sold in the United States at the retail level for OTC products, and at the consumer level for prescription products with expiration dated September 2019 to March 2022.

136. On or about October 1, 2019, Walgreens recalled Zantac brand products and OTC ranitidine 75 mg and 150 mg tablets manufactured by Apotex that Walgreens relabeled.

(e) Walmart Inc.

137. Defendant Walmart Inc. ("Walmart") is a Delaware corporation with its principal place of business located at 702 S.W. 8th Street, Bentonville, Arkansas 72716. Walmart is authorized to conduct business in New Mexico, and its registered agent for service of process in New Mexico is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

138. Walmart conducts business as a licensed wholesale distributor under named business entities, including at least the following in the State: Walmart Supercenter #831 in Albuquerque, New Mexico; Walmart Supercenter #4201 in Edgewood, New Mexico; Walmart Supercenter #821 in Clovis, New Mexico; Walmart Supercenter #2653 in Portales, New Mexico; Walmart Supercenter #5491 in Albuquerque, New Mexico; Walmart Supercenter #3731 in Bernalillo, New Mexico; Walmart Supercenter #1306 in Alamogordo, New Mexico; Walmart Supercenter #868 in Carlsbad, New Mexico; Walmart Store #873 in Taos, New Mexico; Walmart Supercenter #2652 in Grants, New Mexico; Walmart Supercenter #611 in Roswell, New Mexico; Walmart Supercenter #4201 in Edgewood, New Mexico; Walmart Supercenter #1380 in Las Vegas, New Mexico; Walmart Supercenter #835 in Albuquerque, New Mexico; Walmart Supercenter

#850 in Albuquerque, New Mexico; Walmart Supercenter #5492 in Socorro, New Mexico; Walmart Supercenter #2653 in Portales, New Mexico; Walmart Supercenter #3423 in Santa Fe, New Mexico; and Walmart Supercenter #5155 in Las Cruces, New Mexico.

139. As of January 22, 2020, Walmart had 53 retail centers, 34 supercenters, 2 discount stores, 9 neighborhood markets, 7 Sam's Clubs and 1 distribution center in New Mexico.

140. At all times relevant hereto, Walmart distributed Zantac and ranitidine products throughout the United States, including in the State of New Mexico.

141. Walmart has three reportable segments: Walmart U.S., Walmart International and Sam's Club.

142. Dr. Reddy's Laboratories, Inc. manufactured ranitidine capsules and tablets for various retailers including Sam's Club and Walmart.

143. As relevant to this action, Walmart sold its store brand ranitidine products in New Mexico during the relevant period.

144. On or about October 1, 2019, Dr. Reddy's recalled all of its ranitidine medications sold in the United States at the retail level for OTC products, and at the consumer level for prescription products with expiration dated September 2019 to March 2022.

145. On or about October 1, 2019, Walmart recalled Zantac and all OTC ranitidine products that it sold, including 75 mg and 150 mg tablets manufactured by Apotex that Walmart relabeled.

146. In addition, Walmart is Perrigo Company plc's largest customer. On or about October 23, 2019, Perrigo recalled all pack sizes of ranitidine worldwide.

(f) Costco Wholesale Corp.

147. Defendant Costco Wholesale Corp. ("Costco") is a Washington corporation with its principal place of business located at 999 Lake Drive, Issaquah, Washington 98027. Costco is authorized to conduct business in New Mexico, and its registered agent for service of process in New Mexico is C T Corporation System, 206 South Coronado Avenue, Espanola, New Mexico 87532-2792.

148. As of September 1, 2019 Costco operated 782 membership locations, including 543 in the United States. As of May 16, 2020, Costco operated at least three membership locations in New Mexico.

149. Perrigo manufactured Costco's ranitidine in its Allegan, Michigan facility.

150. Costco sold ranitidine in the United States under its Kirkland brand.

151. As relevant to this action, Costco sold Kirkland brand ranitidine products in New Mexico during the relevant period.

152. CVS, Kroger, Smith's, Fred Meyer, Target, Walgreens, WalMart and Costco are referred to herein as "Store Brand Defendants."

II. JURISDICTION AND VENUE

153. This Court has subject matter jurisdiction over this case pursuant to N.M. Const. Art. VI, Sec. 13.

154. This Court has personal jurisdiction over Defendants pursuant to both NMSA 1978, Section 38-1-16(A) (1978) and New Mexico's "sufficient minimum contacts" test. *Sproul v. Rob & Charlies, Inc.*, 2013-NMCA-072, 304 P.3d 18.

155. Defendants supplied, marketed, sold, promoted, advertised, failed to warn and/or distributed Zantac (ranitidine) in New Mexico between 1983 and April 1, 2020 when the FDA instructed manufacturers to withdraw all prescription and OTC ranitidine drugs, including Zantac, from the market immediately due to the presence of NDMA, and committed the wrongful acts and omissions described herein in New Mexico, including specifically in Santa Fe County.

156. This Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. The State of New Mexico brings this action as the sole plaintiff, and no class or mass action is raised herein. Any alleged class or mass action is expressly disavowed, and to the extent that anything in this Complaint is alleged to be to the contrary, this paragraph is controlling.

157. Similarly, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by this Complaint, as it sets forth exclusively state law claims against Defendants. The State of New Mexico does not plead, expressly or implicitly, any

cause of action or request any remedy, which is based on federal law. The issues presented in this Complaint do not implicate significant federal issues, turn on the substantial federal interpretation of federal law, or raise a substantial federal question. Moreover, no federal question is possibly or necessarily raised in this Complaint that is potentially significant to the federal system as a whole, as required for substantial federal question jurisdiction. *See Gunn v. Minton*, 568 U.S. 251, 258, 133 S. Ct. 1059, 185 L. Ed. 2d 72 (2013). The only causes of action claimed, and the only remedies sought by the State of New Mexico herein, are for those based upon the statutory, common, and decisional laws of the State of New Mexico. Any alleged federal claim or federal question is expressly disavowed, and to the extent that anything in this Complaint is alleged to be to the contrary, this paragraph is controlling.

158. Venue is proper in this Court pursuant to NMSA 1978, Section 38-3-1 (1875), because the Office of the Attorney General for the State of New Mexico and the seat of the State Government are located in Santa Fe County, New Mexico, and Defendants are foreign corporations.

III. FACTUAL ALLEGATIONS

A. BRAND MANUFACTURER DEFENDANTS' MARKETING OF ZANTAC AND RANITIDINE

159. The drug ranitidine, commonly sold under the brand name Zantac, is a histamine H2-receptor blocker ("H2 blocker"), which decreases the amount of acid

produced by the stomach, and is used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

160. On June 9, 1983, Glaxo Group, Ltd. launched Zantac 150, an oral tablet form of ranitidine hydrochloride (application number N018703 01). Two years later, on December 9, 1985, Glaxo Group, Inc. launched Zantac 300, an oral tablet form of ranitidine hydrochloride (application number N018703 02).

161. One month after its June 1983 launch, Zantac's sales attained 9% of the histamine-2 receptor market as a result of Glaxo's marketing strategy, and one year after launch, Zantac had obtained 24% of the U.S. market share of H2 blockers.

162. In 1986, the United States became the largest single market for Zantac, and in June of 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease (GERD).

163. By December 1986, Zantac became the first-ever drug to reach $1 billion in annual sales.

164. In March 1987, Zantac overcame competitor Tagamet in sales, and in 1988, Zantac occupied more than 50% of the H2 market in the United States and its sales grew by more than 20%.

165. When Zantac was launched, Glaxo was much smaller than the then-dominant U.S. pharmaceutical companies, so it decided to "co-promote" with Hoffman-La Roche & Co., now known as Roche ("Roche"). At the time, Roche had an established sales force

and a strong presence in the United States. By co-promoting, Roche's experienced sales force was able to disseminate information about Zantac rapidly, which boosted the efforts of Glaxo's newly formed sales team.

166. Initially, Glaxo marketed Zantac primarily to gastroenterologists.

167. After introducing Zantac in 1983, the then-Chief Executive of Glaxo Pharmaceuticals, Paul Girolami, began one of the most expensive advertising campaigns in history. To convince people that heartburn was a terribly serious condition warranting medical intervention, Glaxo began referring to heartburn as "gastroesophageal reflux" rather than simply that "reflux" was largely caused by excessive consumption of foods such as pizza, tacos and other refined carbohydrates.

168. In 1987, Glaxo revised its marketing strategy for Zantac to emphasize the particular features of Zantac, such as dosing, convenience, potency, and safety that were most appealing to each target market. For example, in markets consisting of geriatric patients and patients on multiple medications, Glaxo highlighted that Zantac was not associated with significant drug interactions, mental confusion, or troublesome sexual side effects, such as impotence, gynecomastia, or a loss of libido.

169. In 1988, Glaxo commissioned a Gallup poll to investigate "reflux," *e.g.* heartburn, which showed that 44% of the population suffered from "gastroesophageal reflux disease," *i.e.* GERD, "at least once a month."

170. Armed with the results of its commissioned survey, Glaxo launched a "massive educational" campaign called "Gastroesophageal Reflux across America" to "educate the public on this terrible disease." Glaxo also created the Glaxo Institute for Digestive Health, whose mission was to fund the research of hundreds of doctors and raise "public awareness" of this heartburn problem. These marketing efforts further boosted Zantac's market share.

171. Glaxo's first public "educational" marketing campaign generated more than 500,000 patient visits to doctors. Physicians supported this campaign because it promoted the role of the physician in the process. Glaxo provided literature for physicians of patients with GERD. At the same time, Glaxo's marketing department worked closely with its medical department to improve the credibility of its marketing representations.

172. By focusing its promotion on both GERD and peptic ulcer disease, Glaxo was able to capture both markets and increase its market share.

173. Then, a 1989 study showed the cost-effectiveness of long-term maintenance therapy in preventing recurrence of duodenal ulcers, which again substantially enlarged Zantac's market.

174. In 1991, Zantac was the top mail-order prescription in the United States.

175. By 1993, Glaxo had become the second-largest pharmaceutical firm in the world, with Zantac making up 45% of its pharmaceutical sales, although it only had a 38%

market share. Zantac sales were responsible for up to $1.5 billion of Glaxo's annual revenues.

176. Glaxo began selling OTC versions of Zantac products in 1996, expanding its market still further. It continued selling prescription-only versions.

177. Glaxo teamed with Warner Lambert to market and promote OTC Zantac products in the United States, including New Mexico, from 1996 to 1998.

178. After OTC Zantac was launched in April 1996, Warner Lambert Co.'s Zantac 75 became the No. 2 acid blocker in under a year despite being third to enter this market. The company started with a $125 million "'Z-Day' marketing extravaganza," including lighting major city office building windows in the shape of a Z, engaging actor Brian Dennehy to endorse the brand, and advertising from J. Walter Thompson USA, New York.

179. Glaxo's patent protection for Zantac expired in July 1997. Generic versions of both OTC and prescription ranitidine products immediately entered the market. Glaxo continued to promote and sell its own brand name Zantac products.

180. With competing versions of ranitidine saturating the market beginning in 1997, Glaxo's nationwide advertising efforts ramped up. For instance, in or around 1999, Glaxo aired a national television commercial with an actor portraying a cab driver describing the heartburn he suffered after eating a pastrami on rye sandwich, and touting the benefits of Zantac.

181. At the end of 1998, Warner-Lambert and Glaxo ended their five-year joint venture to sell the OTC versions of Zantac. In return for an undisclosed amount of money, Warner-Lambert gained the sole right to market and sell Zantac 75 in the United States and Canada, and Glaxo acquired, *inter alia*, the rights to sell non-prescription Zantac in all other markets. Warner-Lambert was subsequently acquired by Pfizer in 2000, which began to promote Zantac products at that time, including in New Mexico.

182. In or around 2003, Pfizer ran an advertisement for Zantac 75 touting the benefits of this product, including that "Zantac 75 works fast right when you need it even at night when heartburn can be at its worst" and "Zantac: fast heartburn relief for people who hate to wait."

183. BI obtained the Zantac OTC product line in 2006, and continued the marketing barrage initiated by Glaxo and continued by Pfizer.

184. In or around 2008, Tyler Murree starred in a national Zantac 150 mg television commercial designed and paid for by BI.

185. In or around 2012, BI aired multiple national broadcast commercials with Simon Morgan touting the benefits of Zantac over Prilosec OTC, "Medifacts: Zantac vs. Prilosec OTC," claiming, "Zantac works differently."

186. On or about September 9, 2013, BI launched what it described as an "innovative integrated marketing campaign to educate consumers on heartburn relief," and introduced Captain Zantac, the new face of its Zantac brand.

187. Captain Zantac was part of BI's "powerful new 360-degree brand equity campaign that include[d] national television advertising and other high-profile promotional materials in print, online and at retail."

188. BI's Executive Director of Marketing, BI Consumer Health Care, Ross Ullman, explained Captain Zantac:

> serve[d] as a persuasive and memorable platform to cut through the heartburn advertising clutter and educate consumers on which heartburn solutions are right for them. [BI's] objective with this campaign [was] to help heartburn sufferers understand that not all heartburn medicines are the same – ZANTAC rushes relief in as little as 30 minutes.

189. Although generic versions of Zantac became available in 1997, which led to a decline in sales of name brand Zantac, in 2013 Zantac was the top OTC H2 receptor brand in the United States.

190. Sanofi acquired the right to market and sell OTC Zantac from BI in a product swap in 2017.

191. In or around 2017, Sanofi aired a national broadcast commercial advertising its Zantac 150 with the tag line "Feel the love. Not the heartburn."

192. In 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million, or 3.1% more than in 2017.

193. In or around 2018 through at least 2019, Sanofi ran a national Zantac television commercial featuring Caleb Clark and an appearance by Captain Zantac called "Family Taco Night" with the tagline "Eat Your Way. Treat Your Way," in which Zantac

150 Maximum Strength Cool Mint Tablets, Zantac 150 Maximum Strength and Zantac 75 were advertised as treating heartburn resulting from a family taco night and a spontaneous pizza party.

194. Not once in any of these advertisements nor in any of the other print, television, radio, digital, or any other form of advertisements that each Brand Manufacturer Defendant created, developed, funded and ran in New Mexico did any Brand Manufacturer Defendant disclose that use of its Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

B. THE DANGERS OF NDMA TO HUMAN HEALTH HAVE LONG BEEN RECOGNIZED

195. NDMA is a carcinogen. In the early 1900s, NDMA was a chemical byproduct of making rocket fuel. Currently, NDMA is not produced in pure form or commercially used in the United States, except for research purposes.

196. According to the EPA, "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes. It is [a] member of N-nitrosamines, a family of potent carcinogens. ... Exposure to high levels of NDMA may cause liver damage in humans."

197. The World Health Organization ("WHO") and the International Agency for Research on Cancer ("IARC") have classified N-nitrosamines (NDMA) as "probably

carcinogenic to humans." According to the WHO, scientific testing indicates, "NDMA consumption is positively associated with either gastric or colorectal cancer" and "suggests that humans may be especially sensitive to the carcinogenicity of NDMA."

198. Although the FDA recognizes the danger of NDMA, and has set a daily acceptable limit on NDMA in pharmaceuticals of 96 nanograms ("ng"), in a single dose of Zantac, researchers are discovering over 3,000,000 ng.

199. An article published in 1979 noted, "NDMA has caused cancer in nearly every laboratory animal tested so far."

200. In 1980, most brewers in the United States changed the way they were making beer to significantly reduce the level of nitrosamines in beer after the nitrosamine, NDMA, caused cancer in laboratory animals.

201. In 1990, on the Six Nations Indian Reserve near Brantford, Ontario, Canada, twenty percent of the reserve's residents were "advised not to drink, cook or wash in the water because testing [] found high levels of N-nitroso dimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer."

202. Beginning in Summer 2018, the FDA recalled several generic drugs used to treat high blood pressure and heart failure, including valsartan, losartan, and irbesartan, because the "medicines contain[ed] nitrosamine impurities that don't meet [FDA's] safety standards," *i.e.* because these drugs exceeded the acceptable daily intake limit for NDMA set by the FDA of 96 ng.

203. The highest level of NDMA detected by the FDA in valsartan tablets was 20.19 micrograms ("ug")/tablet or 20,190 ng/tablet. In the case of valsartan, the NDMA was an impurity caused by a manufacturing defect, and thus, NDMA was found in only *some* products containing valsartan.

204. Here, however, ranitidine poses a greater safety risk than any of the recently recalled valsartan tablets because not only is NDMA a byproduct of the ranitidine molecule, but the levels observed in recent testing show NDMA levels in excess of 3,000,000 ng.

205. There is conclusive evidence that NDMA is a potent carcinogen in experimental animals by several routes of exposure. In animal studies, tumors have been seen in the gastrointestinal tract, lungs, kidneys and liver.

206. A Danish study reported: "NDMA is one of the most well characterized and most potent animal carcinogens known and has been shown to be a potent carcinogen across all species that have been investigated, both as single doses and with long term exposure to lower quantities."

207. Numerous human epidemiological studies explore the effects of NDMA dietary exposure to various cancers. For example, a 1995 epidemiological case-controlled study examining, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 ng/day.

208. In a 1999 epidemiological cohort study examining NDMA dietary exposure of 189 cases and a follow-up of 24 years, researchers noted "N-nitroso compounds are potent carcinogens" and found an increased risk of colorectal cancer among individuals with a high intake of NDMA.

209. In a 2000 epidemiological cohort study examining occupational exposure of workers in the rubber industry to NDMA, researchers observed exposure to high concentrations of nitrosamines, such as NDMA, was associated with an increased mortality from cancers of the esophagus, oral cavity, and pharynx.

210. In a 2011 epidemiological cohort study examining the relation between dietary n-nitroso compounds (measured by NDMA) and incidences of cancer, among other things, and a follow-up period of 11-15 years, researchers concluded: "[d]ietary NDMA was associated with increased risk of gastrointestinal cancers, specifically of rectal cancer."

211. In a 2011 epidemiological case-control study examining NDMA dietary intake and colorectal cancer risk in 1,760 case patient with pathologically confirmed adenocarcinoma and 2,481 population controls, NDMA intake was found to be associated with a higher risk of colorectal cancer, specifically rectal carcinoma.

C. RANITIDINE TRANSFORMS INTO NDMA WITHIN THE BODY WHEN USED AS INTENDED

212. The high levels of NDMA produced by ranitidine are not caused by a manufacturing defect, but are inherent to the molecular structure of ranitidine.

213. The ranitidine molecule contains both a nitrite and a dimethylamine (DMA) group, which are known to form NDMA in certain circumstances. Thus, ranitidine produces NDMA by "react[ing] with itself."

214. The formation of NDMA by reaction of DMA and a nitroso source, *e.g.* nitrite, is well characterized in the scientific literature, and multiple sources have identified it as a concern for contamination in the American water supply.

215. For example, in 2003, relatively high levels of NDMA in drinking water processed by wastewater treatment plants was linked to the presence of ranitidine.

216. Similarly, a 2011 scientific study found that ranitidine "show[ed] the strongest potential to form [NDMA]" out of the eight pharmaceuticals that were observed, when present in drinking water during chloramine disinfection. The 2011 study also observed, "[r]anitidine gave a much higher yield of NDMA in the present study than reported in the literature, even with a shorter reaction time." As this study explained, "earlier pharmacokinetics and pharmacodynamics studies have indicated that 30-70% of ranitidine is excreted as the parent form, and its major metabolites in human body include N-oxide, S-oxide, and desmethylranitidine."

217. Another 2011 scientific article investigating the NDMA formation potential of several tertiary amines examined ranitidine in the water supply and found that ranitidine "showed the highest molar conversion to NDMA," and was "an important NDMA precursor."

218. In 2014, a scientific article examining the formation mechanism of NDMA from ranitidine and other tertiary amines during chloramination acknowledged ranitidine and two other pharmaceuticals "have recently caused much concern because they are potent NDMA precursors."

219. When ranitidine was developed, there was already existing scientific literature suggesting that drugs like ranitidine, which contain a DMA group, are highly likely to form NDMA, when combined with other substances, such as nitrile, found in the body.

220. In a study described in October 1981 in *The Lancet* discussing the potential toxicity of cimetidine (an H2 blocker with a similar chemical structure to ranitidine) and ranitidine, Dr. Silvio de Flora described that when ranitidine was exposed to gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects" *in vitro* for cimetidine and ranitidine. Dr. de Flora hypothesized that these effects could have been caused by the "formation of more than one nitroso derivative under our experimental conditions." Recognizing that "[t]hese adverse effects have been observed only in vitro," Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent

to avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals, or by giving inhibitors of nitrosation such as ascorbi[c] acid."

221. The scientific concerns raised by Dr. de Flora's October 1981 study in *The Lancet* were known by Defendant GSK and thus prompted its UK affiliate, Glaxo Group Research Ltd., to seek to give the appearance that it was taking steps to protect its consumers—but in reality, it designed an intentionally deficient study protocol not intended to yield useful data.

222. In a study described the following month in *The Lancet*, a group of researchers from Glaxo Group Research Ltd. acknowledged Dr. de Flora's study and explained they "were obviously concerned as to whether or not a mutagenic N-nitroso derivative of ranitidine could be formed in the stomach." A mutagen is a physical or chemical agent that alters genetic material, potentially harming cells. Mutagens are typically responsible for causing cancers. Thus, this acknowledgment demonstrates that GSK was aware of a link between ranitidine consumption and the risk of developing cancer as early as 1981—just as the Zantac product launch was unfolding.

223. These researchers acknowledged at certain concentrations of sodium nitrite "an N-nitroso nitrolic acid derivative was formed" that "was mutagenic." While these researchers recognized "[t]here can be little doubt that the product formed under the conditions of De Flora's experiment ... is the N-nitroso nitrolic acid derivative of

ranitidine," they dismissed these results because they "[could] not conceive the conditions whereby the N-nitroso nitrolic acid derivative could be formed in the human stomach." Thus, although GSK's researchers confirmed that the scientific evidence demonstrated a link between ranitidine and a known mutagenic nitrosamine in the human body, this evidence was deliberately ignored or downplayed so that the company could continue its successful Zantac product launch.

224. In January 1983, Dr. de Flora and three other researchers published their final findings, which "confirm [their] preliminary finding on the formation of genotoxic derivatives from nitrite and ranitidine and provide more detailed information both on the reaction patterns and on the genotoxic and metabolic properties of the resulting products." Dr. de Flora and his colleagues noted, "there seems to be no doubt about the possibility of formation of genotoxic derivatives from ranitidine and an excess nitrite under *in vitro* conditions." They also concluded "the widespread clinical use 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 ... Ascorbic acid has been proposed as an inhibitor of nitrosation combined with nitrosatable drugs and appears to block efficiently the formation of mutagenic derivatives from ... ranitidine."

225. Two months later, a group of researchers from the Institute of Pharmacology at the University of Genoa, noted:

> The possible formation in gastric juice of N-nitro compounds by the reaction between nitrite, taken in as such or as a precursor in food and drinking water, and nitrosatable substances, such as food constitutes or drugs, has been widely documented. Most N-nitroso derivatives have been shown to be carcinogenic in several species.

226. The researchers from the University of Genoa concluded:

> that the reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitrosoderivative (or derivatives) capable of inducing DNA damage in mammalian cells. The nitrosated analog(s) of ranitidine proved to be an effective direct-acting agent producing about the same amount of DNA fragmentation elicited by approximately equimolar amounts of MNU, a compound which is effective in inducing tumors in laboratory animals. **These findings are consistent with those of De Flora, who showed that preincubation of ranitidine with excess nitrite in human gastric juice resulted in mutagenic effects…. (emphasis added).**

227. After numerous studies published in 1981-1983 raised grave concerns over ranitidine and cancerous nitroso compounds, in 1987, while Zantac was generating billions of dollars in sales revenue, Glaxo Group Research Ltd. published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds, which concluded:

> During treatment with ranitidine median 24 hour intragastric pH, nitrate concentration, and counts of total and nitrate reducing bacteria increased significantly regardless of dietary nitrate content; there was no significant increase in the median day time concentration of N-nitroso compounds.

228. Glaxo Group Research Ltd.'s study, which boosted confidence in the medical community that ranitidine was not associated with N-nitrosamines like NDMA, had significant, intentionally constructed material weaknesses that prevented the detection of

NDMA formation from ranitidine. Indeed, this study is part and parcel of GSK's deceptive campaign of misinformation regarding the safety of its products.

229. For example, rather than using the industry standard mass spectrometry to detect for the presence of nitrosamines, Glaxo Group Research Ltd. decided to use a "nitrogen oxide assay," which is not an appropriate detection method because it only indirectly and non-specifically measures N-nitrosamines.

230. Because of this methodological decision, the researchers explained that only "ranitidine free samples" were utilized in compiling the study results, as "the presence of ranitidine in gastric juice may result in falsely high concentrations of N-nitroso compounds being recorded" using this assay.

231. Use of mass spectrometry would have enabled the researchers to specifically measure N-nitroso compounds produced during metabolization of ranitidine, averting the purported risk of "false" positives associated with use of a nitrogen oxide assay. Instead, GSK adopted this risk, and used it as a pretext for jettisoning samples that would have provided critical safety information about ranitidine.

232. Accordingly, the decision to use an inappropriate analytical assay gave GSK a clear opportunity to manipulate the data. All gastric samples containing ranitidine were discarded and not considered in preparing the study results. In this way, GSK made sure that the study would reveal no new information about the health risks associated with ordinary use of its Zantac/ranitidine products.

233. Glaxo Group Research Ltd.'s study succeeded only in delivering false assurances of ranitidine's safety, materially contributing to the current public health crisis.

234. This 1987 study was designed and performed to respond to the "concern[s]" GSK acknowledged in its 1981 *Lancet* publication as having been raised by the De Flora data.

235. Indeed, the publication observes that "[c]oncern has been expressed about … carcinogenic potential arising from medical treatment of ulcer using potent acid lowering drugs such as the histamine H_2-receptor antagonists [such as ranitidine], particularly when treatment is prolonged in prophylaxis against ulcer recurrence."

236. Because De Flora's studies raised significant red flags regarding the safety of ranitidine and similar H_2 blockers, GSK designed its study to alleviate concerns in the medical and scientific community regarding its blockbuster heartburn medication, but to yield results indicating the product is safe, it had to construct the study with fatal deficiencies, as alleged above. Indeed, its 1981 *Lancet* article demonstrates its actual knowledge of, and "concern[s]" about, De Flora's findings. The 1987 study is simply GSK's attempt to stifle such "concern[s]."

D. VALISURE FINDS EXTREMELY HIGH LEVELS OF NDMA IN RANITIDINE DURING ITS ROUTINE ANALYSIS OF DRUG PRODUCTS AND SUBMITS A CITIZEN PETITION TO THE FDA

237. On September 9, 2019, Valisure LLC and ValisureRX LLC (collectively, "Valisure") submitted a Citizen Petition ("Petition") on ranitidine to the FDA after

"discover[ing] the link between ranitidine and NDMA formation during its routine analysis of drug products in its pharmacy."[2] As the Petition explained, "Valisure ... detected extremely high levels of [NDMA] ... in every lot tested, across multiple manufacturers and dosage forms of the drug ranitidine." "Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng."

238. As shown in the chart below, the results of Valisure's testing show levels of NDMA well above 2,000,000 ng per 150 mg Zantac tablet.

150 mg Tablets or	**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	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311

[2] Valisure, LLC is an online pharmacy currently licensed in 38 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV7431137, Laboratory: RV0484814) and the FDA (FEI #: 3012063246). Valisure, LLC's mission is "to bring transparency and increased quality to the pharmaceutical industry, and to deliver these benefits direct to consumers." "In response to rising concerns about counterfeit medications, generics and overseas manufacturing, Valisure has developed proprietary analytical technology that is used to screen out poor-quality batches."

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
* Estimated NDMA scaled to equivalent of 150 mg.		

239. Valisure's testing shows, on average 2,692,290 ng of NDMA in a 150 mg Zantac tablet. This is more than ***28,000 times*** the FDA's permissible daily NDMA limit of 96 ng.

240. Because of its concern that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameters of 130°C in the FDA recommended GC/MS protocol, Valisure developed a low temperature GC/MS method that could still detect NDMA, but would only subject samples to 37°C, the average temperature in the human body. This method was validated to a lower limit of detection of 100 ng.

241. According to Valisure's Petition:

> Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) was used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs.

242. Notably, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos and pizza.

243. As shown in the table below, the results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present.

Ranitidine Tablet Studies Lot # 77024060A	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not detected	Not detected
Tablet	Not detected	Not detected
Simulated Gastric Fluid	Not detected	Not detected
SGF with 10 mM Sodium	Not detected	Not detected
SGF with 25 mM Sodium	236	23,600
SGF with 50 mM Sodium	3,045	304,500

244. Incredibly high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 times to more than 3,171 times above the FDA-allowable limit, under biologically relevant conditions, when nitrites are present.

245. Based on this discovery, Valisure's pharmacy stopped selling any of the ranitidine products it had acquired.

246. Other, earlier studies of ranitidine are entirely consistent with Valisure's 2019 results.

247. A 2004 study published by the National Cancer Institute investigated 414 cases of peptic ulcer disease reported in 1986, and followed the individual cases for 14

years. One of the variables investigated in this study was the patients' consumption of Zantac (ranitidine) or Tagamet (cimetidine). The authors concluded: "Recent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of bladder cancer, and this association was independent of the elevated risk observed with gastric ulcers." The authors also noted, "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to bladder cancer risk."

248. A 2016 peer-reviewed study published in *Carcinogenesis* by Stanford University observed that healthy individuals, both male and female, who ingested Zantac 150 mg tablets, produced roughly 400 times elevated amounts of NDMA in their urine (over 47,000 ng) in the proceeding 24 hours after ingestion. This study "confirmed the production of [NDMA], a potent carcinogen, by nitrosation of ranitidine under stomach-relevant pH conditions *in vitro*." The study also found "NDMA excretion rates after ranitidine intake equaled or exceeded those observed previously in patient with schistosomiasis, a disease wherein N-nitrosamines are implicated as the etiological agent for bladder cancer." The authors also noted that "such estimates are conservative" and "[a]ctual systemic NDMA exposure is likely much higher than that eliminated in urine," since NDMA has "a high metabolic conversion rate," and only ~0.05% is excreted in urine. According to the study's authors, "[t]he potential cancer risk from ranitidine use should be balanced against its therapeutic benefit," and the results of the study "suggest[] a need to evaluate the risks attributable to NDMA associated with chronic consumption

of ranitidine, and to identify alternative treatments that minimize exposure to N-nitrosamines." The authors concluded that "a more comprehensive risk assessment relevant to chronic ranitidine use or the use of treatment alternatives," including "[e]pidemiological studies evaluating cancer risk, particularly bladder cancer, attributable to the long-term use of ranitidine" are needed.

249. A scientific study published in January 2018 in *Chemosphere* "summarize[d] major findings over the last decade related to [NDMA] in water and wastewater," and again noted that ranitidine had "a relatively high NDMA formation (~80% molar yields) upon chloramination."

E. VALISURE'S PETITION PROMPTS RECALLS OF ZANTAC AND RANITIDINE

250. Since the filing of Valisure's Petition on September 9, 2019, nearly every health regulator worldwide has taken steps to remove Zantac and ranitidine from the marketplace.

251. On September 13, 2019, in response to Valisure's Petition, the FDA issued a statement alerting patients and health care professionals "some ranitidine medicines, including some products commonly known as the brand-name drug Zantac, contain [NDMA]."

252. On October 2, 2019, the FDA stated that it was ordering all manufacturers of Zantac and ranitidine products to conduct testing for NDMA and that preliminary results indicated unacceptable results, so far.

253. By November 1, 2019, the FDA asked manufacturers to voluntarily recall ranitidine after its tests found levels of NDMA exceeding the levels it considered acceptable.

254. On April 1, 2020, the FDA requested manufacturers withdraw all prescription and OTC ranitidine drugs from the U.S. market immediately after "determin[ing] that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity."

255. The FDA also advised consumers to stop taking any OTC ranitidine they may currently have, dispose of such products, and not buy more of any product containing ranitidine. As a result of the FDA's immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

256. Even prior to the FDA's recall, at the request of Health Canada, the organization responsible for Canada's public health, "companies marketing ranitidine products in Canada have stopped any further distribution until evidence is provided to demonstrate that they do not contain NDMA above acceptable levels." According to

Health Canada, "[c]urrent evidence suggests that NDMA may be present in ranitidine, regardless of the manufacturer."

257. South Korea's Ministry of Food and Drug Safety banned the sale and production of Zantac and other ranitidine medicines after its tests "revealed high levels of ... [NDMA] in the samples." The Ministry "found that the NDMA level detected in the seven types of ranitidine-based medications currently in circulation was as high as 53.5ppm, well above the acceptable threshold of 0.16ppm." The ministry further stated: "It suspects NDMA may have been unintentionally produced in the course of natural decomposition and synthesis reactions of the nitrite and dimethylamine chemicals in ranitidine or by dimethylamine accidentally being added during the manufacturing process."

258. In September 2019, Germany, Switzerland and Austria became the first European countries to initiate recalls of ranitidine-based drugs after test showed that certain products contained NDMA.

259. Similarly, Finland has withdrawn drugs containing ranitidine from its pharmacies, and Singapore suspended the sale and supply of several brands of ranitidine.

260. Qatar's Ministry of Public Health "has withdrawn samples of ranitidine, including a medicine known commercially as Zantac, from public and private pharmacies," and has "recommend[ed] patients who use these drugs to review and consult their doctor, and those who use them without a prescription should use other alternative."

261. In addition, at least the following countries have either issued recalls of all ranitidine products, banned the sales of ranitidine and/or Zantac, suspended or stopped the registration, importing and distribution of all products containing ranitidine, issued health alerts, launched their own investigation, and major retailers in certain of these countries have recalled their branded versions and generic versions of ranitidine: Australia, Bangladesh, Bahrain, Cyprus, Denmark, Dominican Republic, Egypt, Fiji, France, Greece, Hong Kong, India, Ireland, Italy, Jamaica, Kenya, Kuwait, Japan, Libya, Lithuania, Morocco, Namibia, New Zealand, Norway, Oman, Palestine, Pakistan, Saudi Arabia, Singapore, South Africa, Suriname, Taiwan, Tanzania, Trinidad and Tobago, UAE, the United Kingdom and Vietnam.

262. In the United States, in September 2019, CVS Pharmacy stopped selling Zantac, and in October 2019, Sanofi voluntarily recalled all of its Zantac from stores in the United States and Canada after the FDA announced it discovered NDMA in Zantac and its generic versions. Also in October, GSK announced it was recalling the prescription-only versions of Zantac.

263. In addition, from late September 2019 through the end of February 2020, the FDA announced the following were voluntarily withdrawing certain of their ranitidine products sold in the United States because they contain or metabolize into carcinogenic NDMA: Sandoz Inc.; Apotex Corp. whose products were labeled by Walgreens, Walmart and Rite-Aid; Perrigo Company plc; Dr. Reddy's Laboratories Ltd. and its subsidiaries

that distribute to Kroger, Walgreens, and others; Lannett Company, Inc.; Novitium Pharma; Aurobindo Pharma USA, Inc.; American Health Packaging; GSMS, Inc.; Precision Dose, Inc.; Amneal Pharmaceuticals, LLC; Glenmark Pharmaceuticals Inc., USA; Appco Pharma LLC; and Denton Pharma, Inc. d/b/a Northwind Pharmaceuticals.

264. The United States drug regulatory system relies largely, if not entirely, on drug manufacturers to perform adequate testing and self-report adverse events. Specifically, manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, *inter alia*:

> The report is required to contain in the order listed:
>
> (i) Summary. 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.
>
> * * *
>
> (v) Nonclinical laboratory studies. 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 applicant concerning the ingredients in the drug product.

21 C.F.R. §§ 314.81(b)(2)(i), (v).

265. Each Brand Manufacturer Defendant ignored these regulations (and their predecessor regulations, which imposed substantially identical reporting requirements throughout the relevant time period), disregarded the scientific evidence available to them, failed to report to the FDA and the public significant new information affecting the safety

of Zantac and/or ranitidine, and thereby flaunted the FDA's lack of resources to police and enforce the foregoing requirements.

266. Not only did each Brand Manufacturer Defendant fail to provide the relevant studies to the FDA, but each Brand Manufacturer Defendant also failed to present the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

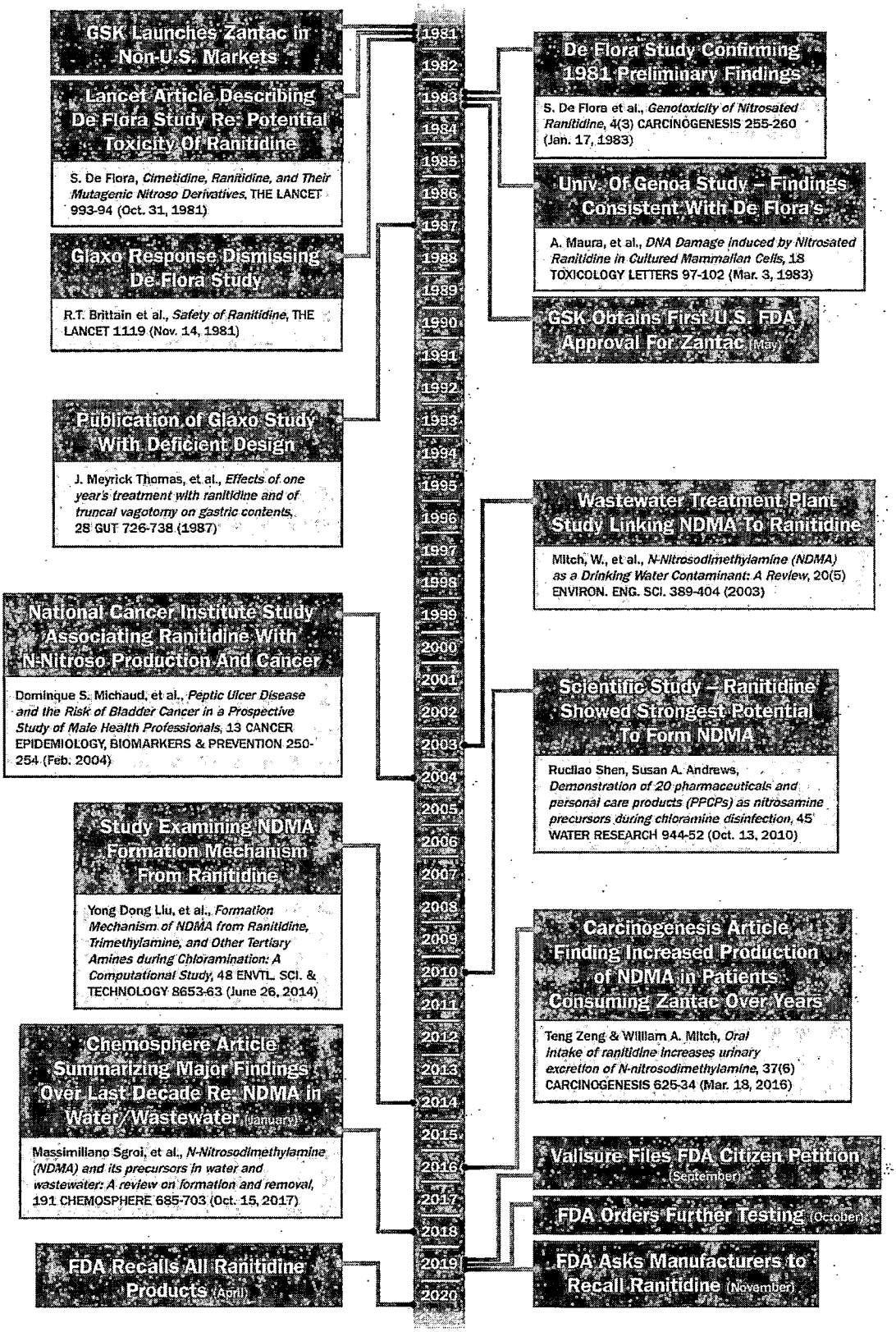
267. Here, all Defendants actually knew and/or, at minimum, should have known about Dr. de Flora's study described in October 1981 in *The Lancet,* his later study published in January 1983 in *The Lancet,* and the 1983 study by the researchers from the Institute of Pharmacology at the University of Genoa.

268. Indeed, as alleged above, in November 1981, Glaxo Group Research Ltd. researchers acknowledged Dr. de Flora's study in their own study described in *The Lancet.* Yet, Brand Manufacturer Defendants failed to provide the FDA or the public with this information at any time, and Generic Manufacturer Defendants and Store Brand Defendants continued to sell ranitidine products.

269. In addition, all Defendants knew or should have known about, *inter alia*, the following: in 2003, relatively high levels of NDMA in drinking water processed by wastewater treatment plants was linked to the presence of ranitidine; the 2004 study published by the National Cancer Institute associating ranitidine consumption with N-nitroso production and development of cancer; the 2011 scientific study finding that ranitidine "show[ed] the strongest potential to form [NDMA]" out of the eight

pharmaceuticals that were observed, when present in drinking water during chloramine disinfection; the 2014 scientific article examining the formation mechanism of NDMA from ranitidine and other tertiary amines during chloramination, which acknowledged ranitidine and two other pharmaceuticals "have recently caused much concern because they are potent NDMA precursors;" the 2016 peer-reviewed study published in *Carcinogenesis* by Stanford University finding increased production of NDMA in patients consuming Zantac tablets; and the scientific study published in January 2018 in *Chemosphere* "summariz[ing] major findings over the last decade related to [NDMA] in water and wastewater" and noting that ranitidine has a "relatively high NDMA formation … upon chloramination."

270. The following graphic illustrates certain key dates in the development of scientific evidence associating ranitidine/Zantac consumption with production of carcinogenic NDMA. This graphic is not intended to be exhaustive.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Chemosphere Article Summarizing Major Findings Over Last Decade Re: NDMA in Water/Wastewater (January)
Massimiliano Sgroi, et al., N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review on formation and removal, 191 CHEMOSPHERE 685-703 (Oct. 15, 2017)
FDA Recalls All Ranitidine Products (April)
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De Flora Study Confirming 1981 Preliminary Findings
S. De Flora et al., Genotoxicity of Nitrosated Ranitidine, 4(3) CARCINOGENESIS 255-260 (Jan. 17, 1983)
Univ. Of Genoa Study – Findings Consistent With De Flora's
A. Maura, et al., DNA Damage induced by Nitrosated Ranitidine in Cultured Mammalian Cells, 18 TOXICOLOGY LETTERS 97-102 (Mar. 3, 1983)
GSK Obtains First U.S. FDA Approval For Zantac (May)
Wastewater Treatment Plant Study Linking NDMA To Ranitidine
Mitch, W., et al., N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review, 20(5) ENVIRON. ENG. SCI. 389-404 (2003)
Scientific Study – Ranitidine Showed Strongest Potential To Form NDMA
Rucliao Shen, Susan A. Andrews, Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection, 45 WATER RESEARCH 944-52 (Oct. 13, 2010)
Carcinogenesis Article Finding Increased Production of NDMA in Patients Consuming Zantac Over Years
Teng Zeng & William A. Mitch, Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine, 37(6) CARCINOGENESIS 625-34 (Mar. 18, 2016)
Valisure Files FDA Citizen Petition (September)
FDA Orders Further Testing (October)
FDA Asks Manufacturers to Recall Ranitidine (November)

271. Evidence of the toxicity and carcinogenicity of NDMA was abundant throughout the relevant time period.

272. The Brand Manufacturer Defendants also should have disclosed to the FDA and the public evidence concerning NDMA's toxicity and carcinogenicity, due to the data strongly linking ranitidine to NDMA production.

273. Among others, such data includes: the 1979 article noting "NDMA has caused cancer in nearly every laboratory animal tested so far;" the 1995 epidemiological case-controlled study in which researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 ng/day; the 1999 epidemiological cohort study examining NDMA dietary exposure, which found an increased risk of colorectal cancer among individuals with a high intake of NDMA; the 2000 epidemiological cohort study examining occupational exposure of workers in the rubber industry to NDMA in which researchers observed exposure to high concentrations of nitrosamines, such as NDMA, was associated with an increased mortality from cancers of the esophagus, oral cavity, and pharynx; the 2011 epidemiological cohort study examining the relation between dietary N-nitroso compounds (measured by NDMA) and incidences of cancer, among other things, in which researchers concluded dietary "NDMA was associated with increased risk of gastrointestinal cancers, specifically of rectal cancer;" and the 2011 epidemiological case-control study examining NDMA dietary

intake and colorectal cancer risk in which NDMA intake was found to be associated with a higher risk of colorectal cancer, specifically rectal carcinoma.

IV. DEFENDANTS SOLD DANGEROUS RANITIDINE PRODUCTS, INCLUDING ZANTAC, IN NEW MEXICO

274. Each Brand Manufacturer Defendant marketed, promoted, and sold Zantac/ranitidine products in New Mexico through the use of unfair and deceptive trade practices, and unconscionable trade practices, including by marketing and selling unreasonably dangerous products that should never have been marketed and sold at all, and misrepresenting or omitting material facts concerning the safety of such products.

275. Each Generic Manufacturer Defendant and Store Brand Defendant sold ranitidine products in New Mexico in violation of their duties of care.

276. Zantac and other ranitidine products posed serious health risks to New Mexico citizens for the entire duration in which they were available for purchase and consumption.

277. Thousands of New Mexico residents purchased prescription and over-the-counter Zantac/ranitidine products manufactured and sold by Defendants during the relevant period.

278. In addition, the State paid or caused payment for substantial quantities of Zantac/ranitidine products manufactured and sold by Defendants through various State-funded insurance and healthcare programs administered for the benefit of New Mexico residents during the relevant period.

279. As further described herein, all Defendants knew or should have known about the grave health risks associated with Zantac/ranitidine consumption based on the studies and literature describing such risks. The products should never have been sold in New Mexico at any point in time due to these health risks, as the worldwide recall of the products demonstrates.

280. Yet no Defendant ceased selling Zantac/ranitidine products until the FDA stepped in to instruct industry participants to recall these unreasonably dangerous products.

281. Further, none of the Brand Manufacturer Defendants disclosed that use of its Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

282. Each Brand Manufacturer Defendant had the opportunity to make such disclosures on the packaging of every Zantac or ranitidine product sold or offered for sale.

283. Each Brand Manufacturer Defendant had the opportunity to make such disclosures in other statements, including all statements made to promote its Zantac or ranitidine products.

284. Each Brand Manufacturer Defendant could have disclosed, but knowingly failed to disclose, on its product packaging that its Zantac/ranitidine products exposed consumers to significant adverse health risks, particularly exposure to toxic and carcinogenic NDMA.

285. Each Brand Manufacturer Defendant made public promotional statements in New Mexico, or to New Mexico residents, about their Zantac/ranitidine products other than product packaging that similarly knowingly failed to disclose that their products exposed consumers to significant adverse health risks, particularly exposure to toxic and carcinogenic NDMA.

286. Through the acts described in this Complaint, Defendants have violated New Mexico law by (with respect to Brand Manufacturer Defendants) knowingly engaging in unfair or deceptive trade practices and/or unconscionable trade practices in the regular course of their trade or commerce by selling unreasonably dangerous products and by making oral and/or written statements or other representations that were false or misleading in connection with the sale of Zantac and/or ranitidine in an attempt to influence New Mexico and its citizens to believe that such dangerously misbranded products were safe for consumption, and (with respect to Generic Manufacturer Defendants and Store Brand Defendants) by selling unreasonably dangerous products.

A. BRAND MANUFACTURER DEFENDANTS

1. GSK

287. For example, in or around April 2009, GSK's prescribing information for Zantac 150 mg tablets, Zantac 300 mg tablets, Zantac 25 mg effervescent tablets, and Zantac syrup failed to disclose that Zantac or ranitidine products would expose consumers

to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer. Instead, it merely noted:

> Carcinogenesis, Mutagenesis, Impairment of Fertility
>
> There was no indication of tumorigenic or carcinogenic effects in life-span studies in mice and rats at dosages up to 2,000 mg/kg/day.
>
> Ranitidine was not mutagenic in standard bacterial tests (*Salmonella, Eschericha coil*) for mutagenicity at concentrations up to the maximum recommended for these assays.
>
> In a dominant lethal assay, a single oral dose of 1,000 mg/kg to male rats was without effect on the outcome of 2 matings per week for the next 9 weeks.

2. Pfizer

288. The bottle carton and blister carton information for Pfizer's OTC Zantac 150 warned users not to take the product if they "are allergic to ranitidine or other acid reducers." It also warned:

> ***Warnings***
> **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers
>
> **Do not use**
> • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
> • with other acid reducers
> • if you have kidney disease, except under the advice and supervision of a doctor

77°F) and avoid excessive heat or humidity.

290. Pfizer's packaging touted the product's "Excellent Safety Record:"

> Excellent Safety Record
>
> • The ingredients in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredients in MAXIMUM

STRENGTH Zantac 150 has been taken safely with many frequently prescribed medications.

291. None of the information in Pfizer's packaging disclosed that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

3. Boehringer Ingelheim

292. BI's September 9, 2013 announcement of its Captain Zantac marketing campaign to educate consumers on heartburn relief claims, *inter alia*: "ZANTAC products of Boehringer Ingelheim Pharmaceuticals, Inc., have been a trusted name in heartburn relief for more than two decades. According to IRI, ZANTAC has experienced a 4.8% growth rate in the latest 52 weeks ending July 14, 2013, and has a 6.6% market share in the heartburn category, continuing to make it a top player." This announcement also states Zantac is "clinically proven to relieve heartburn in 30 to 60 minutes and lasts up to 12 hours." However, it fails to disclose that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

293. The product label for BI's Maximum Strength Zantac 150 (ranitidine 150 mg tablets), Regular Strength Zantac 75 (ranitidine 75 mg tablets), and Cool Mint Maximum Strength Zantac 150 (ranitidine 150 mg tablets) warned users not to take the product if they are allergic to ranitidine or other acid reducers, and instructed them to "store at 20°-25°C (68°-77°F)" and "avoid excessive heat or humidity." BI's product packaging failed

to disclose that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

294. As of June 11, 2020, BI's website stated:

> Zantac® -- available only in USA
>
> Prevent and relieve heartburn with Zantac®
>
> The feeling of heartburn can be described as a burning discomfort that generally occurs in the chest just behind the breastbone. People with heartburn may also experience a sensation of food coming back into the mouth that may be accompanied by a bitter or acid taste.
>
> Heartburn symptoms can occur if your stomach produces too much acid in the digestion process. When this happens, stomach acid can move up into the esophagus, causing discomfort. Heartburn can be caused by diet and lifestyle choices, and different people experience heartburn in different ways.
>
> Zantac® is available in the USA and is a nonprescription acid reducer for the prevention and relief of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages. The active ingredient in Zantac®, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively.
>
> Zantac® products work fast to prevent heartburn when taken 30 to 60 minutes before a meal or to provide quick relief for tough heartburn symptoms once they've started. Zantac® begins to work in as little as 30 minutes and provides heartburn relief for up to 12 hours, day or night. It is available in two different dosages in the US, 75 mg and 150mg, and in Cool Mint flavor.
>
> Zantac® has been a trusted name in heartburn relief for more than two decades. It is the #1 doctor recommended H2 brand among over the counter brands.
>
> Read the patient information leaflet carefully. If you have any questions, ask your doctor or pharmacist.

295. BI's website claims to this day that "[t]he active ingredient in Zantac®, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively," while failing to disclose that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

4. Sanofi

296. In 2016, Sanofi ran digital and print Zantac advertisements with the tagline "No Pill Relieves Heartburn Faster," featuring Captain Zantac.[3] None of these advertisements disclosed that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure including cancer.

297. In or around December 5, 2019, Sanofi's product monograph for OTC Zantac 75 mg and 150 mg tablets noted that the product should be stored between 15 and 30°C, and warned only that the "Cool Mint flavored Tablets should also be protected from heat."

298. In the same product monograph, while failing to disclose that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer, Sanofi noted:

[3] https://www.ispot.tv/ad/wd9e/zantac-cool-mint-fire-engine; https://www.zantacotc.com/heartburn-relief.html

TOXICOLOGY

Animals

Toxicology, Impairment of Fertility, Carcinogenesis and Mutagenesis

Ranitidine hydrochloride has been subjected to exhaustive toxicological testing which has demonstrated the lack of any specific target organ or any special risk associated with its clinical use.

* * *

Mutagenesis

Ranitidine is not mutagenic at doses as great as 30 mg/plate in the Ames Assay utilizing Salmonella typhimurium (TA 1538, TA 98, TA 100 and TA 1537) or in doses of 9 mg/plate utilizing Escherichia coli (WP2 and WP2 uvrA) with or without activation.

Ranitidine at concentrations of 20-30 mg/plate had a weak direct mutagenic action in S. typhimurium TA 1535 and at 9 mg/plate in E.coli WP67. ZANTAC was not mutagenic at a concentration of 2 mg/mL in E. coli or S. typhimurium in the more sensitive Oral Solution microtitre fluctuation assay method. This weak direct mutagenic effect is of no clinical significance; the magnitudes of ranitidine concentration used in these assays are thousands of times greater than that attained therapeutically in human plasma.

The principal metabolites of ranitidine in man were not significantly mutagenic. This conclusion is supported by the following experiment. A test solution obtained by interacting ranitidine (10mM) and sodium nitrite (40mM) was mutagenic in S. typhimurium (TA 1535) but not in S. Typhimurium (TA 1537) or in E. coli (WP67 or WP2 uvrA). This positive result is attributable to the presence of a nitrosonitrolic acid derivative AH 23729, which was mutagenic. When the sodium nitrite concentration was reduced to 15mM or less, the solution was not mutagenic in any of the test microorganisms. The formation of AH 23729 requires concentrations of nitrous acid far in excess of those encountered in any probable physiological conditions. The other nitrosation products were not mutagenic in any of the microorganisms tested. There is no reason, therefore, for supposing that ranitidine is likely to be mutagenic in animals or man as a consequence of nitrosation in the stomach.

There is no evidence from long term toxicology, carcinogenicity and mutagenicity studies in animals to suggest that ranitidine is likely to have

any deleterious effects in man when administered at therapeutic dose levels.

B. GENERIC MANUFACTURER DEFENDANTS

1. Perrigo

299. No claims are asserted herein concerning the adequacy of Perrigo's warnings or the fairness of its marketing statements. However, to ensure Perrigo is adequately placed on notice of the claims against it, the State alleges the following additional facts.

300. The Perrigo Defendants' GoodSense Regular Strength Acid Reducer packaging and "Drug Facts" for ranitidine 75 mg tablets warned: "Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers." The "Drug Fact" insert also touted the product as follows:

> What are Ranitidine Tablets, 75 mg?
>
> * Ranitidine Tablets, 75 mg contain 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
>
> * * *
>
> Excellent Safety Record
>
> - Ranitidine Tablets, 75 mg have been used safely and effectively for years as an over-the-counter medication.

301. The Perrigo Defendants' GoodSense Maximum Strength Acid Reducer label for ranitidine 150 mg tablets, Basic Care Maximum Strength Acid Reducer 150 (ranitidine 150 mg) cool mint tablets (Amazon), Basic Care Maximum Strength Acid Reducer 150

(ranitidine 150 mg) tablets (Amazon), and Basic Care Regular Strength Acid Reducer 75 (ranitidine 75 mg) tablets (Amazon) all had similar warnings.

2. Lannett

302. No claims are asserted herein concerning the adequacy of Lannett's warnings or the fairness of its marketing statements. However, to ensure Lannett is adequately placed on notice of the claims against it, the State alleges the following additional facts.

303. On or about September 2017, the information for Lannett's ranitidine syrup 15 mg/mL noted simply:

> Carcinogenesis, Mutagenesis, Impairment of Fertility
>
> There was no indication of tumorigenic or carcinogenic effects in life-span studies in mice and rats at dosages up to 2,000 mg/kg/day.
>
> Ranitidine was not mutagenic in standard bacterial tests (*Salmonella, Eschericha coil*) for mutagenicity at concentrations up to the maximum recommended for these assays.
>
> In a dominant lethal assay, a single oral dose of 1,000 mg/kg to male rats was without effect on the outcome of 2 matings per week for the next 9 weeks.

3. Novitium

304. No claims are asserted herein concerning the adequacy of Novitium's warnings or the fairness of its marketing statements. However, to ensure Novitium is adequately placed on notice of the claims against it, the State alleges the following additional facts.

305. The labels on Novitium's 150 mg and 300 mg capsules told users to "store at 20°-25°C (68°– 77°F) … in a dry place" and "protect from light." The label warned users not to use "if printed safety seal under cap is broker or missing."

4. Aurobindo

306. No claims are asserted herein concerning the adequacy of Aurobindo's warnings or the fairness of its marketing statements. However, to ensure Aurobindo is adequately placed on notice of the claims against it, the State alleges the following additional facts.

307. The packaging for the ranitidine 15 mg/ML syrup distributed by Aurobindo USA instructed users to "store at 20° to 25°C (68°– 77°F) … Do not freeze." The packaging for the 150 mg capsules and 300 mg capsules distributed by Aurobindo USA instructed users to "store at 20° to 25°C (68°– 77°F) … in a dry place. Protect from light."

5. Amneal

308. No claims are asserted herein concerning the adequacy of Amneal's warnings or the fairness of its marketing statements. However, to ensure Amneal is adequately placed on notice of the claims against it, the State alleges the following additional facts.

309. The product information for Amneal's 150 mg and 300 ranitidine tablets instructed users to "store at 20° to 25°C (68° to 77°F) in a dry place," and to "protect from light." Amneal's 15 mg/mL ranitidine syrup told users to "store between 4° and 25°C (39° and 77°F). … Do not freeze."

6. Glenmark

310. No claims are asserted herein concerning the adequacy of Glenmark's warnings or the fairness of its marketing statements. However, to ensure Glenmark is adequately placed on notice of the claims against it, the State alleges the following additional facts.

311. The product information for Glenmark's 150 mg and 300 mg ranitidine tablets instructed users to "store at 20° to 25°C (68° to 77°F) in a dry place," and to "protect from light." The product information also indicated that these products were manufactured by Strides for Glenmark.

7. Appco and ANI

312. No claims are asserted herein concerning the adequacy of Appco's and ANI's warnings or the fairness of their marketing statements. However, to ensure Appco and ANI are adequately placed on notice of the claims against them, the State alleges the following additional facts.

313. The product information for 150 mg and 300 mg ranitidine capsules manufactured by Appco and distributed by ANI instructed users to "store at 20° to 25°C (68° to 77°F) in a dry place," and to "protect from light."

8. Sandoz

314. No claims are asserted herein concerning the adequacy of Sandoz's warnings or the fairness of its marketing statements. However, to ensure Sandoz is adequately placed on notice of the claims against it, the State alleges the following additional facts.

315. The product information for 150 mg and 300 mg capsules manufactured by Sandoz instructed users to "store at 20° to 25°C (68° to 77°F) in a dry place," and to "protect from light."

9. Apotex

316. No claims are asserted herein concerning the adequacy of Apotex's warnings or the fairness of its marketing statements. However, to ensure Apotex is adequately placed on notice of the claims against it, the State alleges the following additional facts.

317. The packaging for 150 mg ranitidine distributed by Apotex warned users: "Do not use if you are allergic to ranitidine or other acid reducers." It also instructed users to "store at 20° to 25°C (68° to 77°F)" and "avoid excessive heat or humidity."

10. Dr. Reddy's

318. No claims are asserted herein concerning the adequacy of Dr. Reddy's warnings or the fairness of its marketing statements. However, to ensure Dr. Reddy is adequately placed on notice of the claims against it, the State alleges the following additional facts.

319. The packaging for Walgreens Wal-Zan 150 (150 mg) ranitidine tablets, Member's Mark 150 mg ranitidine tablets, Quality Choice Acid Reducer 150 mg ranitidine tablets, Evens 150 mg ranitidine tablets, CVS Health acid reducer 75 mg ranitidine tablets, Kroger Heartburn Relief 150 mg ranitidine tablets, HealthCare Aisle Acid Reducer 150 mg ranitidine tablets, Equate 150 mg ranitidine tablets, and Dr. Reddy's

ranitidine 150 mg capsules – all manufactured by Dr. Reddy's – warned users, *inter alia*, not to take such products if they are allergic to ranitidine or other acid reducers and to store the products within a specific temperature range.

11. Strides

320. No claims are asserted herein concerning the adequacy of Strides' warnings or the fairness of its marketing statements. However, to ensure Strides is adequately placed on notice of the claims against it, the State alleges the following additional facts.

321. On or about November 15, 2016, Strides Pharma's prescribing information for ranitidine 150 mg and 300 mg tablets noted simply:

> Carcinogenesis, Mutagenesis, Impairment of Fertility
>
> There was no indication of tumorigenic or carcinogenic effects in life-span studies in mice and rats at dosages up to 2,000 mg/kg/day.
>
> Ranitidine was not mutagenic in standard bacterial tests (*Salmonella, Eschericha coil*) for mutagenicity at concentrations up to the maximum recommended for these assays.
>
> In a dominant lethal assay, a single oral dose of 1,000 mg/kg to male rats was without effect on the outcome of 2 matings per week for the next 9 weeks.

322. In January 2016, Strides packaging materials for its 75 mg tablets stated, *inter alia*:

> Excellent Safety Record: Ranitidine Tablets USP, 75 mg has been used safely and effectively for years as an over-the-counter medication.

12. Teligent

323. No claims are asserted herein concerning the adequacy of Teligent's warnings or the fairness of its marketing statements. However, to ensure Teligent is adequately placed on notice of the claims against it, the State alleges the following additional facts.

324. Teligent's label information for its prescription ranitidine injectable solution warned users who were known to have a hypersensitivity to the drug, told users how to store the product, and the packaging insert noted:

> Carcinogenesis, Mutagenesis, Impairment of Fertility
>
> There was no indication of tumorigenic or carcinogenic effects in life-span studies in mice and rats at oral dosages up to 2,000 mg/kg/day.
>
> Ranitidine was not mutagenic in standard bacterial tests (Salmonella, Eschericha coil) for mutagenicity at concentrations up to the maximum recommended for these assays.
>
> In a dominant lethal assay, a single oral dose of 1,000 mg/kg to male rats was without effect on the outcome of 2 matings per week for the next 9 weeks.

325. Teligent's label and packaging disclosed:

> The following have been reported as events in clinical trials or in the routine management of patients treated with oral or parenteral ZANTAC. The relationship to therapy with ZANTAC has been unclear in many cases. Headache, sometimes severe, seems to be related to administration of ZANTAC.
>
> Central Nervous System
>
> Rarely, malaise, dizziness, somnolence, insomnia, and vertigo. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly

patients. Rare cases of reversible blurred vision suggestive of a change in accommodation have been reported. Rare reports of reversible involuntary motor disturbances have been received.

Cardiovascular

As with other H2-blockers, rare reports of arrhythmias such as tachycardia, bradycardia, asystole, atrioventricular block, and premature ventricular beats.

Gastrointestinal

Constipation, diarrhea, nausea/vomiting, abdominal discomfort/pain, and rare reports of pancreatitis.

Hepatic

In normal volunteers, SGPT values were increased to at least twice the pretreatment levels in 6 of 12 subjects receiving 100 mg intravenously 4 times daily for 7 days, and in 4 of 24 subjects receiving 50 mg intravenously 4 times daily for 5 days. There have been occasional reports of hepatocellular, cholestatic, or mixed hepatitis, with or without jaundice. In such circumstances, ranitidine should be immediately discontinued. These events are usually reversible, but in rare circumstances, death has occurred. Rare cases of hepatic failure have also been reported.

Musculoskeletal

Rare reports of arthralgias and myalgias.

Hematologic

Blood count changes (leukopenia, granulocytopenia, and thrombocytopenia) have occurred in a few patients. These were usually reversible. Rare cases of agranulocytosis, pancytopenia, sometimes with marrow hypoplasia, and aplastic anemia and exceedingly rare cases of acquired immune hemolytic anemia have been reported.

Endocrine

Controlled studies in animals and humans have shown no stimulation of any pituitary hormone by ZANTAC and no antiandrogenic activity, and cimetidine-induced gynecomastia and impotence in hypersecretory patients have resolved when ZANTAC has been substituted. However, occasional cases of impotence, and loss of libido have been reported in male patients receiving ZANTAC, but the incidence did not differ from that in the general population. Rare cases of breast symptoms and

conditions, including galactorrhea and gynecomastia, have been reported in both males and females.

Integumentary

Rash, including rare cases of erythema multiforme. Rare cases of alopecia and vasculitis.

Respiratory

A large epidemiological study suggested an increased risk of developing pneumonia in current users of histamine-2-receptor antagonists (H2RAs) compared to patients who had stopped H2RA treatment, with an observed adjusted relative risk of 1.63 (95% CI, 1.07-2.48). However, a causal relationship between use of H2RAs and pneumonia has not been established.

Other

Rare cases of hypersensitivity reactions (e.g., bronchospasm, fever, rash, eosinophilia), anaphylaxis, angioneurotic edema, acute interstitial nephritis, and small increases in serum creatinine.

C. STORE BRAND DEFENDANTS

1. CVS

326. No claims are asserted herein concerning the adequacy of CVS's warnings or the fairness of its marketing statements. However, to ensure CVS is adequately placed on notice of the claims against it, the State alleges the following additional facts.

327. The product labels for CVS Health Maximum Strength Acid Reducer 150 mg ranitidine tablets, CVS Health Regular Strength Acid Reducer 75 mg cool mint ranitidine tablets, CVS Health Regular Strength Acid Reducer 75 mg ranitidine tablets, CVS Health Maximum Strength Acid Reducer 150 mg cool mint ranitidine tablets, CVS Pharmacy Maximum Strength Acid Reducer 150 mg ranitidine tablets, and CVS Pharmacy Regular Strength Acid Reducer 75 mg ranitidine tablets instructed user to store the product at 20°–

25°C (68°– 77°F), and avoid excessive heat or humidity. They also warned users not to use these products if they are allergic to ranitidine or other acid reducers.

2. Kroger

328. No claims are asserted herein concerning the adequacy of Kroger's warnings or the fairness of its marketing statements. However, to ensure Kroger is adequately placed on notice of the claims against it, the State alleges the following additional facts.

329. Kroger's packaging for its Kroger Cool Mint Acid Relief Heartburn Relief Tablets (150 mg), Kroger Regular Strength Heartburn Relief 75 (75 mg), and Kroger Regular Strength Heartburn Relief 75 (150 mg) simply warned against taking the product if the user was allergic to ranitidine or other acid reducers, indicated a range of temperatures the product should be stored at and cautioned to avoid excessive heat and humidity.

3. Target

330. No claims are asserted herein concerning the adequacy of Target's warnings or the fairness of its marketing statements. However, to ensure Target is adequately placed on notice of the claims against it, the State alleges the following additional facts.

331. Target's label for its Up & Up regular strength ranitidine tablets 75 (75 mg), Up & Up maximum strength ranitidine tablets 150 (150 mg), and Up & Up maximum strength ranitidine cool mint tablets 150 (150 mg), warned users who were allergic to ranitidine or other acid reducers not to take these products and told them to store the

products at 20°-25°C (68°-77°F) and avoid excessive heat or humidity. These product labels touted the products "Excellent Safety Record:"

> Excellent Safety Record
>
> • The ingredient in MAXIMUM STRENGTH Ranitidine Tablets, 150 mg, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Ranitidine Tablets, 150 mg has been taken safely with many frequently prescribed medications.

4. Walgreens

332. No claims are asserted herein concerning the adequacy of Walgreens' warnings or the fairness of its marketing statements. However, to ensure Walgreens is adequately placed on notice of the claims against it, the State alleges the following additional facts.

333. Walgreen's packaging for its Maximum Strength Wal-Zan 150 (ranitidine), Maximum Strength sugar free Wal-Zan 150 (ranitidine), Regular Strength Wal-Zan 75 (ranitidine), Maximum Strength Well at Walgreens Wal-Zan (ranitidine 150 mg tablets), Well at Walgreens Non-prescription Strength Wal-Zan 75, and Regular Strength Wal-Zan (ranitidine 75 mg tablets) warned users not to use the product if they are allergic to ranitidine or other acid reducers, and instructed them how to store the products. Walgreen's packaging for its Maximum Strength Wal-Zan 150 and Regular Strength Wal-Zan 75 also boasted these products' "Excellent Safety Record." As a representative example, one label stated:

Excellent Safety Record

• The ingredient in MAXIMUM STRENGTH Ranitidine Tablets, 150 mg, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Ranitidine Tablets, 150 mg has been taken safely with many frequently prescribed medications

5. Walmart

334. No claims are asserted herein concerning the adequacy of Walmart's warnings or the fairness of its marketing statements. However, to ensure Walmart is adequately placed on notice of the claims against it, the State alleges the following additional facts.

335. Walmart's packaging for its Equate Maximum Strength Ranitidine tablets 150 mg warned users not to take the product if they are allergic to ranitidine or other acid reducers and instructed users how to store the product.

6. Costco

336. No claims are asserted herein concerning the adequacy of Costco's warnings or the fairness of its marketing statements. However, to ensure Costco is adequately placed on notice of the claims against it, the State alleges the following additional facts.

337. Costco's Kirkland Signature Indigestion Relief 75 mg Tablets (ranitidine) package information leaflet and Kirkland Signature Maximum Strength Acid Reducer (ranitidine 150 mg tablets) warned users not to take the product if they are allergic to

ranitidine or other acid reducers and instructed users how to store the product. The products' labels touted the "Excellent Safety Record" of ranitidine.

V. NEW MEXICO RESIDENTS SUFFER INCREASED RATES OF ADVERSE HEALTH EFFECTS ASSOCIATED WITH RANITIDINE.

338. According to the New Mexico Department of Health, "[o]f cancers that affect both men and women, colorectal cancer is the second leading cause of new cancer cases and cancer deaths in New Mexico."

339. Indeed, as of 2017, New Mexico residents have a greater incidence of colorectal cancer deaths than the United States in general.

340. Across 2012-2016, colorectal cancer accounted for 9.7% of all new cancer cases in New Mexico males, which is significantly more than the average national rate of 8.1%.

341. Across 2012-2016, colorectal cancer accounted for 9.7% of all cancer deaths in New Mexico males, which is significantly more than the average national rate of 8.5%.

342. Across 2012-2016, colorectal cancer accounted for 8.2% of all new cancer cases in New Mexico females, which is more than the average national rate of 8.0%.

343. Across 2012-2016, colorectal cancer accounted for 8.9% of all cancer deaths in New Mexico females, which is more than the average national rate of 8.7%.

344. Across 2012-2016, stomach cancer accounted for 2.1% of all new cancer cases in New Mexico males, which is more than the average national rate of 1.6%.

345. Across 2012-2016, stomach cancer accounted for 2.5% of all cancer deaths in New Mexico males, which is more than the average national rate of 2.2%.

346. Across 2012-2016, stomach cancer accounted for 1.4% of all new cancer cases in New Mexico females, which is more than the average national rate of 1.0%.

347. Across 2012-2016, stomach cancer accounted for 2.4% of all cancer deaths in New Mexico females, which is significantly more than the average national rate of 1.6%.

348. As described above, Zantac/ranitidine consumption is also linked to liver injuries.

349. According to the U.S. Centers for Disease Control and Prevention, for 2017, chronic liver disease is the seventh leading cause of death among New Mexico residents.

350. Unfortunately, New Mexico ranks first in the nation on this metric, with the highest rate of deaths caused by liver disease.

COUNT I:
VIOLATIONS OF THE NEW MEXICO UNFAIR PRACTICES ACT, NMSA 1978, SECTIONS 57-12-1 TO -26
(AGAINST THE BRAND MANUFACTURER DEFENDANTS)

351. The State re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

352. This is a claim against the Brand Manufacturer Defendants for restitution, disgorgement, injunctive relief, and civil penalties under the Unfair Practices Act. NMSA 1978, Sections 57-12-1 to -26 (1967, as amended through 2018).

353. Under the Unfair Practices Act, "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce are unlawful." NMSA 1978, Section 57-12-3.

354. An "unfair or deceptive trade practice" is an act "specifically declared unlawful pursuant to the Unfair Practices Act, a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale ... of goods ... by a person in the regular course of the person's trade or commerce, that may, tends to or does deceive or mislead any person." NMSA 1978, Section 57-12-2(D). Omissions of material information, such as potential adverse safety or health risks associated with product use, are actionable under the UPA.

355. Unfair or deceptive trade practices include representing that goods, i.e. Zantac and/or ranitidine products, have characteristics, ingredients, uses, or benefits that they do not have; representing that goods, i.e. Zantac and/or ranitidine products, are of a particular standard, quality, or grade if they are of another; and failing to state a material fact if doing so deceives or tends to deceive. NMSA 1978, Sections 57-12-2(D)(5), (7), (14).

356. An "'[u]nconscionable trade practice' means an act or practice in connection with the sale ... or in connection with the offering for sale ... of any goods ... that to a person's detriment: [] takes advantage of the lack of knowledge, ability, experience or capacity of a person to a grossly unfair degree." NMSA 1978, Sections 57-12-2(E)(1).

357. By designing, packaging, distributing, supplying, marketing, promoting, advertising and/or selling Zantac and/or ranitidine products, the Brand Manufacturer Defendants have willfully engaged in unfair or deceptive trade practices and unconscionable trade practices in violation of the Unfair Practices Act.

358. The Brand Manufacturer Defendants' acts and omissions in violation of the Unfair Practices Act include, *inter alia*:

a. Misrepresenting that Zantac and/or ranitidine have characteristics, uses or benefits that they do not have in violation of NMSA 1978, Section 57-12-2(D)(5);

b. Misrepresenting that Zantac and/or ranitidine is of a particular standard, quality or grade when, in fact, Zantac (ranitidine) was not of that standard, quality or grade in violation of NMSA 1978, Section 57-12-2(D)(7); and

c. Failing to state that Zantac and/or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer, when failing to do so deceives or tends to deceive New Mexico and the citizens of New Mexico in violation of NMSA 1978, Section 57-12-2(D)(14).

359. By marketing and selling unreasonably dangerous products that should never have been marketed and sold in New Mexico at all, the Brand Manufacturer Defendants violated the UPA. Each Brand Manufacturer Defendant unfairly or deceptively marketed its Zantac/ranitidine products as safe, knowing such products were not safe.

360. In addition, the Brand Manufacturer Defendants' knowing misrepresentations in violation of the Unfair Practices Act include, *inter alia*:

a. knowingly concealing from New Mexico and the citizens of New Mexico the dangerous carcinogenic effects of N-Nitrosodimethylamine (NDMA) contained in Zantac and/or ranitidine even though the Brand Manufacturer Defendants knew or should reasonably have known of the dangerous carcinogenic effects of NDMA in Zantac (ranitidine);

b. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that the benefits of such products in treating gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease could outweigh the adverse health risks even though the Brand Manufacturer Defendants knew or should reasonably have known of the dangerous carcinogenic effects of NDMA in Zantac (ranitidine);

c. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that such products did not contain NDMA at levels higher than the FDA's recommended daily allowance even though the Brand Manufacturer Defendants knew or should reasonably have known that a single dose of ranitidine and/or Zantac exceeds the FDA's recommended daily allowance of NDMA;

d. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that persons who consumed Zantac (ranitidine) would not be exposed to dangerous levels of NDMA even though the Brand Manufacturer Defendants knew or should reasonably have known that the consumption of ranitidine and/or Zantac caused users to be exposed to dangerous amounts of NDMA;

e. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that such products were not highly likely to form NDMA when digested by the human body even though the Brand Manufacturer Defendants knew or should reasonably have known that they were;

f. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that the NDMA in such products would not

increase over time resulting in the consumption of unacceptable levels of NDMA even though the Brand Manufacturer Defendants knew or should reasonably have known that they would;

g. representing to New Mexico and the citizens of New Mexico through the design, product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that NDMA in such products would not increase when stored at higher than room temperatures resulting in the consumption of unacceptable levels of NDMA even though the Brand Manufacturer Defendants knew or should reasonably have known that they would;

h. knowingly concealing from New Mexico and the citizens of New Mexico that when ingested, Zantac and/or ranitidine metabolizes and forms high levels of NDMA in the body even though the Brand Manufacturer Defendants knew or should reasonably have known that they would;

i. knowingly concealing from New Mexico and the citizens of New Mexico the connection between ranitidine and/or Zantac and NDMA formation even though the Brand Manufacturer Defendants knew or should reasonably have known that (i) NDMA was highly likely to form in Zantac (ranitidine) when digested by the human body; (ii) the levels of NDMA in Zantac (ranitidine) would increase over time resulting in the consumption of unacceptable levels of NDMA; (iii) NDMA in Zantac (ranitidine) was likely to increase when stored at higher than room temperatures resulting in the consumption of unacceptable levels of NDMA; and (iv) when ingested, Zantac (ranitidine) metabolizes and forms high levels of NDMA in the body;

j. knowingly concealing from New Mexico and the citizens of New Mexico that the levels of NDMA to which Zantac (ranitidine) users would be exposed exceeds levels of NDMA assumed to be non-toxic by regulatory agencies, including the FDA and the EPA, even though the Brand Manufacturer Defendants knew or should reasonably have known that it did;

k. representing to New Mexico and the citizens of New Mexico through the product packaging, promotion, distribution and/or sale of ranitidine and/or Zantac that ranitidine and/or Zantac was safe for human consumption and did not break down into NDMA and other harmful

metabolites in the body even though the Brand Manufacturer Defendants knew or should reasonably have known that Zantac (ranitidine) was not safe for human consumption and breaks down into NDMA and other harmful metabolites in the body;

l. manufacturing, designing, marketing, promoting, distributing and/or selling ranitidine and/or Zantac to New Mexico and the citizens of New Mexico even though the Brand Manufacturer Defendants knew or should reasonably have known that the ranitidine molecule would likely break down into NDMA and other harmful metabolites in the body;

m. packaging, marketing and promoting Zantac and/or ranitidine without disclosing to New Mexico and the citizens of New Mexico the safety risks of Zantac and/or ranitidine, particularly the carcinogenic potential of Zantac and/or ranitidine as it transforms into NDMA within the chemical environment of the human body even though the Brand Manufacturer Defendants knew or should reasonably have known of the safety risks of Zantac and/or ranitidine, particularity the carcinogenic potential of Zantac and/or ranitidine as it transforms into NDMA within the chemical environment of the human body; and

n. packaging, marketing and promoting Zantac and/or ranitidine without disclosing to New Mexico and the citizens of New Mexico that consumption of Zantac and/or ranitidine poses a material risk of adverse health effects, including cancer due to the presence of NDMA.

361. The Brand Manufacturer Defendants made, orally and in writing, unfair or deceptive representations in advertisements, promotions, marketing materials, statements, and product packaging for Zantac (ranitidine) to New Mexico and the citizens of New Mexico regarding the health risks associated with Zantac (ranitidine) in the regular course of their business in violation of NMSA 1978, Sections 57-12-2(D)(5), (7).

362. The Brand Manufacturer Defendants concealed and failed to disclose that Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or

to the adverse health effects associated with NDMA exposure, including cancer, and failing to state these material facts deceived or had a tendency to deceive New Mexico and the citizens of New Mexico in violation of NMSA 1978, Section 57-12-2(D)(14).

363. By way of example only, each misleading and/or deceptive brochure that contained a false or deceptive representation regarding Zantac (ranitidine); each misleading and/or deceptive communication by the Brand Manufacturer Defendants' sales representatives regarding Zantac (ranitidine); each misleading and/or deceptive piece of information provided directly or indirectly by the Brand Manufacturer Defendants regarding Zantac (ranitidine); each misleading and/or deceptive television, print, and/or radio advertisement that reached New Mexico that contained false or deceptive representations regarding Zantac (ranitidine); and each piece of marketing material, including product packaging, used or disseminated in New Mexico that contained false or deceptive representations regarding Zantac (ranitidine) constitutes a separate violation of the Unfair Practices Act pursuant to NMSA 1978, Section 57-12-11.

364. Each such statement or omission and each sale of Zantac (ranitidine) constitutes a separate violation of the Unfair Practices Act pursuant to NMSA 1978, Section 57-12-11.

365. The Brand Manufacturer Defendants' unfair or deceptive trade practices were knowingly and willfully made because the Brand Manufacturer Defendants were actually aware that their products were unreasonably dangerous to all consumers, and that their

statements were unfair or deceptive when made, and/or in the exercise of reasonable diligence, the Brand Manufacturer Defendants should have been aware that their statements were unfair and/or deceptive.

366. The Brand Manufacturer Defendants' unfair or deceptive and/or unconscionable representations in advertisements, brochures, promotions, marketing materials, statements and/or product packaging for Zantac (ranitidine) are of the type that tended to deceive and/or mislead New Mexico and the citizens of New Mexico into believing Zantac (ranitidine) was safe for its intended use.

367. The State of New Mexico seeks all recoverable penalties under NMSA 1978, Section 57-12-11 for violations of the Unfair Practices Act.

COUNT II:
VIOLATIONS OF THE NEW MEXICO FALSE ADVERTISING ACT, NMSA 1978, SECTIONS 57-15-1 TO -10
(AGAINST THE BRAND MANUFACTURER DEFENDANTS)

368. The State re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

369. The State brings this claim against the Brand Manufacturer Defendants under the False Advertising Act, NMSA 1978, Section 57-15-1 to -10 (1965, as amended through 1967), which prohibits "[f]alse advertising in the conduct of any business, trade or commerce."

370. The False Advertising Act defines "false advertising" as "advertising, including labeling, which is misleading in any material respect." The False Advertising

Act instructs that "in determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity to which the advertising relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual." NMSA 1978, Section 57-15-2.

371. As described herein, each Brand Manufacturer Defendant has engaged in false advertising in the conduct of its business, trade or conduct in violation of the False Advertising Act.

372. Each Brand Manufacturer Defendant engaged in false advertising in the course of its marketing of its Zantac and/or ranitidine products in violation of NMSA 1978, Section 57-15-1.

373. Specifically, as described herein, each Brand Manufacturer Defendant's advertising in New Mexico of its Zantac and/or ranitidine products was and is misleading because not once in any of the Brand Manufacturer Defendant's marketing, promotional, or advertising statements described herein, including product packaging, nor in any of the other print, television, radio, digital, or any other form of advertisements, that each Brand Manufacturer Defendant created, developed, funded and ran did any Brand Manufacturer Defendant disclose that use of its Zantac or ranitidine products would expose consumers

to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

374. Each Brand Manufacturer Defendant's advertising in New Mexico of its Zantac and/or ranitidine products was and is misleading because not once on any of the materials affixed to or included with these products did any Brand Manufacturer Defendant disclose that use of its Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the adverse health effects associated with NDMA exposure, including cancer.

375. Pursuant to NMSA 1978, Section 57-15-5, the State of New Mexico seeks injunctive relief in the form of corrective advertising requiring each Brand Manufacturer Defendant to disseminate truthful information about the risks to which New Mexico residents who have consumed Zantac and/or ranitidine are exposed.

376. The False Advertising Act provides that, "[a]ny person, firm, corporation or association or agent or employee thereof who engages in any of the acts or practice made unlawful by the [False Advertising Act] shall be liable to a civil penalty of not more than five hundred dollars ($500) for each violation." NMSA 1978, Section 57-15-4.

377. Each and every time a Brand Manufacturer Defendant created, developed, funded and ran in New Mexico a print, television, radio, digital, or any other form of advertisement for Zantac and/or ranitidine without disclosing that use of its Zantac or ranitidine products would expose consumers to dangerous levels of NDMA or to the

adverse health effects associated with NDMA exposure, including cancer, the Brand Manufacturer Defendant committed a separate and independent violation of the False Advertising Act.

378. Each Brand Manufacturer Defendant has engaged in violations of the False Advertising Act by making misleading statements and by omitting material information from its advertisements and product packaging for Zantac and/or ranitidine.

379. Each Brand Manufacturer Defendant should therefore be assessed a civil penalty in the amount of $500 for each violation of the False Advertising Act.

380. The State notified each Brand Manufacturer Defendant, in compliance with NMSA 1978, Section 57-15-3 by certified mail, prior to initiating this action.

COUNT III:
VIOLATIONS OF THE NEW MEXICO PUBLIC NUISANCE STATUTE, NMSA 1978, SECTIONS 30-8-1 TO -14
(AGAINST ALL DEFENDANTS)

381. The State re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

382. The State brings this claim against all Defendants under the Public Nuisance Statute, NMSA 1978, Sections 30-8-1 to -14 (1963, as amended through 2018).

383. The statute renders unlawful "knowingly creating, performing or maintaining anything affecting any number of citizens without lawful authority which is either (A) injurious to public health, safety, morals or welfare; or (B) interferes with the exercise and enjoyment of public rights[.]" NMSA 1978, Section 30-8-1(A)-(B).

384. The Attorney General is authorized to enforce the statute in court by seeking abatement from "any person, corporation or association of persons who shall create, perform or maintain a public nuisance." NMSA 1978, Section 30-8-8.

385. Each Defendant has knowingly created, performed, or maintained a public nuisance injurious to public health, safety, and welfare, which interferes with the New Mexico public's right to avoid dangerous, carcinogenic substances in prescription and retail products.

386. As alleged above, health ailments associated with ranitidine/Zantac consumption include colorectal cancer, stomach cancer, and other gastrointestinal disorders, as well as liver disease, and State health data confirms that New Mexico residents suffer significant and, indeed, elevated incidences of such disorders.

387. By selling ranitidine/Zantac products in New Mexico, Defendants created a public nuisance that may be abated by a comprehensive medical monitoring program under State supervision.

388. Because Defendants created, performed, or maintained the nuisance over many years, and the adverse health effects of this conduct will be felt for many years to come, Defendants must bear the burden of funding a statewide medical monitoring program designed to detect and assess medical disorders associated with ranitidine/Zantac consumption, such as colorectal cancer, stomach cancer, and other gastrointestinal disorders, and liver disease, under State supervision.

389. In addition, the State seeks all further injunctive relief necessary to abate the public nuisance.

COUNT IV:
COMMON LAW PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

390. The State re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

391. The State brings this claim against all Defendants under the New Mexico common law of public nuisance in its *parens patriae* capacity.

392. A common law public nuisance is an unreasonable interference with a right common to the general public.

393. Each Defendant has created, maintained, or contributed to the creation or maintenance of a public nuisance that unreasonably interferes with the New Mexico public's right to avoid dangerous, carcinogenic substances in prescription and retail products, and exposes New Mexico residents to unreasonable health and safety risks.

394. As alleged above, health ailments associated with ranitidine/Zantac consumption include colorectal cancer, stomach cancer, and other gastrointestinal disorders, as well as liver disease, and State health data confirms that New Mexico residents suffer significant and, indeed, elevated incidences of such disorders.

395. By selling ranitidine/Zantac products in New Mexico, Defendants created a public nuisance that may be abated by a comprehensive medical monitoring program under State supervision.

396. Because Defendants created, maintained, or contributed to the creation or maintenance of the nuisance over many years, and the adverse health effects of this conduct will be felt for many years to come, Defendants must bear the burden of funding a statewide medical monitoring program designed to detect and assess medical disorders associated with ranitidine/Zantac consumption, such as colorectal cancer, stomach cancer, and other gastrointestinal disorders, and liver disease, under State supervision.

397. In addition, the State seeks all further injunctive relief necessary to abate the public nuisance.

COUNT V:
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

398. The State re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

399. The State brings this claim against all Defendants under the New Mexico common law of negligence and in its *parens patriae* capacity.

400. Defendants failed to exercise ordinary care because a reasonably careful company that knew or learned of the presence of toxic and carcinogenic NDMA in its products would not sell or distribute those products.

401. Defendants failed to exercise ordinary care because a reasonably careful company would not continue to sell or distribute such products in mass quantities and to the extent that Defendants sold and distributed Zantac/ranitidine products in New Mexico.

402. Defendants were grossly negligent because they failed to exercise even slight care, placing revenue and profit generation above human health and safety.

403. Defendants owed the State and its citizens a duty of care in the sale and distribution of Zantac/ranitidine products.

404. Defendants' negligent conduct has caused and continues to cause injury to New Mexico and to the physical and economic health and well-being of New Mexico citizens.

405. The State has purchased or paid for Zantac/ranitidine products through a variety of State-funded insurance and healthcare programs over the relevant time period, but would not have done so had Defendants satisfied their duty of care.

406. As a result of the foregoing, the State seeks monetary damages in amounts to be proven at trial.

VI. JURY DEMAND

407. New Mexico respectfully requests trial by jury on all claims so triable.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of New Mexico, requests that judgment be entered against the Defendants, as follows:

408. Damages according to proof;

409. Award of punitive damages sufficient to punish Defendants' malicious, willful, reckless, and/or wanton misconduct and deter others from engaging in similar misconduct in the future;

410. A declaration that each Brand Manufacturer Defendant engaged in conduct in violation of the New Mexico Unfair Practices Act, the New Mexico False Advertising Act, the Public Nuisance Statute, caused, maintained, and/or contributed to a common law public nuisance, and acted negligently;

411. A declaration that each Generic Manufacturer Defendant and each Store Brand Defendant engaged in conduct in violation of the Public Nuisance Statute, caused, maintained, and/or contributed to a common law public nuisance, and acted negligently;

412. An order requiring each Brand Manufacturer Defendant to make restitution to the State, including for losses incurred by the State and by New Mexico residents, as described herein;

413. An order requiring each Brand Manufacturer Defendant to disgorge revenues obtained as a result of violations of law, as described herein;

414. An order requiring each Defendant to abate the public nuisance it caused, maintained, and/or contributed to, including to pay costs of all appropriate abatement measures;

415. An order requiring Defendants to fund a medical monitoring program designed to detect and assess medical disorders associated with use of Zantac/ranitidine, including gastric/colorectal cancer and other gastrointestinal disorders and illnesses or ailments, and liver disorders, known to be caused by Zantac and/or ranitidine, under State supervision;

416. An order requiring each Brand Manufacturer Defendant to pay a civil penalty of $5,000 for each willful violation of the Unfair Practices Act, NMSA 1978, Section 57-12-11;

417. An order requiring each Brand Manufacturer Defendant to pay a civil penalty of $500 for each violation of the False Advertising Act, NMSA 1978, Section 57-15-4;

418. An order requiring each Defendant to pay all interest due and owing under law, including pre-judgment interest and post-judgment interest, on any funds unlawfully detained; and

419. Such other and further relief as the Court deems just and proper.

Dated: June 18, 2020

Respectfully submitted,
HECTOR H. BALDERAS
ATTORNEY GENERAL OF NEW MEXICO

/s/ Brian E. McMath
P. Cholla Khoury
Brian McMath
Assistant Attorneys General

P.O. Drawer 1508
Santa Fe, New Mexico 87504-1508
ckhoury@nmag.gov
bmcmath@nmag.gov
Tel.: 505.717.3500

IN THE FIRST JUDICIAL DISTRICT COURT, COUNTY OF SANTA FE
STATE OF NEW MEXICO

STATE OF NEW MEXICO, *ex rel.* HECTOR H. BALDERAS, Attorney General, **Plaintiff,** **v.** **GLAXOSMITHKLINE LLC; PFIZER INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; CHATTEM, INC.; SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; PERRIGO RESEARCH & DEVELOPMENT COMPANY; LANNETT COMPANY, INC.; NOVITIUM PHARMA LLC; AUROBINDO PHARMA USA, INC.; AMNEAL PHARMACEUTICALS, LLC; GLENMARK PHARMACEUTICALS INC., USA; APPCO PHARMA LLC; ANI PHARMACEUTICALS, INC.; SANDOZ INC.; APOTEX CORP.; DR. REDDY'S LABORATORIES, INC.; STRIDES PHARMA, INC.; TELIGENT, INC.; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; THE KROGER CO.; SMITH'S FOOD & DRUG CENTERS, INC.; FRED MEYER, INC.; TARGET CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WALGREENS CO.; WALMART INC., AND COSTCO WHOLESALE CORP.,** **Defendants.**	No. D-101-CV-2020-01289

VERIFICATION OF BRIAN E. MCMATH
PURSUANT TO NMSA 1978, Section 30-8-8 (1978)

STATE OF NEW MEXICO)
) S.S.
COUNTY OF SANTA FE)

I, Brian E. McMath, being duly sworn, do hereby state as follows:

1. I am an Assistant Attorney General in the New Mexico Attorney General's Office. The State of New Mexico ("Plaintiff"), by the Honorable Hector H. Balderas, the Attorney General of the State of New Mexico, has filed the above-captioned action pursuant to its inherent *parens patriae* authority, as well as pursuant to its statutory authority. I am authorized to make this Verification pursuant to NMSA 1978, Section 30-8-8 (1978) on behalf of Plaintiff.

2. To the extent the allegations in the Complaint concern facts related to Plaintiff, I know those allegations to be true. To the extent the allegations in the Complaint concern facts and actions of parties other than Plaintiff, I believe those allegations to be true and correct, to the best of my knowledge, information and belief.

I make this Verification under penalty of perjury that the foregoing is true and correct.

Executed this *18th* day of *June*, 2020.

_____

/s/ Brian E. McMath
Assistant Attorney General
New Mexico Attorney General's Office

EXHIBIT A

EXHIBIT A: GLOSSARY

1. **Amine**: any member of a family of nitrogen-containing organic compounds that is derived from ammonia (NH_3).

2. **Chloramination**: a water treatment technique consisting of dosing a controlled amount of ammonia to chlorinated water.

3. **Cimetidine**: an H2-receptor blocker/antagonist used to treat gastroesophageal reflux disease and other gastric disorders.

4. **Gastroesophageal reflux disease (GERD)**: acid reflux.

5. **GC/MS**: gas chromatography/mass spectrometry; an analytical method combining the features of gas chromatography and mass spectrometry to identify different substances within a test sample.

6. **Genotoxic**: the ability of chemicals to damage the generic information within a cell resulting in mutations, which may lead to malignancies.

7. **H2-receptor blocker/antagonist**: any member of a class of medications used to treat conditions that cause excess stomach acid; the class includes ranitidine (Zantac) and cimetidine (Tagamet), among others.

8. **Mutagen**: A physical or chemical agent that alters genetic material, potentially harming cells. Mutagens are typically responsible for causing cancers.

9. **Nitrosamine (N-nitrosamine)**: a class of chemical compounds with the chemical structure $R_2N—N=O$.

10. **Nitrosation**: a process of converting organic compounds into nitroso derivatives.

11. **Nitroso derivatives**: chemical compounds containing the R—NO functionality.

12. **N-nitrosodimethylamine (NDMA)**: an organic compound with the formula $(CH_2)_2NNO$. NDMA is a member of the class of nitrosamines.

13. **Ranitidine**: an H2-receptor blocker/antagonist used to treat gastroesophageal reflux disease and other gastric disorders.

14. **Tagamet**: brand name for cimetidine.

15. **Zantac**: brand name for ranitidine.