UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
/ MAGISTRATE JUDGE BRUCE E. REINHART

CONSOLIDATED THIRD PARTY PAYOR CLASS COMPLAINT

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Plaintiffs file this Consolidated Third Party Payor Class Complaint ("CTPPC") against the Defendants identified below. Plaintiffs NECA-IBEW Welfare Trust Fund, Plumbers & Pipefitters Local Union 630 Welfare Fund and Indiana Laborers Welfare Fund (collectively, "Plaintiffs") bring this consolidated action on behalf of themselves and all others similarly situated against the Defendants named herein (collectively, "Defendants") for damages and equitable relief to address the harms caused by Defendants' design, manufacture, false marketing, packaging, handling, distribution, storage, and/or sale of prescription ranitidine-containing medication, including both the brand-name medication, Zantac, and its various generic forms (collectively, "Ranitidine-Containing Products"). As more particularly set forth herein, Plaintiffs maintain that, as a direct and proximate result of Defendants' actions, Plaintiffs and Third Party Payor ("TPP" or "TPPs") Class members paid or reimbursed for Ranitidine-Containing Products when they otherwise would not have because the Ranitidine-Containing Products were defective, dangerous to human health, unfit and unsuitable to be sold in the United States, were manufactured improperly, stored and distributed improperly, and lacked proper warnings of the dangers associated with their use.

INTRODUCTION

1. From 1983 until 2020 when Ranitidine-Containing Products were pulled from shelves following the U.S. Food and Drug Administration ("FDA")'s confirmation of "unacceptable levels" of a known carcinogen, Defendants made billions of dollars by uniformly deceiving millions into purchasing and ingesting a defective, misbranded, adulterated, and harmful drug that would not have been available for sale in the U.S. Through their failures in design, manufacture, marketing, packaging, labeling, handling, distribution, storage, and/or sale of Ranitidine-Containing Products, each Defendant in the pharmaceutical supply chain violated federal law and/or state law. As a direct and proximate result of Defendants' unlawful conduct

alleged herein, Plaintiffs and the Class (defined below), suffered economic losses for the reimbursement and/or purchase of economically worthless Ranitidine-Containing Products.

2. Zantac was one of the most widely prescribed prescription and Over-the-Counter ("OTC") heartburn and indigestion medications on the market.[1] It was the first-ever "blockbuster" drug to reach $1 billion in sales. Zantac's unprecedented sales were made possible only because of a deceptive and unlawful scheme to defraud the public regarding the purported safety of Ranitidine-Containing Products and to conceal the known dangers and risks associated with these products.

3. As alleged herein, the Brand-Name Manufacturer Defendants (defined below) engaged in a uniform national, pervasive, and decades-long campaign of misrepresentations and omissions designed to conceal the inherent dangers and risks associated with ranitidine use and to hide the fact that Zantac was not safe. Through product labels and packaging; print, TV, radio, and online advertising; Internet websites; and social media, the Brand-Name Manufacturer Defendants uniformly represented that Zantac was safe, e.g., so safe that it could be used frequently, for chronic conditions, and for fast relief with nitrite- and nitrate-rich foods (i.e. foods that induce heartburn).

4. These representations were false, deceptive, and misleading when made, and they omitted material facts known to Defendants regarding the true risks of Ranitidine-Containing Products. Contrary to the Brand-Name Manufacturer Defendants' misrepresentations, ranitidine is a dangerous chemical that is unsafe and unfit for human consumption. The ranitidine molecule

[1] The Ranitidine-Containing Products at issue in the CTPPC are prescription drugs, but much of the information contained in marketing and regulatory submissions were common to both prescription and OTC products as referenced herein.

itself is unstable and has a propensity to degrade into high levels of N-Nitrosodimethylamine ("NDMA"), a chemical the World Health Organization ("WHO") has described as "***clearly carcinogenic***."[2]

5. NDMA was discovered through the manufacture of rocket fuel. Its only use today is to cause cancer in laboratory animals. While any exposure to NDMA can be harmful, the FDA has set the maximum allowable daily limit of NDMA to 96 nanograms (ng). For comparison, one filtered cigarette contains between 5 to 43 ng of NDMA. Tests of ranitidine revealed NDMA levels as high as 304,500 ng per tablet, which is 3,171 times the maximum daily limit.

6. The breakdown process of ranitidine into NDMA is accelerated and/or exacerbated by exposure to heat during the manufacturing, transportation, and/or storage processes. Each Defendant in the pharmaceutical supply chain failed to (1) comply with "current Good Manufacturing Practices" ("cGMPs") to ensure their products meet safety, quality, purity, identity, and strength standards; (2) conduct stability testing of their Ranitidine-Containing Products to assess the stability characteristics of those products and ensure bioequivalence; (3) take necessary steps to ensure proper manufacture, transportation, handling, and storage of their Ranitidine-Containing Products so as to avoid exposure to heat; and (4) to disclose these material facts to purchasers of the drug.

7. Defendants knew or should have known of the instability of the ranitidine molecule that has a propensity to break down under normal conditions into dangerous NDMA, and that this breakdown process is made worse when ranitidine is used in the directed manner or when it is

[2] R.G. Liteplo, et al., Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine, WORLD HEALTH ORGANIZATION (2002), available at https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf (last accessed June 20, 2020).

exposed to heat. Indeed, in 1981 – two years before Zantac hit the market – Dr. Silvio de Flora published the results of experiments exposing ranitidine to human gastric fluid in combination with nitrites, which showed "toxic and mutagenic effects[.]"[3] As a result, Dr. de Flora cautioned that "it would seem prudent to … suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals[.]" *Id.*

8. Brand-Name Manufacturer Defendant GlaxoSmithKline ("GSK"), the originator of the ranitidine molecule, had actual knowledge of this study. Rather than investigate the concerns raised in Dr. de Flora's study to ensure its product was safe and not harmful to users, GSK attempted to discredit the study. Two weeks after its publication, GSK responded to Dr. de Flora's findings, claiming that the levels of nitrite needed to induce the production of NDMA were unrealistic and not likely to be experienced in the real world and, thus, the results had no "practical clinical significance."[4] Numerous other studies raised concerns over ranitidine and cancerous nitroso compounds. GSK attempted to parry these studies with its own studies that were clearly rigged in order to avoid reaching the same undeniable conclusion: ranitidine breaks down into carcinogenic NDMA when used in the manner Defendants directed. In the study that was presented to the FDA for approval of Zantac, however, GSK admitted that ranitidine could convert into NDMA and cause cancer, but GSK dismissed this risk because Ranitidine-Containing Products were purportedly intended to be used for a short-term period. These material facts were known, or should have been known, by each Defendant, which was duty-bound to investigate the

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

[4] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

potential dangers and risks associated Ranitidine-Containing Products and to ensure that such products were safe for human consumption.

9. Despite Defendants' knowledge of these material facts related to the dangers and risks associated with the use of Ranitidine-Containing Products, which were well known and widely available to the scientific community but not the public, Defendants did not disclose to consumers, nor to Plaintiffs and the Class, that their Ranitidine-Containing Products were unsafe, that the ranitidine molecule has a propensity to break down into carcinogenic NDMA, and that their Ranitidine-Containing Products were manufactured in such a way it rendered them adulterated, misbranded, and therefore illegal to sell and economically worthless. To the contrary, Defendants made affirmative misrepresentations to Plaintiffs and the Class regarding each of these material facts and the safety of ranitidine in general, which further created a duty for Defendants to disclose these material facts.

10. In 2019, an analytical pharmacy ("Valisure") ran tests on Zantac and discovered the link between ranitidine and NDMA and that ranitidine itself is unstable and can break down into NDMA, particularly in the environment of the stomach. On September 13, 2019, Valisure filed a citizen petition with the FDA asking the agency to recall all products that contain ranitidine. Valisure provided copies of the petition to the WHO and the International Agency for the Research of Cancer ("IARC"). Less than a month later, in early October 2019, the FDA ordered testing on Ranitidine-Containing Products and specified the protocols for such testing. Within days of the FDA's announcement, certain Brand-Manufacturing Defendants recalled all their Ranitidine-Containing Products in the U.S. and internationally. On November 1, 2019, the FDA announced that its recent testing showed "unacceptable levels" of NDMA in Ranitidine-Containing Products and requested that all manufacturers recall their Ranitidine-Containing Products. Ultimately, on

April 1, 2020, the FDA called for a withdrawal of all Ranitidine-Containing Products from in the United States, citing unacceptable levels of NDMA in those drugs.

11. By designing, manufacturing, distributing, packaging, labeling, marketing, and/or selling Ranitidine-Containing Products without adequate labels and warnings; failing to ensure the proper conditions for the manufacture, transportation, handling, and storage of Ranitidine-Containing Products; and misrepresenting and not disclosing material facts regarding the safety of Ranitidine-Containing Products, that the drugs were adulterated and misbranded, illegal to sell, and economically worthless, Defendants violated federal and/or state law and common law, as alleged herein.

12. As a direct and proximate result of Defendants' violations of law, Plaintiffs and other members of the Class have suffered economic losses from making payments or reimbursements for purchases of a product that should not have been available for sale in the U.S., for which they would not have made payments or reimbursements, but for Defendants' unlawful conduct.

13. As detailed below, Plaintiffs, individually and on behalf of the Class assert claims for violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1962(c)-(d), the Magnuson-Moss Warranty Act, 15 U.S.C. §2301, *et seq.*, and state consumer protection laws; breach of express and implied warranties; fraud; negligence; and unjust enrichment.

14. As detailed below, Plaintiffs, individually and on behalf of the Class, seek redress for their economic losses they suffered because they made payments or reimbursements for a product that was economically worthless, and to strongly deter the type of misconduct that gave rise to their injuries suffered by Plaintiffs and the Class.

JURISDICTION AND VENUE

15. This Court has original subject-matter jurisdiction over this action under 28 U.S.C. §1331 (federal question) and 18 U.S.C. §1964 (civil remedies). This Court also has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005, 28 U.S.C. §1332(d)(2), because: (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interest and costs; and (c) at least one Plaintiff is a citizen of a different state than at least one Defendant. In addition, this Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. §1367.

16. This Court has personal jurisdiction over Defendants under Fla. Stat. Ann. §48.193 and 18 U.S.C. §1965(b) and (d). This Court also has pendent personal jurisdiction over Defendants.

17. In addition and/or in the alternative, Defendants and/or their agents or alter egos each have significant contacts with each of the States and territories of the United States because they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products within each of the States and territories of the United States, and/or they derived revenue from the sale of their Ranitidine-Containing Products in each of the States and territories of the United States, through the purposeful direction of their activities to the States and territories of the United States and purposeful availment of the protections of the laws of the States and territories of the United States, such that personal jurisdiction would be proper in those States and territories under traditional notions of fair play and substantial justice.

18. In addition and/or in the alternative, the district to which each Plaintiff's action may be remanded upon conclusion of these pretrial proceedings pursuant to 28 U.S.C. §1407(a) will have personal jurisdiction over the Defendants who themselves or through an agent or alter ego

are incorporated within that district, have a principal place of business in that district, or conduct a substantial amount of business in that district, such that they are essentially at home in that district, or who have sufficient minimum contacts with that district through the purposeful direction of their activities to that district and/or purposeful availment of the protections of the laws of that district, such that personal jurisdiction would be proper in that district under traditional notions of fair play and substantial justice.

19. Venue is proper in this District under 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, and otherwise conducted extensive business, within this District, and Plaintiffs reimbursed for Defendants' Ranitidine-Containing Products in this District. In addition and/or in the alternative, venue is proper under 28 U.S.C. §1407(a) and the Conditional Transfer Orders of the Judicial Panel on Multidistrict Litigation.

PARTIES

I. PLAINTIFFS

A. NECA-IBEW Welfare Trust Fund

20. Plaintiff, NECA-IBEW Welfare Trust Fund ("NECA-IBEW"), is a duly organized and existing 501(c)(9) tax-exempt trust that qualifies as a multiple employer welfare benefit plan. NECA-IBEW was organized in Illinois and has its principal place of business in Decatur, Illinois.

21. NECA-IBEW is established for the sole purpose of funding a plan of benefits, both on a self-funded basis and through the purchase of policies of insurance. NECA-IBEW provides eligible members and their dependents with retirement and health and welfare benefits, including prescription drug care benefits.

22. NECA-IBEW pays for and/or reimburses prescription drugs on behalf of its 29,000 members and their dependents throughout the country, and has members who have filled prescriptions requiring reimbursement for Defendants' Ranitidine-Containing Products in at least Alabama, Arizona, Colorado, Florida, Georgia, Iowa, Illinois, Indiana, Kentucky, Louisiana, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, Nebraska, New Jersey, New Mexico, Nevada, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Wisconsin, and Wyoming.

B. Plumbers & Pipefitters Local Union 630

23. Plaintiff, Plumbers & Pipefitters Local Union 630 Welfare Fund ("Plumbers 630"), is a duly organized and existing 501(c)(3) tax-exempt trust that qualifies as a not for profit self-funded welfare benefit plan. Plumbers 630 was organized in Florida and has its principal place of business in West Palm Beach, Florida.

24. Plumbers 630 is established for the sole purpose of funding a plan of benefits on a self-funded basis. Plumbers 630 provides eligible members with health and welfare benefits, including prescription drug care benefits.

25. Plumbers 630 pays for and/or reimburses prescription drugs on behalf of its 1,000 members and their dependents throughout the country and has members who have filled prescriptions requiring reimbursement for Defendants' Ranitidine-Containing Products in at least Alabama, Florida, Georgia, Illinois, Louisiana, Maryland, North Carolina, Pennsylvania, Tennessee, and Texas.

C. Indiana Laborers Welfare Fund

26. Plaintiff, Indiana Laborers Welfare Fund ("Indiana Laborers"), is a duly organized and existing 501(c)(9) tax-exempt trust that administers a self-funded employee welfare benefit plan. The Fund was organized in Indiana and has its principal place of business in Indiana.

27. Indiana Laborers is established for the sole purpose of funding a plan of benefits, both on a self-funded basis and through the purchase of policies of insurance. Indiana Laborers provides eligible members with various retirement, health and welfare benefits, including prescription drug care benefits.

28. Indiana Laborers pays for and/or reimburses prescription drugs on behalf of its 23,000 members and their dependents throughout the country and has members who have filled prescriptions requiring reimbursement for Defendants' Ranitidine-Containing Products in at least Alabama, Arizona, Florida, Georgia, Illinois, Indiana, Kentucky, Maryland, Michigan, Missouri, Ohio, and Texas.

II. DEFENDANTS

29. Defendants are collectively composed of entities that invented, made, distributed, labeled, marketed, advertised, distributed, stored, and sold ranitidine.

A. Brand-Name Manufacturer Defendants

1. GlaxoSmithKline (GSK)

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

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

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

33. GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are subsidiaries of GlaxoSmithKline plc. Collectively, these entities shall be referred to as "GSK."

2. Boehringer Ingelheim (BI)

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

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

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

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

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

39. Boehringer Ingelheim Pharmaceuticals, Inc. is a direct or indirect subsidiary of Boehringer Ingelheim Corporation and Boehringer Ingelheim USA Corporation, which are themselves wholly owned, directly or indirectly, by Boehringer Ingelheim USA Corporation. Collectively, these entities shall be referred to as "Boehringer Ingelheim" or "BI."[5]

3. Pfizer

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

4. Sanofi

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

[5] Boehringer Ingelheim also manufactured generic ranitidine under ANDA 074622, as well as through its former subsidiary Ben Venue Laboratories, Inc., d/b/a Bedford Laboratories (ANDA 074764). Ben Venue Laboratories Inc. is no longer in operation.

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

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

44. Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are subsidiaries of Sanofi S.A.. Collectively, these entities shall be referred to as "Sanofi."

* * *

45. Defendants BI, GSK, Pfizer, and Sanofi, shall be referred to collectively as the "Brand-Name Manufacturer Defendants." At all relevant times, the Brand-Name Manufacturer Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, and sale of Zantac within each of the States of the United States, the District of Columbia, and Puerto Rico.[6]

B. GENERIC MANUFACTURER DEFENDANTS

1. Ajanta

46. Defendant Ajanta Pharma USA Inc. is a New Jersey corporation with its principal place of business located at 440 U.S. Highway 22, Suite 150, Bridgewater, New Jersey 08807. Ajanta Pharma USA Inc.is a citizen of New Jersey.

[6] All references to "States" herein includes the District of Columbia and Puerto Rico.

47. Defendant Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India with its principal place of business located in 9 Ajanta House Charkop, Kandivili (West), Mumbai, Maharashtra, India. Ajanta Pharma Ltd. is a citizen of India.

48. Ajanta Pharma USA Inc. is a subsidiary of Ajanta Pharma Ltd. Collectively, these entities shall be referred to as "Ajanta."

49. Defendant Ajanta Pharma Ltd. purchased ranitidine and repackaged and/or relabeled it under Defendant Ajanta Pharma Ltd.'s own brand, therefore all allegations referring to "Repackagers" apply to Defendant Ajanta.

2. Amneal

50. Defendant Amneal Pharmaceuticals LLC is a Delaware limited liability company with its principal place of business located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807. The sole member of Amneal Pharmaceuticals, LLC is Amneal Pharmaceuticals, Inc., a Delaware Corporation with its principal place of business in New Jersey. Amneal Pharmaceuticals LLC is a citizen of Delaware and New Jersey.

51. Defendant Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company with its principal place of business located at 50 Horseblock Road, Brookhaven, New York 11719. The membership interest of Amneal Pharmaceuticals of New York, LLC is owned by Amneal Pharmaceuticals, Inc., through an intervening limited liability company. Amneal Pharmaceuticals of New York, LLC is a citizen of Delaware and New Jersey.

52. Defendant Amneal Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807. Defendant Amneal Pharmaceuticals, Inc. is a citizen of Delaware and New Jersey.

53. Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC, are subsidiaries of Amneal Pharmaceuticals, Inc. Collectively, these entities shall be referred to as "Amneal."

54. Defendant Amneal purchased ranitidine and repackaged and/or relabeled it under Defendant Amneal's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Amneal.

3. Apotex

55. Defendant Apotex Corporation is a Delaware corporation with its principal place of business located at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex Corporation is a citizen of Delaware and Florida.

56. Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada with its principal place of business located at 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada. Apotex Inc. is a citizen of Canada.

57. Apotex Corporation is a subsidiary of Apotex Inc. Collectively, these entities shall be referred to as "Apotex."

58. Defendant Apotex purchased ranitidine and repackaged and/or relabeled it under Defendant Apotex's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Apotex.

4. Aurobindo

59. Defendant Auro Health LLC is a New Jersey limited liability company with is principal place of business located at 2572 U.S. Highway 1, Lawrenceville, New Jersey 08648. The sole member of Aurohealth LLC is Aurobindo Pharma USA, Inc., a Delaware corporation

with its principal place of business located in New Jersey. Auro Health LLC is a citizen of Delaware and New Jersey.

60. Aurobindo Pharma USA, Inc. is a Delaware corporation with its principal place of business located at 279 Princeton Highstown Road, East Windsor, New Jersey 08520. Aurobindo Pharma USA, Inc. is a citizen of Delaware and New Jersey.

61. Defendant Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India. Aurobindo Pharma, Ltd. is a citizen of India.

62. Aurohealth LLC and Aurobindo Pharma USA, Inc. are subsidiaries of Aurobindo Pharma, Ltd. Collectively, these entities shall be referred to as "Aurobindo."

63. Defendant Aurobindo purchased ranitidine and repackaged and/or relabeled it under Defendant Aurobindo's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Aurobindo.

5. Contract Pharmacal

64. Defendant Contract Pharmacal Corp. is a New York corporation with its principal place of business located at 135 Adams Avenue, Hauppauge, New York 11788. Contract Pharmacal Corp. is a citizen of New York.

6. Dr. Reddy's

65. Defendant Dr. Reddy's Laboratories Inc. is a New Jersey corporation with its principal place of business located at 107 College Road East, Princeton, New Jersey 08540. Dr. Reddy's Laboratories Inc. is a citizen of New Jersey.

66. Defendant Dr. Reddy's Laboratories, Ltd. is corporation organized and existing under the laws of India with its principal place of business located at 8-2-337, Road No. 3, Banjara Hills, Hyderabad Telangana 500 034, India. Dr. Reddy's Laboratories, Ltd. is a citizen of India.

67. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories, Ltd. are subsidiaries of Dr. Reddy's Laboratories SA. Collectively, these entities shall be referred to as "Dr. Reddy's."

68. Defendant Dr. Reddy's purchased ranitidine and repackaged and/or relabeled it under Defendant Dr. Reddy's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Dr. Reddy's.

7. Geri-Care

69. Defendant Geri-Care Pharmaceuticals, Corp. is a New York corporation with its principal place of business located at 1650 63rd Street, Brooklyn, New York 11204. Geri-Care Pharmaceuticals, Corp. is a citizen of New York.

70. Defendant Geri-Care Pharmaceuticals, Corp. purchased ranitidine and repackaged and/or relabeled it under Defendant Geri-Care Pharmaceutical's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Geri-Care Pharmaceuticals, Corp.

8. Glenmark

71. Defendant Glenmark Pharmaceuticals, Inc., USA is a Delaware corporation with its principal place of business located at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark Pharmaceuticals, Inc., USA is a citizen of Delaware and New Jersey

72. Glenmark Pharmaceuticals, Inc., USA is a subsidiary of Glenmark Pharmaceuticals Ltd. Collectively, these entities shall be referred to as "Glenmark."

73. Defendant Glenmark purchased ranitidine and repackaged and/or relabeled it under Defendant Glenmark's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Glenmark.

9. Heritage

74. Defendant Heritage Pharma Labs Inc. is a New Jersey corporation with its principal place of business located at 21 Cotters Lane, Suite B, East Brunswick, New Jersey, 08816-2050. Heritage Pharma Labs Inc. is a citizen of New Jersey.

75. Defendant Heritage Pharmaceuticals, Inc. is a New Jersey corporation with its principal place of business located at 21 Cotters Lane, Suite B, East Brunswick, New Jersey 08816-2050. Heritage Pharmaceuticals, Inc. is a citizen of New Jersey.

76. Heritage Pharma Labs Inc. and Heritage Pharmaceuticals, Inc. are subsidiaries of Emcure Pharmaceuticals Ltd. Collectively, these entities shall be referred to as "Emcure."

10. Hi-Tech

77. Defendant Hi-Tech Pharmacal Co., Inc. is a Delaware corporation with its principal place of business located at 369 Bayview Avenue, Amityville, New York 11701. Hi-Tech Pharmacal Co., Inc. is a citizen of Delaware and New York.

11. Lannett

78. Defendant Lannett Co., Inc. is a Delaware corporation with its principal place of business located at 9000 State Road, Philadelphia, Pennsylvania 19136. Lannett Co., Inc. is a citizen of Delaware and Pennsylvania.

79. Defendant Lannett purchased ranitidine and repackaged and/or relabeled it under Defendant Lannett's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Lannett.

12. Mylan

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

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

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

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

84. Mylan Pharmaceuticals, Inc., Mylan Institutional LLC, Mylan Laboratories Ltd., and Mylan, Inc. are subsidiaries of Mylan N.V., a non-party. Collectively, these entities shall be referred to as "Mylan."

85. Defendant Mylan purchased ranitidine and repackaged and/or relabeled it under Defendant Mylan's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Mylan.

13. Nostrum

86. Defendant Nostrum Laboratories Inc. is a New Jersey corporation with its principal place of business located at 1370 Hamilton Street, Somerset, New Jersey 08873. Nostrum Laboratories Inc. is a citizen of New Jersey.

87. Nostrum Laboratories Inc. is a subsidiary of Nostrum Investments, Inc., a non-party. These entities shall be referred to as "Nostrum."

88. Defendant Nostrum purchased ranitidine and repackaged and/or relabeled it under Defendant Nostrum's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Nostrum.

14. PAI

89. Defendant PAI Holdings, LLC f/k/a Pharmaceutical Associates, Inc., is a South Carolina limited liability company with its principal place of business located at 1700 Perimeter Road, Greenville, South Carolina 29605. Upon information and belief, the member(s) of PAI Holdings, LLC and the company itself are citizens of South Carolina.

15. Par Pharmaceutical

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

91. Par Pharmaceutical Inc. is a subsidiary of Endo International PLC, a non-party. Collectively, these entities are referred to as "Par."

16. Sandoz

92. Defendant Sandoz Inc. is a Colorado corporation with its principal place of business located at 100 College Road West, Princeton, New Jersey 08540. Sandoz Inc. is a citizen of Colorado and New Jersey.

93. Sandoz Inc. is a subsidiary of Novartis AG, a non-party; and these entities shall be referred to as "Novartis."

17. Strides

94. Defendant Strides Pharma, Inc. is a New Jersey corporation with its principal place of business located at 2 Tower Center Boulevard, Suite 1102, East Brunswick, New Jersey 08816. Strides Pharma, Inc. is a citizen of New Jersey.

95. Defendant Strides Pharma Global Pte. Ltd. is a corporation organized and existing under the laws of Singapore with its principal place of business located at 8 Eu Tong Sen Street, #15-93, The Central, Singapore 059818. Strides Pharma Global Pte. Ltd. is a citizen of Singapore.

96. Defendant Strides Pharma Science Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560 076, India. Strides Pharma Science Ltd. is a citizen of India.

97. Strides Pharma, Inc., Strides Pharma Global Pte. Ltd, and Strides Pharma Science Ltd. are subsidiaries of Strides Arcolab International Ltd., a non-party. Collectively, these entities shall be referred to as "Strides."

98. Defendant Strides purchased ranitidine and repackaged and/or relabeled it under Defendant Strides' own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Strides.

18. Taro

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

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

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

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

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

104. Taro Pharmaceuticals U.S.A., Inc., Ranbaxy Inc., Sun Pharmaceutical Industries, Inc. (f/k/a Ranbaxy Pharmaceuticals Inc.), and Sun Pharmaceutical Industries Ltd. are subsidiaries of Taro Pharmaceutical Industries Ltd. Collectively, these entities shall be referred to as "Taro Pharmaceutical."

19. Teva

105. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business located at 1877 Kawai Rd., Lincolnton, North Carolina 28092. The membership interest of Actavis Mid Atlantic LLC is owned by Teva Pharmaceuticals U.S.A., Inc., either directly or through an intervening limited liability company. Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business in Pennsylvania. Actavis Mid Atlantic LLC is a citizen of Delaware and Pennsylvania.

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

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

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

109. Actavis Mid Atlantic LLC, Teva Pharmaceuticals U.S.A., Inc., and Watson Laboratories, Inc. are subsidiaries of Teva Pharmaceutical Industries Ltd. Collectively, these entities shall be referred to as "Teva."

20. Torrent

110. Defendant Torrent Pharma Inc. is a Delaware corporation with its principal place of business located at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920. Torrent Pharma Inc. is a citizen of Delaware and New Jersey.

111. Torrent Pharma Inc. is a subsidiary of Torrent Pharmaceuticals, Ltd., a non-party, and shall be referred to as "Torrent."

21. Wockhardt

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

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

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

115. Wockhardt USA LLC and Wockhardt USA, Inc. are subsidiaries of Wockhardt, Ltd. Collectively, these entities shall be referred to as "Wockhardt."

116. Defendant Wockhardt purchased ranitidine and repackaged and/or relabeled it under Defendant Wockhardt's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Wockhardt.

22. Zydus-Cadila

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

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

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

120. Defendant Zydus-Cadilla purchased ranitidine and repackaged and/or relabeled it under Defendant Zydus-Cadilla's own brand. Therefore all allegations referring to the "Repackagers" apply to Defendant Zydus-Cadilla.

* * *

121. The Defendants identified in paragraphs 36 to 120 above shall be referred to collectively as the "Generic Manufacturer Defendants." At all relevant times, the Generic Manufacturer Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, distribution, storage and/or sale of Ranitidine-Containing Products within each of the States and Territories of the United States.

FACTUAL ALLEGATIONS

I. Pharmaceutical Drug Reimbursement

122. The pharmaceutical supply chain in the United States consists of the following major actors: pharmaceutical manufacturers, repackagers, relabelers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

123. Pharmaceutical manufacturers produce drugs which they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. TPPs reimburse for these drugs.

124. TPP refers to those entities, other than government agencies, that pay the vast majority of the purchase price of prescription medications on behalf of a group of beneficiaries. TPPs include health insurance plans, as well as Taft-Hartley union health and welfare funds, and self-funded employers with active employee and/or retiree benefit programs.

125. TPPs provide medical and pharmacy benefits to a wide range of organizations nationally, including employers, state and local governments and Medicaid programs.

126. PBMs are organizations that provide services to TPPs, such as Plaintiffs, for the purpose of providing pharmacy benefits. Rather than processing their own pharmacy claims, most health plans contract with a PBM for this purpose. Likewise, some employers choose to contract directly with a PBM for the management of their pharmacy benefit, rather than acquiring pharmacy benefits through a health plan.

127. There are more than fifty-five PBMs currently operating in the United States and the range of services provided by these individual companies is substantially similar. All PBMs provide point-of-service claim processing services as described below. In addition, PBMs may contract with retail pharmacies, provide mail order pharmacy services, negotiate rebates with drug manufacturers, develop formularies, and conduct drug utilization review activities.

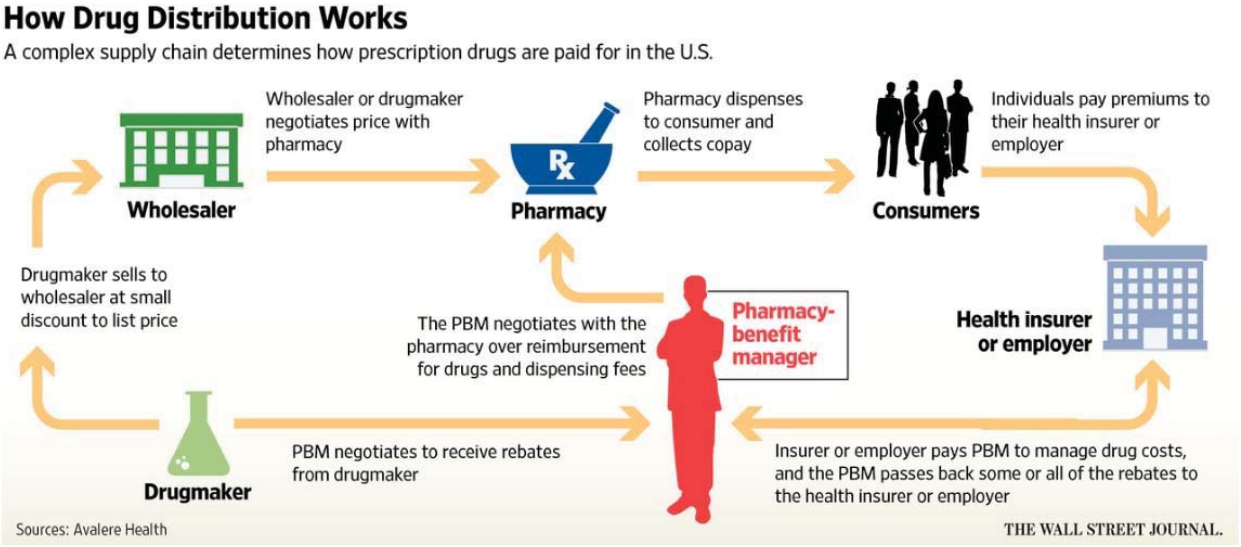
128. Electronic data interchanges ("EDIs") serve to route the pharmacy claim from the pharmacy, where the claim is generated, to the appropriate payer. This process is completed in the same manner as many forms of electronic claim transmission for credit card and banking procedures through direct managed network connection options, frame relay and Virtual Private Network ("VPN") technology.

A. Coverage of Pharmaceutical Drugs

129. A drug formulary is a list of brand-name and generic prescription drugs that are approved to be prescribed by a particular health insurance policy, or in a specific health system or hospital. Drug formularies are developed based on the efficacy, safety and cost of the drugs. Formularies list both generic and brand-named pharmaceutical products for coverage.

130. The Pharmacy & Therapeutics Committee ("P&T Committee") is an entity established by TPPs and/or PBMs for the purpose of evaluating products that are being considered for formulary placement and developing programs to promote appropriate utilization of pharmaceuticals. The use of P&T Committees is a requirement for health plan accreditation and is widely used and accepted as the basis for decisions related to a TPP or PBM's formulary. P&T Committees are an established component of health care delivery throughout the TPP sector, including at PBMs, health plans, and government agencies.

131. The following chart, published by the Wall Street Journal[7], broadly illustrates the pharmaceutical supply chain:



132. When a patient presents his/her prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBMs for reimbursement. PBMs then cumulate those individual reimbursements and present them to TPPs for payment.

B. Drug Manufacturers Provide Marketing Materials to TPPs for Formulary Placement

133. Placing a drug on a formulary is primarily a clinical decision. The TPP's P&T Committee and/or the P&T Committee of its contracted PBM will review the product indications, Manufacturer labeling information, and Manufacturer medication guides for the product and any comments associated with the approval of the products.

[7] Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), available at https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336 (last accessed June 15, 2020).

134. Also, when available, the P&T Committee compares the product to other agents in the appropriate therapeutic category or with comparable clinical uses.

135. Drug Manufacturers often submit a formulary dossier (also called "monograph") about the product, which is used by the P&T Committee during the review process. These formulary dossiers and/or monographs are often referred to as "AMCP Dossiers." AMCP stands for the Academy of Managed Care Pharmacy.

136. Drug Manufacturers use various common strategies to influence plans' decisions to allow access to their drug formularies. Among those strategies are (a) direct marketing to TPPs and/or their contracted PBMs and (b) marketing through third parties.

137. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher the likelihood that the drug will be purchased by plan beneficiaries in lieu of a more expensive alternative, and vice versa. As such, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

138. For new pharmaceutical products, obtaining widespread formulary access is a key driver to determining the ultimate success or failure of the product.

139. For example, in 2009, GSK stopped its development of a type 2 diabetes drug during phase 2 testing based on feedback from TPPs on the drug class for diabetes medication, and an assessment of the competitive environment. [8]

[8] https://www.formularywatch.com/view/drug-manufacturers-seek-payer-feedback-new-products (last accessed June 19, 2020).

140. Pharmaceutical companies consequently invest millions of dollars and have entire divisions dedicated to calling on TPPs who cover and reimburse for pharmaceutical drugs.

141. Upon the entry of generic competition, many TPPs automatically cover the generic version of brand name drugs, with the assurance provided by the drug application process with the FDA that these products are safe, effective, and bioequivalent to the brand name drug, and manufactured in such a way that they are not misbranded and/or adulterated.

142. As is the case with all generic drugs, TPPs seek to include the lowest cost generic drugs possible in their formularies. This is only made possible because of the manufacturers' and distributors' representations that these drugs, such as the Defendants' Ranitidine-Containing Products, comply with their respective NDAs and ANDAs, which state that the Ranitidine-Containing Products have been manufactured in compliance with the Food and Drug Cosmetic Act (FDCA) which requires the Defendants to assure their Ranitidine-Containing Products met legal requirements for safety, and that they have the quality, purity, identity and strength that they are represented to possess.

143. Thus, the TPPs permitted the Ranitidine-Containing Products to be included on their formularies based on the Defendants' misrepresentations that their Ranitidine-Containing Products complied with their drug applications, were safe for consumption, and were not manufactured in such a way to render them adulterated and/or misbranded.

C. Drugs in the Drug Supply Chain Must be Manufactured According to Current Good Manufacturing Practices ("cGMPs")

144. Under federal law, the pharmaceutical drugs placed on Plaintiffs' formularies and paid for, or reimbursed by, Plaintiffs must be manufactured in accordance with "current Good

Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. See 21 U.S.C. §351(a)(2)(B).

145. 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

146. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

147. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

148. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products."

21 U.S.C. §351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

149. FDA regulations require a "quality control unit" to independently test drug products manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. §211.22(a).

150. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. §211.100.

151. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. §211.160.

152. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. §211.194.

II. Drug Approval Framework

A. Regulatory Process for the Approval of New Drugs

153. As part of the research and development ("R&D") for new pharmaceutical products to be distributed and sold in the United States, drug manufacturers, such as Defendant GSK, are required to prepare Investigational New Drug applications ("IND").

154. The purpose of this regulatory filing is to request authorization from the FDA to administer an investigational or biological drug to humans. 21 C.F.R. §312.1, *et seq.*

155. Contained within the IND, an applicant must provide any preclinical testing animal pharmacology and toxicology studies to assess whether the drug is safe for testing in humans, as well as documentation regarding any previous experiences with the drug in humans in foreign countries. 21 C.F.R. §312.8, *et seq.*

156. The IND applicant is also required to include detailed information regarding the manufacture of the drug, such as composition, facility and manufacturers, stability of, and the controls used for the manufacturing of the drug, and whether the facilities are in compliance with cGMPs. 21 C.F.R. §312.23, *et seq.*

157. While an IND is required in order to receive approval from the FDA for the administration of a new drug in human patients through clinical trials in the United States, a New Drug Application ("NDA") is required and necessary for commercial approval to sell new drugs in the United States. 21 C.F.R. §314.1, *et seq.*

158. The NDA requires the applicant to provide patent information, drug safety and efficacy information, information regarding clinical trial designs, reports regarding the clinical trials, and the ultimate conclusion of those trials, as well as proposed labeling. 21 C.F.R. §314.50

159. Information in the NDA regarding the chemistry, manufacturing and controls section is required to contain data and information in sufficient detail to permit the agency to make a knowledgeable judgment about whether to approve the NDA. 21 C.F.R. §314.50

160. This information includes a description of the drug substance including its physical and chemical characteristics and stability, the method of synthesis (or isolation) and purification of the drug substance, the process controls used during manufacture and packaging, and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance. 21 C.F.R. §314.50.

161. Additionally, the NDA applicant is required to provide analytical procedures, and acceptance criteria relating to sterility, dissolution rate, container closure systems; and stability data with proposed expiration dating. 21 C.F.R. §314.50.

B. Regulatory Process for Approval of Generic Drugs

162. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. §355(j).

163. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

164. Brand drug companies submitting a NDA are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. §355 *et seq*.

165. By contrast, generic drug companies are allowed to submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug

companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. §320.1(e).

1. ANDA Applicants Must Demonstrate Bioequivalence and Stability

166. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

167. As part of its showing of bioequivalence pursuant to 21 C.F.R. §314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

- a full description of the drug's substance, including its physical and chemical characteristics and stability; and
- the specifications necessary to ensure the identity strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

168. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. §355(j), the generic manufacturer must show that the the active ingredient(s) are the same as the RLD, §355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id*. at (A)(vi); *see also* §355(b)(1)(C).

169. Though an ANDA applicant's drug must be bioequivalent to the RLD, no two manufacturers' drugs will be exactly the same. For that reason, generic manufacturers are responsible for conducting their own, independent stability testing, which must be "designed to assess the stability characteristics of drug products." 21 C.F.R. §314.94(a)(8)(iv)

170. Because a generic manufacturer's drug must be bioequivalent to the RLD, a compliant generic label should be "the same as the labeling of the reference listed drug" in many respects. But because a generic drug may not be exactly the same as the RLD, the generic label "may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance…" *Id*.

171. Pursuant to this regulation, it is common for a generic drug's label to differ from the RLD by setting a different expiration date, requiring the drug to be shipped and stored under different temperature conditions, and/or requiring the drug to receive different (or no) exposure to light. Several of the Generic Manufacturer Defendants relied on 21 C.F.R. §314.94(a)(8)(iv) and their independent stability studies to sell approved, generic ranitidine with labels that differed from the RLD label.

C. NDA and ANDA Applicants Must Comply with cGMPs

172. All new drug applications (including both NDA and ANDAs) must include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

173. Under federal law, a manufacturer filing for a new drug application (either an NDA or ANDA) must attest that it will manufacture, store, warehouse, and distribute pharmaceutical

drugs in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards.[9]

174. 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

175. Pursuant to 21 C.F.R**.** §211.142(b), procedures for the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine.

176. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" and may not be distributed or sold in the United States.[10] State common law and statutory law mirror these federal standards.

177. The new drug application is required to contain certifications of compliance with cGMPs for both the applicant itself, and also the drug product manufacturer (if they are different entities).

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[9] 21 U.S.C. §351(a)(2)(B).

[10] 21 U.S.C. §§331(a), 351(a)(2)(B).

D. New Drug Application Approval is Contingent upon Continuing Compliance with Representations Made in the Application

178. After final approval by the FDA, NDAs and ANDAs are required to continually comply with the representations made in their applications.

179. Indeed, this ongoing and continuing compliance is codified by a drug manufacturers' obligation to provide annual submissions indicating continuing compliance.

180. If a drug manufacturer ceases to manufacture a drug that meets all terms of its NDA ANDA approval, then the manufacturer has created a drug which is no longer approved to be sold, purchased or reimbursed in the United States because it is adulterated and/or misbranded.

E. Drugs That Do Not Comply Are Considered Adulterated and/or Misbranded

181. The manufacture of any adulterated or misbranded drug is prohibited under federal law.[11]

182. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[12]

183. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[13]

184. Among the ways a drug may be adulterated and/or misbranded are:

> (a) "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[14]

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[11] 21 U.S.C. §331(g).

[12] 21 U.S.C. §331(a).

[13] 21 U.S.C. §331(c).

[14] 21 U.S.C. §351(a)(2)(A).

(b) "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[15]

(c) "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[16]

(d) "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[17]

185. A drug is misbranded:

(a) "If its labeling is false or misleading in any particular."[18]

(b) "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[19]

(c) If the labeling does not contain, among other things, "the proportion of each active ingredient…"[20]

(d) "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. …"[21]

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15 21 U.S.C. §351(a)(2)(B).

16 21 U.S.C. §351(b).

17 21 U.S.C. §351(d).

18 21 U.S.C. §352(a)(1).

19 21 U.S.C. §352(c).

20 21 U.S.C. §52(e)(1)(A)(ii).

21 21 U.S.C. §352(f).

(e) "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[22]

(f) "if it is an imitation of another drug;"[23]

(g) "if it is offered for sale under the name of another drug."[24]

(h) "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[25]

(i) If the drug is advertised incorrectly in any manner; [26] or

(j) If the drug's "packaging or labeling is in violation of an applicable regulation…"[27]

III. Sale of Zantac and Ranitidine in the United States

186. Ranitidine belongs to a class of medications called histamine H_2-receptor antagonists (or H_2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Tazac).

187. GSK [28] predecessor Smith, Kline & French discovered and developed Tagamet, the first H_2 blocker and the prototypical histamine H_2 receptor antagonist from which the later

[22] 21 U.S.C. §352(g).

[23] 21 U.S.C. §352(i)(2).

[24] 21 U.S.C. §352(i)(3).

[25] 21 U.S.C. §352(j).

[26] 21 U.S.C. §352(n).

[27] 21 U.S.C. §352(p).

[28] GSK, as currently constituted, was created through a series of mergers and acquisitions. In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000,

members of the class were developed. Zantac was specifically developed in response to the success of cimetidine.

188. In 1976, scientist John Bradshaw, on behalf of GSK-predecessor Allen & Hanburys Ltd., synthesized and discovered ranitidine.

189. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

A. GSK Introduced Zantac to the Lucrative Antacid Market to Compete with the Successful Cimetidine, and Other Manufacturers Quickly Capitalized

190. In 1983, the FDA granted approval to Glaxo to sell Zantac, pursuant to the NDA No. 18-703, and it quickly became GSK's most successful product – a "blockbuster." Indeed, ranitidine became the first prescription drug in history to reach $1 billion in sales. GSK manufactured its own prescription Zantac from 1983 but ceased manufacturing its own Active Pharmaceutical Ingredient ("API") in 2014.[29]

191. In 1993, GSK (through Glaxo Wellcome plc) entered into a joint venture with Pfizer-predecessor Warner-Lambert Co. to develop an OTC version of Zantac. In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC 75 mg effervescent tablets through NDA 20-745.

Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

[29] In 2014, GSK began using ranitidine API manufactured by Defendant Dr. Reddy's, Orchev Pharma PVT and SMS Pharmaceuticals.

192. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their joint venture.[30] As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada, but it was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK regained rights to sell OTC Zantac outside of the United States and Canada,[31] and it retained control over the Zantac trademark internationally.[32]

193. In 2000, Pfizer Inc. acquired Warner-Lambert Co. Pfizer then controlled the Zantac OTC NDAs until December 2006.

194. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of this agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription Ranitidine-Containing Drug in the United States, such as those for which Plaintiffs made payments or reimbursemenets.

195. In October 2003, Pfizer submitted a application for approval to market OTC Zantac 150 mg. The FDA approved Pfizer's NDA on August 31, 2004.

196. Throughout the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

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[30] Throughout the time of the joint venture, GSK continued to manufacture the Zantac product.

[31] GSK also still held the right to sell prescription Zantac in the United States.

[32] *See Warner-Lambert and Glaxo End A Venture on Ulcer Drug Zantac*, WALL ST. J. (Aug. 4, 1998), https://www.wsj.com/articles/SB902188417685803000 (last accessed June 21, 2020).

197. In 2006, pursuant to the 2006 Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson & Johnson ("J&J"). Because of antitrust issues, however, Zantac was transferred to Boehringer Ingelheim. Nevertheless, Pfizer has made a demand for indemnification per the Stock and Asset Purchase against J&J as to legal claims related to OTC Zantac products.

198. Pfizer, through a divestiture agreement, transferred all assets pertaining to its Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, Research and Development ("R&D"), and customer and supply contracts, to Boehringer Ingelheim. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the Zantac OTC NDAs.

199. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S."[33]

200. Boehringer Ingelheim Pharmaceuticals, Inc. owned and controlled the NDAs for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.

201. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to a Sales and Purchase Agreement ("SPA"). As part of this deal, Sanofi obtained control and

[33] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.

responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. However, Boehringer Ingelheim and Patheon Manufacturing Services LLC continued to manufacture and package all drugs subject to the agreement, including Zantac.

202. Boehringer Ingelheim also owned and controlled ANDA 074662.

203. Sanofi has controlled the NDAs for OTC Zantac and has distributed Zantac in the United States since January 2017.[34]

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

205. Sanofi has made a demand for indemnification from J&J pursuant to a 2016 Asset Purchase Agreement between J&J and Sanofi.

B. Obtaining Formulary Status on Plaintiffs' Formularies Was Necessary to Grow Profits

206. Formulary decisions of TPPs have a large effect on physicians' prescribing behavior, and such decisions consequently can be the difference between a blockbuster drug and a bust.

207. In order to achieve their ultimate goal of market domination, GSK sought formulary placement so that TPPs, such as Plaintiffs, would pay for and reimburse for Zantac.

208. As part of these efforts, GSK provided dossiers, monographs, labeling information, medication guides, and other marketing information to TPPs (such as Plaintiffs) and PBMs (such as those utilized by Plaintiffs), including Express Scripts and CVS Caremark.

209. GSK was ultimately successful at achieving formulary coverage, as Plaintiffs covered and reimbursed for Zantac.

[34] Throughout the entire time period Boehringer Ingelheim manufactured OTC Zantac, it sourced its API from Union Quimico Farmaceutica SA ("UQUIFA") in Barcelona, Spain.

210. Once having achieved formulary status, GSK also had to ensure that Zantac maintained that formulary status.

211. Indeed, GSK even went so far as to partner with certain PBMs, such as CVS Caremark[35] (Plaintiff NECA-IBEW's PBM), for their products, including Zantac.

C. Generic Defendants Quickly Followed Suit with Generic Ranitidine

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

213. After GSK and Pfizer's patent on the original OTC Zantac product expired, generic manufacturers were allowed to sell OTC ranitidine to consumers.

214. The FDA approved the applications of dozens of generic manufacturers for the sale of prescription and OTC ranitidine through the ANDA process.

215. Despite generic entry, Brand-Name Manufacturer Defendants continued to sell prescription and OTC Zantac. Although sales of Zantac declined as a result of generic competition, ranitidine sales remained strong over time. Zantac was still ranked among the best-selling prescription drugs in the United States prior to its recall.[36] In 2016 alone, there were approximately 15,285,992 prescriptions written for Zantac.[37] And as recently as 2018, Zantac was one of the top 10 antacid tablets in the United States, with sales of OTC Zantac 150 totaling $128.9 million – a 3.1% increase from the previous year.

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[35] https://www.caremark.com/portal/asset/GSK_Zero_Copay_Prescription_Drug_List.pdf (last accessed June 18, 2020).

[36] The Top 200 of 2019, ClincCalc. https://clincalc.com/DrugStats/Top200Drugs.aspx (last accessed June 19, 2020).

[37] The Top 200 of 2019 ClincCalc. https://clincalc.com/DrugStats/Top200Drugs.aspx (last accessed June 19, 2020).

IV. Plaintiffs Paid for Thousands of Prescriptions for Defendants' Ranitidine-Containing Products

216. At all times material hereto, Plaintiffs reimbursed for Ranitidine-Containing Products throughout the United States, including drugs manufactured by Defendant GlaxoSmithKline. These reimbursements included reimbursements made for Zantac in 2011 in New Mexico in the amounts of $34.62, and $41.00.

217. With respect to Ranitidine-Containing Products manufactured by the Generic Manufacturer Defendants, Plaintiffs allege some exemplar payments made for generic ranitidine in the table below. In each instance, Plaintiffs received a request to reimburse for a prescription drug on behalf of an enrollee for a particular date of service indicated below. Plaintiffs then paid the amounts indicated for the Ranitidine-Containing Drug manufactured and sold by Generic Manufacturer Defendants.

A. Plaintiff NECA-IBEW

218. Between 2010 and 2019, Plaintiff NECA-IBEW reimbursed for Defendants' Ranitidine-Containing Products, including a sampling of the below reimbursements made between 2010 and 2019.

Date	Pharmacy	State	Defendant	NDC	Amount Paid
2/9/2010	WALGREENS	AZ	Sandoz	00781286531	$11.20
3/29/2010	WALGREENS	AL	Amneal	65162066490	$9.01
4/1/2010	CVS PHARMACY	IL	Glenmark	68462024920	$9.40
4/9/2010	COUNTY MARKET PHARMACY	IL	Pharmaceutical Associates	00121072716	$97.26
4/29/2010	WALGREENS	FL	Amneal	65162066490	$61.56
4/30/2010	CVS PHARMACY	IL	Glenmark	68462024920	$9.40

6/7/2010	EXPRESS SCRIPTS	NJ	Par	49884054501	$54.32
7/7/2010	WALGREENS	FL	Sandoz	00781285505	$19.27
7/14/2010	BIG C DISCOUNT DRUGS	AL	Apotex	60505002603	$0.45
7/20/2010	SOUTHEAST PHARMACY	MO	Sandoz	00781188360	$2.68
7/24/2010	CVS PHARMACY PHARMARCY PHAPHARMACY	IN	Sandoz	00781285560	$19.27
7/30/2010	WALGREENS	IL	Amneal	65162066490	$166.80
8/13/2010	SARTORIS SUPER	IL	Wockhardt	64679090603	$2.79
8/29/2010	WALGREENS	FL	Sandoz	00781285505	$19.27
10/20/2010	ATHENS PHARMACY	AL	Pharmaceutical Associates	00121072716	$61.56
11/12/2010	EXPRESS SCRIPTS	OH	Actavis	00472038316	$264.14
11/30/2010	KROGER PHARMACY	IL	Actavis	00472038316	$11.56
12/13/2010	EXPRESS SCRIPTS	OH	Actavis	00472038316	$66.91
12/14/2010	WAL-MART	IN	Actavis	00472038316	$20.68
12/21/2010	CVS PHARMACY	IN	Sandoz	00781285560	$19.27
1/27/2011	RICK'S PHARMACY	KY	Amneal	65162066490	$116.64
2/7/2011	RITE AID PHARMACY	KY	Wockhardt	64679069401	$24.24
2/8/2011	WAL-MART	IN	Actavis	00472038316	$61.46
3/10/2011	KROGER PHARMACY	IL	Actavis	00472038316	$44.04
3/16/2011	CVS PHARMACY	IL	Glenmark	68462024805	$2.71
4/8/2011	EXPRESS SCRIPTS	NV	Par	49884054501	$33.78
4/22/2011	CVS PHARMACY	IN	Glenmark	68462024805	$2.68
5/8/2011	EXPRESS SCRIPTS	NJ	Par	49884054501	$34.39
6/27/2011	RICK'S PHARMACY	KY	Actavis	00472038316	$61.56
6/28/2011	CVS PHARMACY	IN	Dr. Reddy's	55111060216	$61.56

7/28/2011	EXPRESS SCRIPTS	NJ	Amneal	53746025401	$34.39
8/8/2011	PADUCAH PHARMACY	KY	Actavis	00472038316	$166.64
8/23/2011	WALGREENS	FL	Amneal	65162066490	$137.25
8/26/2011	EXPRESS SCRIPTS	NV	Amneal	53746025401	$33.85
9/16/2011	CVS PHARMACY	IL	Dr. Reddy's	55111060216	$166.78
1/25/2012	LIBERTY DRUG STORE INC	TN	Amneal	53746025402	$0.89
1/30/2012	EXPRESS SCRIPTS	OH	Actavis	00472038316	$24.39
2/24/2012	LYON DRUG STORE	KY	Par	00603941858	$13.94
3/7/2012	WALGREENS	WI	Amneal	65162066490	$24.14
6/14/2012	CVS PHARMACY	FL	Glenmark	68462024805	$3.30
6/26/2012	WALGREENS	MN	Dr. Reddy's	55111012905	$20.21
8/2/2012	WALGREENS	IL	Amneal	65162066490	$13.21
8/7/2012	WALGREENS	IL	Amneal	65162066490	$18.71
10/2/2012	WALGREENS	IN	Amneal	65162066490	$46.10
11/20/2012	PEARMAN PHARMACY	IL	Lannett Company	54838055080	$30.01
12/10/2012	CVS PHARMACY	IL	Akorn	50383005116	$46.30
12/12/2012	VILLAGE DISCOUNT DRUGS	AL	Actavis	00472038316	$10.49
12/27/2012	BAPTIST MEDICAL ARTS PHCY	FL	Amneal	53746025305	$3.38
2/20/2013	PUBLIX PHARMACY # 0010	FL	Lannett Company	54838055080	$13.24
2/21/2013	WALGREENS	WI	Teva	00172435770	$3.38
4/29/2013	CVS PHARMACY	WI	Akorn	50383005116	$2.26
5/14/2013	MEIJER PHARMACY	IN	Akorn	50383005116	$40.96
5/15/2013	CVS PHARMACY	IL	Akorn	50383005116	$101.32
5/22/2013	WALGREENS	WI	Glenmark	68462024920	$0.97

5/29/2013	KROGER PHARMACY	IL	Par	00603941858	$12.51
6/25/2013	WALGREENS	TN	Amneal	65162066490	$99.76
7/11/2013	EXPRESS SCRIPTS	OH	Par	00603941858	$79.05
7/14/2013	CVS PHARMACY	FL	Glenmark	68462024920	$0.97
10/3/2013	MANITO PHARMACY	IL	Wockhardt	64679069401	$2.81
10/7/2013	CVS PHARMACY	KY	Akorn	50383005116	$46.18
10/16/2013	CVS PHARMACY	FL	Glenmark	68462024805	$3.38
10/18/2013	WALGREENS	WI	Sandoz	00781285505	$20.20
12/8/2013	CVS PHARMACY	FL	Glenmark	68462024805	$4.49
2/26/2014	PICK 'N SAVE PHARMACY	WI	Amneal	53746025301	$4.49
3/10/2014	CVS PHARMACY	FL	Akorn	50383005116	$10.13
3/24/2014	EXPRESS SCRIPTS	NV	Dr. Reddy's	55111012905	$127.44
3/30/2014	WALGREENS	IL	Caraco	57664014134	$38.52
4/8/2014	EXPRESS SCRIPTS	OH	Par	00603941858	$15.84
4/12/2014	WALGREENS	FL	Dr. Reddy's	55111013001	$37.89
4/14/2014	EXPRESS SCRIPTS	OH	Par	00603941858	$47.56
5/9/2014	WALGREENS	IL	Caraco	57664014134	$55.51
5/14/2014	ASSISTED LIVING PHCY SVC	WI	Amneal	53746025310	$12.43
6/10/2014	WALGREENS	WI	Teva	00172435770	$13.94
6/13/2014	WALGREENS	WI	Teva	00172435770	$13.94
7/9/2014	CVS PHARMACY	IL	Sandoz	00781286531	$33.37
7/14/2014	GIBSON DISCOUNT PHARMACY	KY	Glenmark	68462024805	$10.73
7/21/2014	WALGREENS	IL	Teva	00172435770	$10.98
9/2/2014	CVS PHARMACY	GA	Teva	00172435770	$10.73
9/24/2014	WALGREENS	WI	Teva	00172435770	$10.73
10/11/2014	WALGREENS	FL	Teva	00172435770	$10.73

10/17/2014	WALGREENS	WI	Teva	00172435770	$10.73
11/12/2014	SHOPKO PHARMACY	WI	Heritage Pharma	23155029151	$1.99
11/13/2014	CVS PHARMACY	KY	Teva	00172435770	$10.73
11/19/2014	KROGER PHARMACY	KY	Par	00603941858	$31.22
11/28/2014	EXPRESS SCRIPTS	OH	Par	00603941858	$124.11
12/4/2014	CVS PHARMACY	IN	Teva	00172435770	$10.73
12/8/2014	WALGREENS	WI	Sandoz	00781285505	$48.33
12/16/2014	EXPRESS SCRIPTS	NV	Dr. Reddy's	55111012905	$151.48
2/19/2015	EXPRESS SCRIPTS	IN	Dr. Reddy’s	55111012905	$135.52
5/5/2015	MEIJER PHARMACY	IN	Dr. Reddy’s	55111013030	$76.17
2/26/2016	WAL-MART	IL	Lannett	54838055080	$3.17
4/22/2016	CVS PHARMACY	TX	Sandoz	00781285560	$29.79
10/31/2016	EXPRESS SCRIPTS	MO	Pharmaceutical Associates	00121072716	$0.54
11/30/2016	WALGREENS	WI	Sandoz	00781285505	$82.01
12/8/2016	EXPRESS SCRIPTS	NJ	Dr. Reddy's	55111012905	$177.18
12/9/2016	EXPRESS SCRIPTS	MO	Dr. Reddy's	55111012905	$179.20
12/27/2016	EXPRESS SCRIPTS	AZ	Dr. Reddy's	55111013001	$277.37
1/7/2017	CVS PHARMACY	IN	Dr. Reddy's	55111013030	$27.09
3/1/2017	WALGREENS	TN	Dr. Reddy's	55111012905	$25.99
6/17/2017	EXPRESS SCRIPTS	IN	Dr. Reddy's	55111013001	$244.08
9/11/2017	CVS PHARMACY	AL	Dr. Reddy's	55111012960	$8.56
10/25/2019	CVS PHARMACY	AL	Strides	68462024805	$34.99

B. Plaintiff Plumbers 630

219. Between 2010 and 2019, Plaintiff Plumbers 630 reimbursed for Defendants’ Ranitidine-Containing Products, including a sampling of the below reimbursements made between 2010 and 2019.

Date	Pharmacy	State	Defendant	NDC	Amount Paid
1/13/2010	CAREMARK MIRAMAR PHARMACY LLC	FL	Par	49884054402	$104.36
7/17/2010	CAREMARK PRESCRIPTION SRVC BHM	AL	Par	49884054401	$38.67
10/13/2010	CAREMARK PRESCRIPTION SRVC BHM	AL	Amneal	53746025301	$38.54
10/7/2011	WALGREENS	FL	Teva	00172435770	$6.47
12/2/2011	CVS PHARMACY	FL	Glenmark	68462024920	$7.92
12/23/2011	CAREMARK MIRAMAR PHARMACY LLC	FL	Amneal	53746025301	$97.09
1/30/2012	JUPITER DRUGS	FL	Wockhardt	64679090603	$1.47
9/4/2012	CAREMARK PRESCRIPTION SVCS SAT	TX	Amneal	53746025301	$79.74
11/20/2012	OMNICARE OF KING OF PRUSSIA	PA	Teva	00172435770	$1.30
2/25/2013	CVS PHARMACY	FL	Akorn Hi Tech	50383005116	$154.72
5/24/2013	CVS PHARMACY	MD	Akorn Hi Tech	50383005116	$26.66
12/19/2013	CAREMARK PRESCRIPTION SRVC WBP	PA	Amneal	53746025301	$89.74
6/5/2014	WALGREENS	LA	Teva	00172435770	$3.06

8/19/2014	WALGREENS	LA	Sandoz	00781285505	$52.39
10/15/2014	WALMART PHARMACY	GA	Sandoz	00781285560	$52.32
12/17/2014	CAREMARK PRESCRIPTION SVC-CHI	IL	Amneal	53746025301	$100.80
10/22/2015	WALGREENS	TN	Glenmark	68462024805	$2.33
7/11/2016	CAREMARK PRESCRIPTION SRVC WBP	PA	Sandoz	00781285560	$24.91
7/18/2016	CVS PHARMACY	NC	Sandoz	00781188310	$2.33
8/3/2016	RITE AID PHARMACY	NC	Amneal	53746025360	$2.33
8/20/2016	PUBLIX PHARMACY	FL	Lannett	54838055080	$21.42
9/28/2016	INGLES PHARMACY	GA	Glenmark	68462024805	$0.00
9/30/2016	CAREMARK PRESCRIPTION SVC-CHI	IL	Sandoz	00781285560	$24.91
11/28/2016	CVS PHARMACY	AL	Sandoz	00781188310	$2.33
12/5/2016	CVS PHARMACY	FL	Sandoz	00781285560	$37.75
12/14/2016	PUBLIX PHARMACY	FL	Nostrum	70408014134	$21.42

12/22/2016	CAREMARK PRESCRIPTION SVC-CHI	IL	Par	55111012960	$24.91
4/15/2017	CVS PHARMACY	AL	Strides	64380080307	$1.79
5/2/2017	PUBLIX PHARMACY	FL	Nostrum	70408014134	$20.18
6/5/2017	PUBLIX PHARMACY	FL	Nostrum	70408014134	$20.18
6/14/2017	WALGREENS	FL	Lannett	54838055080	$4.52
9/19/2017	PARK PHARMACY	FL	Amneal	53746025305	$3.80
10/18/2017	CAREMARK PRESCRIPTION SVC-CHI	IL	Dr. Reddy's	55111012960	$125.45
3/9/2018	CAREMARK PRESCRIPTION SVC-CHI	IL	Amneal	65162025311	$7.96
11/15/2018	CVS PHARMACY	FL	Glenmark	68462024920	$7.50
12/17/2018	PUBLIX PHARMACY	FL	Strides	64380080308	$3.80
4/18/2019	CVS PHARMACY	FL	Glenmark	68462024920	$2.42
9/13/2019	CVS PHARMACY	FL	Dr. Reddy's	55111012960	$55.28

C. Plaintiff Indiana Laborers

220. Between 2010 and 2019, Indiana Laborers reimbursed for Defendants' Ranitidine-Containing Products, including a sampling of the below reimbursements made between 2010 and 2019.

Date	State	Defendant	NDC	Amount Paid
1/3/2012	MI	Glenmark	68462024920	$14.42
1/13/2012	OH	Amneal	53746025305	$4.09
1/19/2012	KY	Glenmark	68462024805	$53.62
2/10/2012	FL	Wockhardt	64679090603	$16.00
3/19/2012	IN	Wockhardt	64679090603	$3.50
4/17/2012	FL	Amneal	53746025430	$40.93
8/27/2012	IN	Amneal	53746025430	$106.85
9/6/2012	KY	Amneal	65162066490	$22.11
1/2/2013	IN	Glenmark	68462024920	$90.42
12/13/2013	AZ	Glenmark	6846024805	$12.48
6/6/2014	IL	Glenmark	68462024860	$1.91
9/24/2014	KY	Amneal	53746025310	$12.00
10/1/2014	OH	Dr. Reddy's	55111013030	$9.88
1/13/2015	TX	Glenmark	68462024805	$12.48
3/30/2015	MI	Amneal	53746025401	$12.20
7/1/2015	TX	Amneal	53746025301	$15.10
8/10/2016	IN	Sandoz	00781188425	$81.41
9/8/2016	IL	Sandoz	00781188310	$10.29
11/16/2016	MD	Amneal	53746025360	$4.93
4/24/2017	TX	PAI	00121072716	$15.33
8/15/2017	IN	PAI	00121072716	$67.54
10/3/2017	IL	Strides	64380080307	$28.35

11/6/2017	IN	Strides	64380080438	$70.35
11/15/2017	FL	Glenmark	68462024805	$27.65
11/18/2017	IN	Dr. Reddy's	55111013030	$68.82
12/11/2017	GA	Dr. Reddy's	55111013030	$21.91
7/27/2018	IL	PAI	00121072716	$31.65
10/20/2018	GA	Sandoz	00781286531	$59.34
01/07/2019	IL	Dr. Reddy's	55111012960	$43.68
01/18/2019	KY	PAI	00121072716	$22.88
1/18/2019	KY	Lannett	54838055080	$31.13
3/25/2019	TX	Lannett	54838055080	$6.45
06/05/2019	IN	Lannett	54838055080	$28.38
06/24/2019	IN	Lannett	54838055080	$49.34

V. Defendants Knew and Had an Obligation to Further Investigate the Dangers of Their Ranitidine-Containing Products

A. Defendants Knew or Should Have Known of the NDMA Risk in Their Ranitidine-Containing Products

221. As early as 1981, two years before Zantac entered the market, research showed elevated levels of NDMA in raniditine, when properly tested. This material fact was available in medical literature, known, or should have been known, by the Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants, and any other maker or distributor of Ranitidine-Containing Products. This information would not have been easily accessible to all, but should have been accessed and reviewed by each company in the ranitidine chain of distribution.

222. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[38] Many metabolites were listed, though there is no indication that the study looked for NDMA. This was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in its product. All Defendants knew or should have known about this study and, therefore, were obligated to investigate this issue properly. None did.

223. Indeed, in that same year, Dr. Silvio de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body. GSK was aware of this study and specifically responded to the note in an attempt to discredit it. The Brand-Name Manufacturers and Generic Manufacturer Defendants knew or should have known about this scientific event as it was published in a popular scientific journal, and Defendants were obligated to investigate this issue properly through due diligence or otherwise.

224. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[39] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was rigged. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines,

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[38] P.F. Carey, et al., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed-Phase Ion-Pair High-Performance Liquid Chromatography*, 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPLICATION 1, 161-68 (1981).

[39] J.M. Thomas, et al., *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 28 GUT. 6, 726-38 (1987).

which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of this test was knowable from its publication in 1987. Each Defendant either knew or should have known about the inadequacy of this study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

225. Upon information and belief, no Defendant ever used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with their trials associated with the ranitidine NDA. That is so because mass spectrometry requires heating of up to 130 degrees Celsius, which can result in the formation of excessive amounts of nitrosamines. Had the Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants used a mass spectrometry assay, it would have revealed large amounts of NDMA in ranitidine. They chose not to do so.

226. In 2019, Valisure LLC and ValisureRX LLC (collectively "Valisure"), an analytical pharmacy that puts medicine and drugs through rigorous chemical analysis to screen out bad batches, ran tests on Zantac and discovered the link of Zantac and its generics to the carcinogen NDMA. Valisure first notified the FDA of its initial findings in June of 2019.

227. On September 13, 2019, Valisure filed a citizen petition with the FDA asking the agency to recall all products that contain ranitidine[14] and provided the World Health Organization and International Agency for the Research of Cancer ("IARC") with copies of the petition.

228. Valisure conducted follow-up testing and determined that the Zantac batch tested was not contaminated but that the molecule within the drug itself is unstable and can form NDMA, particularly in the conditions found in the stomach.[15]

229. This set off a cascade of recalls by both the Brand-Name Manufacturer Defendants and the Generic Manufacturer Defendants.

230. From that point forward, Defendants could no longer ignore and/or conceal the truth that their Ranitidine-Containing Products are unsafe and unfit for human use.

B. NDMA Has Long Been Deemed a Carcinogen, with Well-Established Dangerous Properties Not Suitable for Prescription Drugs

231. According to the Environmental Protection Agency ("EPA"), "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes."[40] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[41] NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

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[40] U.S. Environmental Protection Agency, Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA) (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf (last accessed June 12, 2020).

[41] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, GLOBE and MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water*, GLOBE and MAIL (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); S.A. Kyrtopoulos, *DNA adducts in humans after exposure to methylating agents*, 405 MUTATION RES. 2, 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

232. Both the EPA and the IARC classify NDMA as a probable human carcinogen.[42]

233. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[43]

234. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[44] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[45]

235. The FDA considers NDMA a chemical that "could cause cancer" in humans.[46]

236. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[47]

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[42] *See* International Agency for Research on Cancer (IARC) - Summaries & Evaluations, N-NITROSODIMETHYLAMINE (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html (last accessed June 12, 2020).

[43] *See* EPA Technical Fact Sheet, https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf (last accessed June 19, 2020).

[44] *Id.* at 3.

[45] *Id.* or *see* EPA Technical Fact Sheet, https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf (last accessed June 19, 2020).

[46] U.S. Food & Drug Administration, *Statement Alerting patients and healthcare professionals of NDMA found in samples of ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine (last accessed June 19, 2020).

[47] World Health Organization, *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3rd ed. 2008), https://apps.who.int/iris/bitstream/handle/10665/204411/9789241547611_eng.pdf;jsessionid=E0F38FD1EB0B5BADD19EDD2CA7579D9E?sequence=1 (last accessed June 19, 2020).

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

238. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure – Valsartan, Losartan, and Irbesartan – because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

239. The no-observed-adverse-effect level ("NOAEL") is the level of exposure at which there is no biologically significant increase in the frequency or severity of any adverse effects of the chemical. Due to NDMA's ability to affect deoxyribonucleic acid ("DNA") at a microscopic level, there is no NOAEL for NDMA. This means any amount of NDMA exposure increases the risk of cancer.

240. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. This means that consumption of 96 ng of NDMA per day will increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.[48] For comparison, one filtered cigarette contains between 5 to 43 ng of NDMA.

241. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, cancers were observed in the liver, pancreas, and stomach. In comparable guinea-pig studies, cancers were

[48] U.S. Food & Drug Administration, *FDA updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Nov. 7, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last accessed June 19, 2020).

observed in the liver and lung. In comparable rabbit studies, cancers were observed in the liver and lung.

242. In other long-term animal studies in mice and rats utilizing different routes of exposures – inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) – cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

243. Prior to the withdrawal of ranitidine, the FDA considered the drug as category B for birth defects, meaning it was considered safe to take during pregnancy. Yet animals exposed to NDMA during pregnancy birthed offspring with elevated rates of cancer in the liver and kidneys.

244. NDMA is, itself, a very small molecule. This allows it to freely pass through all areas of the body, including the blood-brain and placental barrier.

245. In addition, NDMA breaks down into various derivative molecules that, themselves, are also associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine (including colon).

246. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[49]

247. Pursuant to the EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[50]

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[49] *Id.*

[50] *See* U.S. Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf (last accessed June 18, 2020).

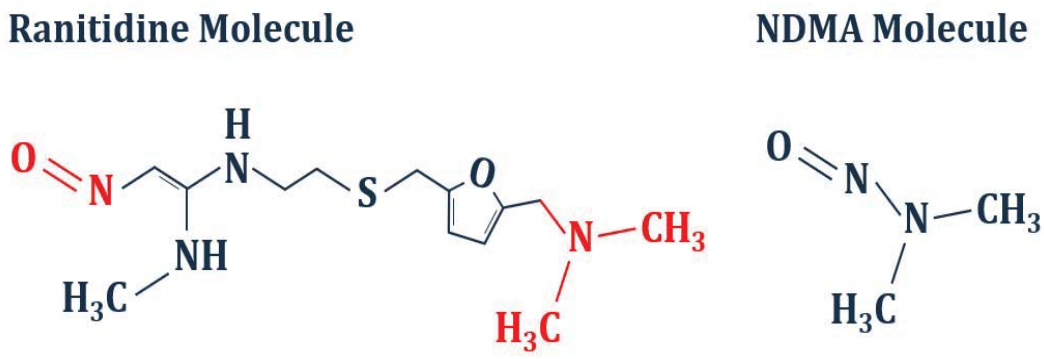
248. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[51]

C. How Ranitidine Transforms into NDMA

249. The ranitidine molecule itself contains the constituent molecules to form NDMA. *See* Figure 1.

250. Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H_3C-N-CH_3 (DMA) on the other side to form NDMA.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



251. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for

[51] *N-Nitrosodimethylamine (NDMA)* (3rd ed. 2008), *available at* https://apps.who.int/iris/bitstream/handle/10665/204411/9789241547611_eng.pdf;jsessionid=E0F38FD1EB0B5BADD19EDD2CA7579D9E?sequence=1.

contamination of the American water supply.[52] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[53]

252. These studies underscore the instability of the ranitidine molecule and its ability to form NDMA in the environment of water treatment plants, which supply many American cities with water.

253. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratory's technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

254. In its September 9, 2019 Citizen's Petition to the FDA, Valisure disclosed as part of its testing of Ranitidine-Containing Products that every lot tested showed exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS

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[52] T. Ogawa, et al., Purification and Properties of a New Enzyme, NG NG-Dimethylarginine Dimethylaminohydrolase, from Rat Kidney, 264 J. BIOLOGICAL CHEMISTRY 17, 10205-209 (June 15, 1989).

[53] William A. Mitch, et al., N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review, 20 ENVTL. ENGINEERING SCI. 5, 389-404 (Sept. 2003).

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.[54]

255. Valisure's September 2019 testing shows, on average, 2,692,291 ng of NDMA in a 150 mg ranitidine tablet. The results from this testing (shown below in Table 1) demonstrated the instability of the ranitidine molecule and its propensity to break down under higher temperatures and in a high nitrite environment.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder*	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

256. Following the September 2019 testing, Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average

[54] U.S. Food & Drug Administration, *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, by GC/MS-Headspace* (Jan. 28, 2019), https://www.fda.gov/media/117843/download (last accessed on June 19, 2020).

temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

257. The instability of the molecule, and its propensity to degrade into NDMA is impacted by the factors exclusively within the control of Defendants, such as those described below.

258. The stability of finished pharmaceutical products depends on both manufacture-related factors (such as the chemical and physical properties of the active substance and of pharmaceutical excipients, the dosage form and its composition, the manufacturing process, the nature of the container-closure system and the properties of the packaging materials) as well as storage and environmental factors (such as ambient temperature, humidity and light).

1. Stability of the Ranitidine Molecule is Impacted by Manufacturing Choices and Practices

259. During the manufacturing process, the stability of Ranitidine-Containing Products will depend to a large extent on compliance with appropriate formulation and packaging-closure systems.[55]

260. Manufacturers must have intimate knowledge of the chemical and physical properties of the active pharmaceutical ingredient ("API"), and of the various pharmaceutical excipients required in the manufacturing process, in order to understand how the interactions of these elements impact the overall stability of the product.[56]

261. Because of the obvious importance of establishing stability in drug products, cGMPs require drug manufacturers to conduct extensive testing and sampling (and to have

[55] WHO Technical Report

[56] WHO Technical Report

comprehensive written control procedures and operating procedures delineating how and when a specific drug product must be tested), in order to establish that the drug is, in fact, stable.

262. As discussed more fully below in §XI, Defendants did not have the adequate processes, measures, or controls (due to rampant and willful violations of cGMPs), to establish whether their specific Ranitidine-Containing Products were initially stable, what conditions were required to keep their specific Ranitidine-Containing Products stable and prevent them from degrading into NDMA, and for how long their Ranitidine-Containing Products would remain stable before it began to degrade into NDMA.

263. In addition to impacting the stability of Ranitidine-Containing Products, unacceptable and substandard manufacturing practices themselves have the potential to create NDMA beyond that which exists in a drug because of degradation of the original molecule.

264. Recent testing conducted under the authority of the FDA involving a number of drugs within the last two years made the FDA aware that NDMA can form during the manufacturing process.

265. On July 13, 2018, the FDA announced the first of what would be many recalls of Valsartan and other angiotensin receptor blockers ("ARB") drugs used to treat high blood pressure, such as Losartan and Irbesartan.[57]

266. Specifically, the recalls were due to NDMA and other nitrosamines being present in the APIs manufactured by four API manufacturers located in China and India.

[57] U.S. Food & Drug Administration, *FDA Announces Voluntary recall of several medicines containing valsartan following detection of impurity* (July 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

267. According to the U.S. Council on Foreign Relations, "approximately 80% of the APIs used to make drugs in the United States are said to come from China" as well as other foreign countries including India.[58]

268. As the FDA's investigation into the ARB contamination continued, it became clear that NDMA had made its way into the API through the use of recovered solvents or as a result of using less expensive solvents during the manufacturing process.[59]

269. Similarly, API was noted as a possible source of NDMA in Ranitidine-Containing Products, "Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA in Ranitidine-Containing Products."[60]

270. Knowing the inherent instability of the ranitidine molecule, Defendants understood the heightened importance of compliance with cGMP requirements and failed to do so here.

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

271. In addition to the above-described manufacturing practices which contributed to the Manufacturer Defendants' inherently unstable Ranitidine-Containing Products, environmental

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[58] Yanzhong Huang, U.S. Dependence on Pharmaceutical Products from China (Aug. 14, 2019), https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

[59] FDA https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

[60] U.S. Food & Drug Administration, *Lannett Issues Voluntary Nationwide Recall of Ranitidine Syrup (Rantitidine Oral Solution, USP), 15mg/ml due to an Elevated Level of the Unexpected Impurity, N-Nitrosodimethylamine* (Oct. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lannett-issues-voluntary-nationwide-recall-ranitidine-syrup-ranitidine-oral-solution-usp-15mgml-due (last accessed June 21, 2020).

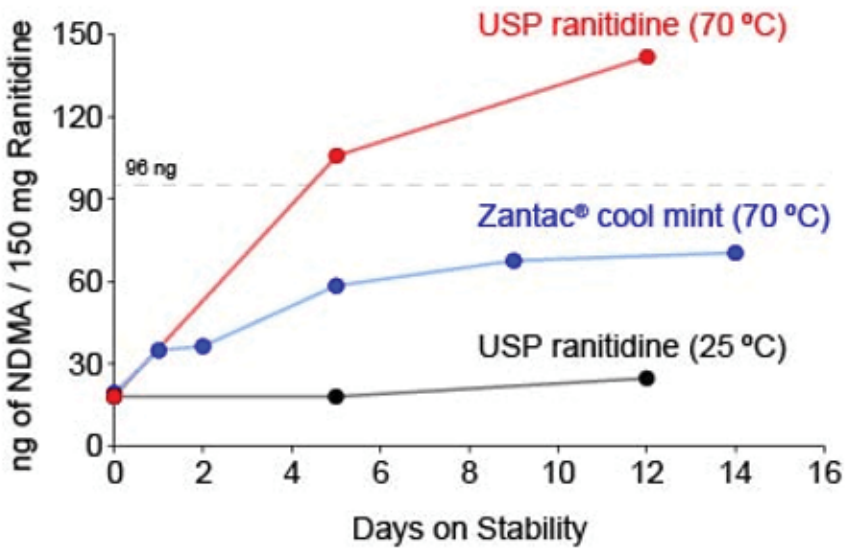
factors, such as exposure to heat and/or time also contribute to the propensity for the ranitidine molecule to degrade to NDMA.

272. Indeed, the risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that NDMA formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method (but also specifically developed a detection protocol that did not use heat).

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

274. On January 2, 2020, Emery Pharma ("Emery"), an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ˚C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. The following diagram reveals how NDMA accumulates over time when exposed to 70 ˚C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



275. The researchers cautioned that:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, ***which would be routinely reached during shipment and during storage***. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption.[61]

276. The results of this data demonstrate that when exposed to heat, even through normal transport and storage, a ranitidine molecule that has been manufactured in such a way that it is inherently unstable will systematically break down into NDMA, accumulating over time in the finished product. Considering Ranitidine-Containing Products have an approved shelf life of 36 months, the probability of the drug accumulating dangerously high levels of NDMA was too great

[61] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 7, 2020), https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/ (last accessed on June 12, 2020).

for Defendants to allow distribution of the product without proper transport and storage requirements – a point underscored by the FDA's swift removal of the product from the market.

VI. Defendants Failed to Uphold their NDA and ANDA Obligations

277. During the time that Defendant GSK and the Generic Manufacturer Defendants (hereafter defined as "Manufacturer Defendants") manufactured and sold Ranitidine-Containing Products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. Manufacturer Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and they failed to report these risks to the FDA.

278. Manufacturer Defendants concealed the ranitidine–NDMA link by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

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

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

280. 21 C.F.R. §314.81(b)(2)(v) provides:

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

281. Manufacturer Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine-Containing Products.

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

283. Manufacturer Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the link between ranitidine and NDMA. Accordingly, because Manufacturer Defendants never properly disclosed the risk to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport / storage.

284. When the FDA eventually learned about the NDMA risks posed by Ranitidine-Containing Products, it quickly ordered manufacturers to voluntarily remove the products from the market. Thus, had any Manufacturer Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove Ranitidine-Containing Products from the market and Plaintiffs and other TPPs would not have reimbursed for these Ranitidine-Containing Products.

VII. Brand-Name Manufacturer Defendants Developed and Implemented a Marketing Scheme to Mislead Consumers and Health Professionals into Believing that Zantac Was Safe

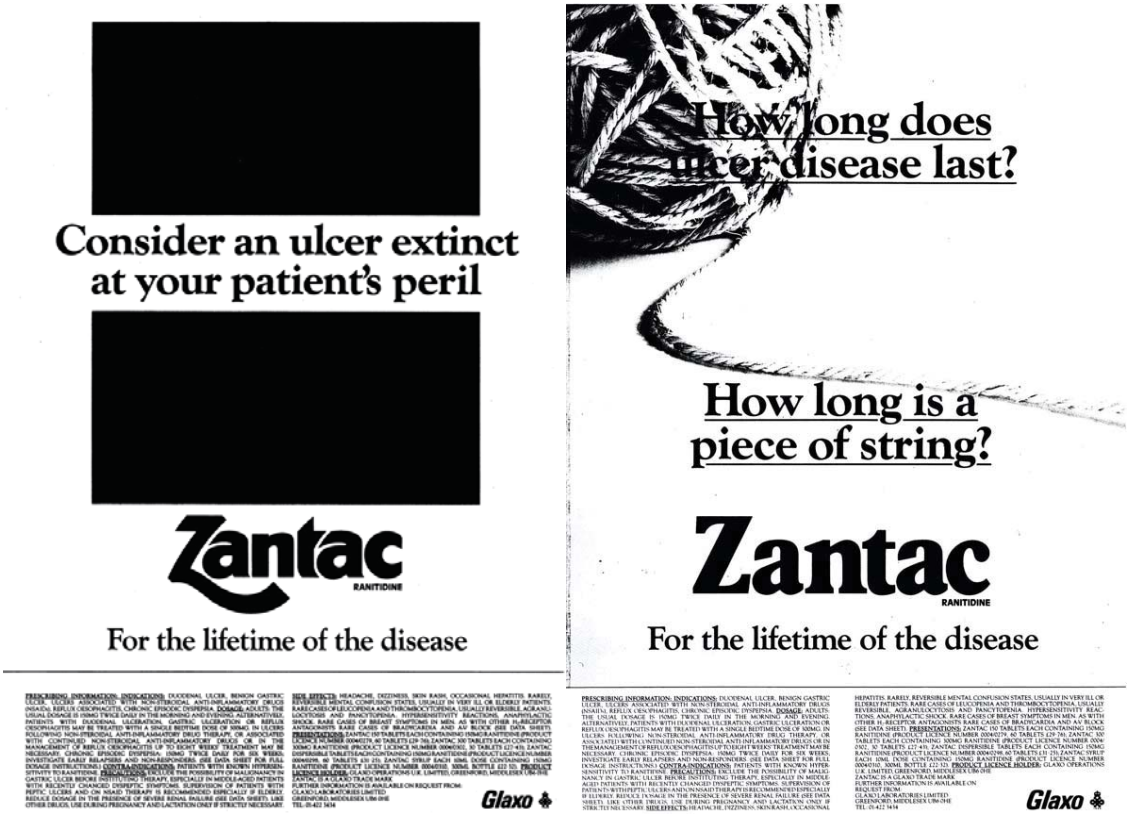
285. Having created an inherently unstable and unsafe product, the Brand-Name Manufacturer Defendants had to mislead TPPs, consumers and health professionals into believing Zantac was safe, including safe for use with chronic conditions and for fast, immediate relief with nitrite- and nitrate-rich foods. The Brand-Name Manufacturer Defendants thus engaged in a pervasive and decades-long campaign of misrepresentations and omissions to convince consumers that Zantac was safe and to conceal the existence of and the risks posed by NDMA.

286. The Brand-Name Manufacturer Defendants devised and knowingly carried out a material scheme to defraud consumers by misrepresenting the safety, and concealing the true health risks, of Zantac. The marketing campaign was national in scope and spanned decades, and although it came via separate missives, the fundamental message was uniform: Zantac (in both prescription and OTC form) is safe, can be used frequently and poses no serious health risks.

A. Brand-Name Manufacturer Defendants Marketed Zantac as a Safe Treatment Method for Chronic Conditions to Health Professionals and as a Medication Trusted and Recommended by Doctors to Consumers

287. The Brand-Name Manufacturer Defendants presented Zantac as being a safe and effective treatment for chronic conditions, and touted Zantac as being the treatment method trusted and recommended by doctors. However, despite knowing that Ranitidine-Containing Products had carried unreasonable risk due to its propensity to degrade to NDMA, Brand-Name Manufacturer Defendants wholly omitted any information from their advertisements that disclosed the serious risks posed by Ranitidine-Containing Drug.

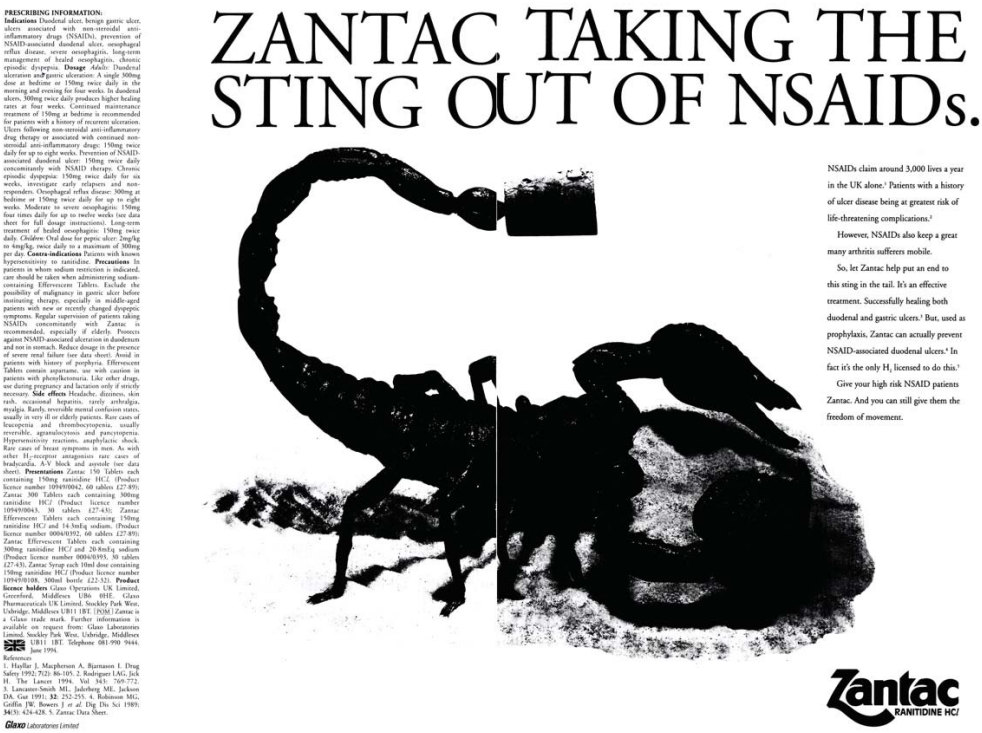
288. For example, in 1990, GSK ran ads in *Gut*, an international medical journal published by the *British Society of Gastroenterology*, representing that Zantac was a medication that could be taken "[f]or the lifetime of the disease":[62]



289. From at least 1994-1995, GSK also placed ads in *Gut*, touting Zantac as an effective prophylaxis to be used in conjunction with NSAIDs to prevent NSAID-associated duodenal ulcers:[63]

[62] *Advertising*, 31-5 GUT 489 (May 1, 1990), https://gut.bmj.com/content/gutjnl/31/5/local/advertising.pdf; *Advertising*, 31-4 GUT 365 (Apr. 1, 1990), https://gut.bmj.com/content/gutjnl/31/4/local/advertising.pdf; *see also Advertising*, 31-3 GUT 245 (Mar. 1, 1990), https://gut.bmj.com/content/gutjnl/31/3/local/advertising.pdf (advertisement representing Zantac for use "[f]or the lifetime of the disease").

[63] *Advertising*, 35-9 GUT 1155 (Sept. 1, 1994), https://gut.bmj.com/content/gutjnl/35/9/local/advertising.pdf; *Advertising*, 37-1 GUT 1 (July 1, 1995), https://gut.bmj.com/content/gutjnl/37/1/local/advertising.pdf.



PRESCRIBING INFORMATION:
Indications Duodenal ulcer, benign gastric ulcer, ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), prevention of NSAID-associated duodenal ulcer, oesophageal reflux disease, severe oesophagitis, long-term management of healed oesophagitis, chronic episodic dyspepsia. **Dosage** *Adults*: Duodenal ulceration and gastric ulceration: A single 300mg dose at bedtime or 150mg twice daily in the morning and evening for four weeks. In duodenal ulcers, 300mg twice daily produces higher healing rates at four weeks. Continued maintenance treatment of 150mg at bedtime is recommended for patients with a history of recurrent ulceration. Ulcers following non-steroidal anti-inflammatory drug therapy or associated with continued non-steroidal anti-inflammatory drugs: 150mg twice daily for up to eight weeks. Prevention of NSAID-associated duodenal ulcer: 150mg twice daily concomitantly with NSAID therapy. Chronic episodic dyspepsia: 150mg twice daily for six weeks, investigate early relapsers and non-responders. Oesophageal reflux disease: 300mg at bedtime or 150mg twice daily for up to eight weeks. Moderate to severe oesophagitis: 150mg four times daily for up to twelve weeks (see data sheet for full dosage instructions). Long-term treatment of healed oesophagitis: 150mg twice daily. *Children*: Oral dose for peptic ulcer: 2mg/kg to 4mg/kg, twice daily to a maximum of 300mg per day. **Contra-indications** Patients with known hypersensitivity to ranitidine. **Precautions** In patients in whom sodium restriction is indicated, care should be taken when administering sodium-containing Effervescent Tablets. Exclude the possibility of malignancy in gastric ulcer before instituting therapy, especially in middle-aged patients with new or recently changed dyspeptic symptoms. Regular supervision of patients taking NSAIDs concomitantly with Zantac is recommended, especially if elderly. Protects against NSAID-associated ulceration in duodenum and not in stomach. Reduce dosage in the presence of severe renal failure (see data sheet). Avoid in patients with history of porphyria. Effervescent Tablets contain aspartame, use with caution in patients with phenylketonuria. Like other drugs, use during pregnancy and lactation only if strictly necessary. **Side effects** Headache; dizziness, skin rash, occasional hepatitis, rarely arthralgia, myalgia. Rarely, reversible mental confusion states, usually in very ill or elderly patients. Rare cases of leucopenia and thrombocytopenia, usually reversible, agranulocytosis and pancytopenia. Hypersensitivity reactions, anaphylactic shock. Rare cases of breast symptoms in men. As with other H_2-receptor antagonists rare cases of bradycardia, A-V block and asystole (see data sheet). **Presentations** Zantac 150 Tablets each containing 150mg ranitidine HCl (Product licence number 0049/0042, 60 tablets £27.49); Zantac 300 Tablets each containing 300mg ranitidine HCl (Product licence number 0049/0043, 30 tablets £27.43); Zantac Effervescent Tablets each containing 150mg ranitidine HCl and 34.3mEq sodium, (Product licence number 0004/0392, 60 tablets £27.49); Zantac Effervescent Tablets each containing 300mg ranitidine HCl and 20.8mEq sodium (Product licence number 0004/0393, 30 tablets £27.43). Zantac Syrup each 10ml dose containing 150mg ranitidine HCl (Product licence number 0049/0108, 300ml bottle £22.32). **Product licence holders** Glaxo Operations UK Limited, Greenford, Middlesex UB6 0HE. Glaxo Pharmaceuticals UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. [R]M Zantac is a Glaxo trade mark. Further information is available on request from: Glaxo Laboratories Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Telephone 081-990 9444. June 1994.

References
1. Hayllar J, Macpherson A, Bjarnason I. Drug Safety 1992; 7(2): 86-105. 2. Rodriguez LAG, Jick H. The Lancet 1994; Vol 343: 769-772. 3. Lanza-Smith ML, Jaderberg ME, Jackson DA. Gut 1991; **32**: 252-255. 4. Robinson MG, Griffin JW, Bowers J *et al*. Dig Dis Sci 1989; **34**(3): 424-428. 5. Zantac Data Sheet.

Glaxo Laboratories Limited

ZANTAC TAKING THE STING OUT OF NSAIDs.

NSAIDs claim around 3,000 lives a year in the UK alone.[1] Patients with a history of ulcer disease being at greatest risk of life-threatening complications.[2]

However, NSAIDs also keep a great many arthritis sufferers mobile.

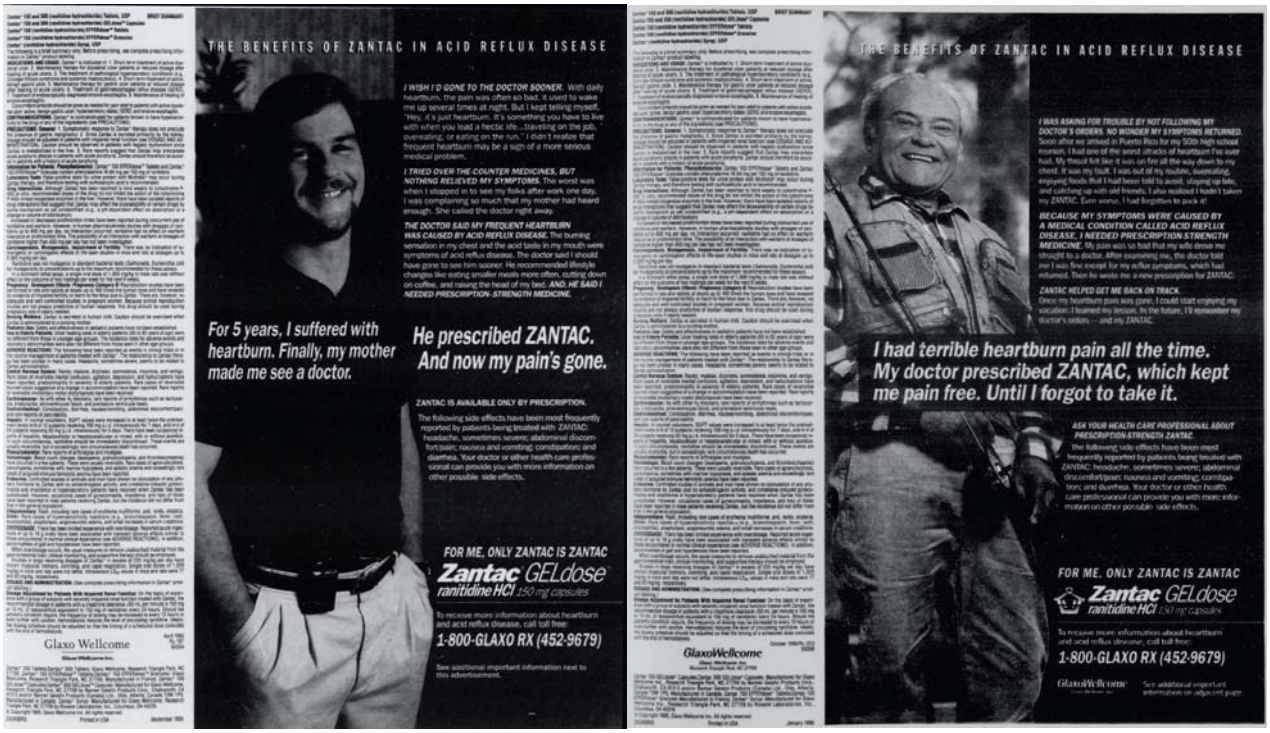
So, let Zantac help put an end to this sting in the tail. It's an effective treatment. Successfully healing both duodenal and gastric ulcers.[3] But, used as prophylaxis, Zantac can actually prevent NSAID-associated duodenal ulcers.[4] In fact it's the only H_2 licensed to do this.[5]

Give your high risk NSAID patients Zantac. And you can still give them the freedom of movement.

Zantac RANITIDINE HCl

290. And GSK ran the following newspaper ads in 1995 and 1996, which featured narrative accounts of patients suffering from Acid Reflux Disease visiting their doctors and being prescribed Zantac:[64]

[64] GSK, *Zantac Ad*, BLUEFIELD DAILY TELEGRAPH, Nov. 5, 1995, https://newspaperarchive.com/bluefield-daily-telegraph-nov-05-1995-p-56/ (publication located in Bluefield, WV); GSK, *Zantac Ad*, ALAMOGORDO DAILY NEWS, Feb. 25, 1996, https://newspaperarchive.com/alamogordo-daily-news-feb-25-1996-p-40/ (publication located in Alamogordo, NM).



291. From at least 2009-2015, BI represented in Zantac OTC advertisements that the active ingredient ranitidine had been "prescribed by doctors for years to treat millions of patients safely and effectively":[65]

[65] *See, e.g.*, *Zantacotc.com*, BOEHRINGER INGELHEIM (June 8, 2009), https://web.archive.org/web/20090608184215/http://www.zantacotc.com/products/zantac150cool.jsp; *Zantacotc.com*, BOEHRINGER INGELHEIM (May 13, 2013), https://web.archive.org/web/20130513180645/http://www.zantacotc.com/products/zantac150cool.jsp.

292. In 2019, Sanofi made the same representation through its own advertising, which stated that Zantac OTC "has the same active ingredient ranitidine, which doctors have prescribed for years to treat millions of patients safely and effectively."[66]

B. The Brand-Name Manufacturer Defendants Marketed Zantac OTC as a Safe and Effective Medication to Prevent and Relieve Heartburn Caused by the Consumption of Nitrite- and Nitrate-Rich Foods

293. The Brand-Name Manufacturer Defendants misrepresented to the public in print, radio, and television advertisements and on social media that Zantac OTC was safe to be taken for fast heartburn relief before or after consumption of nitrite- and nitrate-rich foods. The Brand-Name Manufacturers wholly omitted any information from their advertisements that disclosed the serious health risks posed by use or ingestion of Ranitidine-Containing Products – particularly when taken with nitrite- and nitrate-rich foods – despite knowing that Ranitidine-Containing

[66] *Zantacotc.com*, SANOFI (Feb. 7, 2019), https://web.archive.org/web/20190207202602/https://www.zantacotc.com/heartburn-relief.html.

Products presented a dangerous and unreasonable risk of degrading into NDMA, a known human carcinogen.

294. For instance, in 2006, Pfizer ran a television advertisement depicting a man and a woman standing outside of a BBQ restaurant, with the man promising to the woman that taking Zantac OTC before their meal will prevent her heartburn. This advertisement also represented that Zantac OTC taken after a meal can provide fast-acting heartburn relief.

295. In 2009, BI ran a television advertisement depicting a woman drinking coffee and eating a burrito at work, with a voiceover saying: "Chug that coffee. Gulp that burrito. No matter what life throws at you, you can take the heat. Until it turns into heartburn. Good thing you've got what it takes to beat that heat too. Zantac—it's strong. Just one pill can knock out the burn." In 2011, BI also ran a similar television advertisement depicting a man drinking coffee and eating a hotdog, with a voiceover saying: "Chug that java. Down that dog. No matter what life throws at you, you can take the heat. Until it turns into heartburn. Good thing you've got what it takes to beat that heat too. Zantac—it's strong. Just one pill can knock out the burn."

296. In 2010, BI advertised its "Zantac Beat the Heat Sweepstakes," through both radio[67] and print advertisements. BI's newspaper advertisements included the slogan, "Zantac BEAT THAT HEARTBURN HEAT," and featured the host of the television program, Man v. Food, holding a box of Zantac OTC in front of a basket of buffalo chicken wings.[68] Another newspaper

[67] BI advertised its "Zantac Beat the Heat Sweepstakes" via radio on at least two occasions: in the Cleveland, Ohio market on May 20, 2010, and in the Chicago, Illinois market on June 30, 2010.

[68] This advertisement was placed in a Cleveland, Ohio newspaper on May 23, 2010.

advertisement[69] placed in the same year showed a pizza with a frowning face and promised that Zantac products would provide "fast and long-lasting heartburn relief":

297. In 2013, BI announced the introduction of Captain Zantac, "the new face of the…ZANTAC Brand."[70] Captain Zantac was a miniature animated fire captain who was used in television, radio, and print advertisements.

[69] This advertisement was placed in newspapers in Atlanta, Georgia and Dallas, Texas on November 10, 2010.

[70] https://www.prnewswire.com/news-releases/zantac-launches-innovative-integrated-marketing-campaign-to-educate-consumers-on-heartburn-relief-222968201.html (last accessed June 20, 2020).

298. In discussing the introduction of Captain Zantac, the first animated character to appear in advertising for OTC heartburn medication, Ross Ullman, the Executive Director of Marketing for BI stated the use of an "iconic" character serves as a "persuasive and memorable platform to cut through the heartburn advertising clutter and educate consumers on which heartburn solutions are really right for them."[71] The stated goal for Captain Zantac was to "help heartburn sufferers understand that . . . ZANTAC rushes relief in as little as 30 minutes."[72]

299. In addition to a prolific presence on television airways, Captain Zantac was also used and displayed in retail pharmacies to draw attention to Zantac:

[71] https://www.prnewswire.com/news-releases/zantac-launches-innovative-integrated-marketing-campaign-to-educate-consumers-on-heartburn-relief-222968201.html (last accessed June 20, 2020).

[72] https://www.prnewswire.com/news-releases/zantac-launches-innovative-integrated-marketing-campaign-to-educate-consumers-on-heartburn-relief-222968201.html

300. Like the radio and print advertisements involving the Zantac Heartburn Challenges, Captain Zantac also encouraged[73] consumers to take Zantac with food:

301. From at least 2017-2019, Sanofi continued marketing Zantac as a safe and effective treatment medication for the treatment of heartburn caused by consuming nitrite- and nitrate-rich foods.

302. In furtherance of these marketing goals, Sanofi retained ownership of the Captain Zantac trademark[74] on or around February 2018 and continued to use Captain Zantac in television, radio, and print advertisements.

303. Captain Zantac (or "Cap Z" as he was so colloquially referred in materials created and used by Sanofi) also maintained an active social media presence, tweeting frequently[75] and inducing consumers to interact with the twitter account through the use of free giveaways and sweepstakes.

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[73] https://twitter.com/ZantacOTC/status/756858939732439041/photo/1 (last accessed June 22, 2020).

[74] https://trademarks.justia.com/864/26/captain-86426387.html (last accessed June 20, 2020).

[75] https://twitter.com/zantacotc (last accessed June 20, 2020).

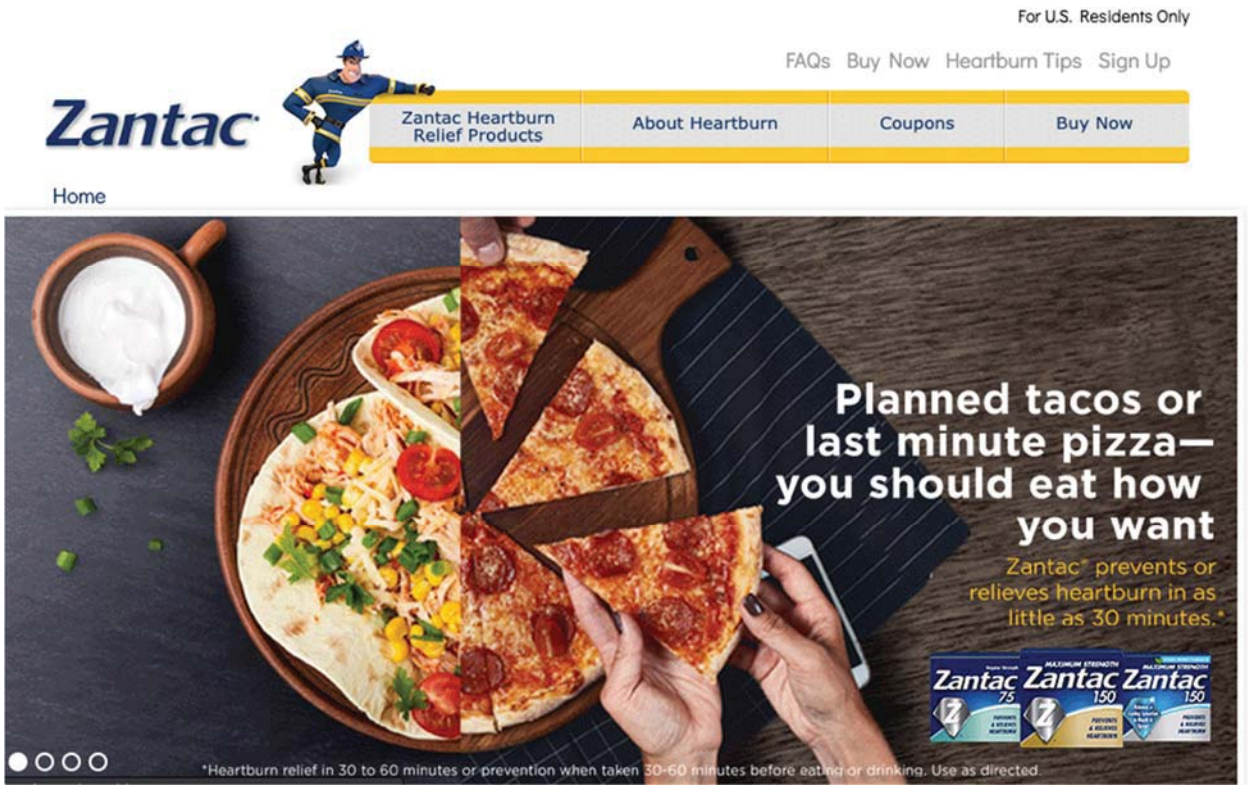
304. Cap Z's twitter presence also offered "#ZanHacks" which were tips that he offered to consumers to induce them to take Zantac with food consumption.

305. Cap Z likewise encouraged consumers to take Zantac with nitrite-rich foods, through the use of social media engagement campaigns.

306. Captain Zantac was also integrated into Sanofi's other consumer marketing piece, a branded website called zantacotc.com, which also served to promote the use of Zantac with nitrate rich foods.

307. For example, Sanofi presented the following on zantacotc.com:[76]

[76] *Zantacotc.com*, SANOFI (Apr. 5, 2019), https://web.archive.org/web/20190405064719/https:/www.zantacotc.com/ *Zantacotc.com*, SANOFI (Feb. 7, 2019), https://web.archive.org/web/20190207202602/https://www.zantacotc.com/heartburn-relief.html.


For U.S. Residents Only
FAQs Buy Now Heartburn Tips Sign Up
Zantac
Zantac Heartburn Relief Products
About Heartburn
Coupons
Buy Now
Home
Planned tacos or last minute pizza—you should eat how you want
Zantac® prevents or relieves heartburn in as little as 30 minutes.*
*Heartburn relief in 30 to 60 minutes or prevention when taken 30-60 minutes before eating or drinking. Use as directed.


SANOFI
For U.S. Residents Only
Like Follow
FAQs Buy Now Heartburn Tips Sign Up
Zantac
Zantac Heartburn Relief Products
About Heartburn
Coupons
Buy Now
Home » Heartburn Relief | Zantac Products
Plan a meal or roll the dice—Zantac® both prevents* or relieves heartburn
Why Zantac®?
You probably want to eat and drink your favorite things without heartburn getting in the way. That's why there's Zantac®, which prevents* and relieves heartburn, giving you the flexibility to take it before or after you eat. And it lasts up to 12 hours.† Convenient, right?
You can buy Zantac® over the counter at most retailers. It has the active ingredient ranitidine, which doctors have prescribed for years to treat millions of patients safely and effectively.
00:15
No pill relieves heartburn faster™‡
Zantac® prevents heartburn when taken 30 to 60 minutes before a meal, and it provides quick relief§ of heartburn symptoms once they've already started. Zantac® begins to work in as little as 30 minutes§ and last up to 12 hours†.

308. From at least 2018-2019, Sanofi ran a television ad campaign that featured the slogan, "Eat your way. Treat your way." One of these television advertisements depicted a family enjoying "taco night" and a man suffering from heartburn after unexpectedly having pizza for lunch. Another television advertisement attached to this campaign showed a man and woman at a cookout both rubbing their stomachs in pain in front of a plate of hamburgers, while a voiceover said, "Zantac works in as little as 30 minutes. Eat your way. Treat your way.

309. Indeed, the Brand-Name Manufacturer Defendants ran myriad television, print, radio, and internet ads that communicated this misleading message:

First Date	Brand-Name Manufacturer Defendant	Advertising Medium	Title	Market
04/17/2006	Pfizer	Television	MAN OFFERS PEOPLE FAST RELIEF	Salt Lake City, UT
04/28/2006	Pfizer	Radio	Family Controls Heartburn	Los Angeles, CA
01/01/2008	BI	Radio	Woman Calls It Here It Comes Again	Tampa, FL
01/01/2008	BI	Radio	Woman Calls It Here It Comes Again	New York, NY
01/01/2008	BI	Radio	Heartburn Isn't Funny	Washington, D.C.
01/01/2008	BI	Radio	Woman Calls It Here It Comes Again	Baltimore, MD
01/01/2008	BI	Radio	Man Goes to Bed at Nine	Phoenix, AZ
01/03/2008	BI	Radio	Heartburn Isn't Funny!	Atlanta, GA
01/03/2008	BI	Radio	Heartburn! Attack It. Zantac	Tampa, FL
01/03/2008	BI	Radio	I Will Go to Bed at Nine	Los Angeles, CA
01/04/2008	BI	Radio	Heartburn! Attack It. Zantac	Orlando, FL
01/04/2008	BI	Radio	Take Zantac to Relieve Heartburn	Boston, MA
01/07/2008	BI	Radio	Heartburn! Attack It. Zantac	Los Angeles, CA
01/09/2008	BI	Radio	The Embarrassing Part of Heartburn	Los Angeles, CA
12/16-17/2008	BI	Newspaper	Because these days, breakfast while reading the	Miami, FL

First Date	Brand-Name Manufacturer Defendant	Advertising Medium	Title	Market
			morning paper may be all it takes to trigger heartburn.	
04/08/2009	BI	Radio	Heartburn Won't Slow You Down	San Francisco, CA
10/12/2009	BI	Television	Woman Gets Heartburn at Work	USA
11/17/2009	BI	Television	Woman Gets Heartburn at Work	St. Louis, MO
05/23/2010	BI	Newspaper	BEAT THAT HEARTBURN HEAT.	Cleveland, OH
09/05/2010	BI	Television	Beat that Heartburn Heat	Orlando, FL
11/10/2010	BI	Newspaper	Can't find your usual heartburn remedy?	Atlanta, GA; Dallas, TX
08/22/2011	BI	Television	Fast Relief in a Short Time	USA
01/12/2015	BI	Magazine	CAPTAIN Zantac IN HEARTBURN RESCUE	US
03/02/2015	BI	Magazine	CAPTAIN Zantac IN HEARTBURN RESCUE	ESPN
09/13/2015	BI	Television	Zantac Heartburn Challenge	LMN
09/27/2015	BI	Online Video	Take the Challenge	YAHOOENT Video
11/14/2015	BI	Television	Get Faster Relief	LMN
12/09/2016	BI	Television	Get the Fast Heartburn Relief	Denver, CO
02/05/2017	Sanofi	Television	Fast Heartburn Relief	FNEW
03/07/2017	Sanofi	Online Video	Releases Cooling Sensation in Mouth and Throat	Answers.com Video
06/26/2017	Sanofi	Television	Better for Heartburn Relief	Portland, OR
11/13/2017	Sanofi	Television	Best Relief from Heartburn	TVL
04/09/2018	Sanofi	Television	The Fast Relief	San Francisco, CA
07/03/2018	Sanofi	Online Video	No Mess Fast Relief Heartburn Night	TLC.com Video
07/27/2018	Sanofi	Television	Best Relief from Heartburn	Raleigh, NC
03/14/2019	Sanofi	Online Video	The Fast Relief	Maxpreps.com Video
04/08/2019	Sanofi	Television	Prevent or Relief Heartburn	San Francisco, CA
04/08/2019	Sanofi	Online Video	Man & Boy Are Eating Taco in the Dining Table	Xfinity.com Video
04/21/2019	Sanofi	Television	Relieves It Fast	Atlanta, GA

C. BP and Sanofi Used Ostensibly Unbranded Websites to Market Zantac as Safe

310. BI and Sanofi also misrepresented via an ostensibly unbranded website and Defendant-funded journal articles purporting to offer neutral scientific evidence that Zantac had no long-term safety concerns or any known clinically significant integrations with other commonly prescribed drugs, without disclosing the instability of ranitidine--the active ingredient in Zantac.

311. On November 15, 2015, BI bought/registered the domain name rethinkppis.com, which transferred to Sanofi on February 24, 2017. The unbranded website included data connecting another competitor class of antacid drugs, proton pump inhibitors ("PPIs") with increased cardiovascular risks, kidney disease, low magnesium, bone fractures, and gut bacteria, and noted that H2 blockers were not proven to be associated with those same risks:

PPIs have other safety concerns H2 blockers don't

- H2 blockers like non-prescription Zantac® have no long-term safety concerns when used as directed or no known clinically significant interactions with other commonly prescribed drugs people may be taking, unlike PPIs such as Nexium®.
- Unlike PPIs, increased risk of fractures of the hip, wrist, and spine have not been reported in clinical studies with H2 blockers.[77]

312. Neither BI or Sanofi contemporaneously, or at any time, disclosed on the rethinkppis.com website. the dangers of NDMA or that the active ingredient in Zantac – ranitidine – was unstable and broke down in to cancer-causing NDMA.

[77] *RethinkPPIs.com*, BOEHRINGER INGELHEIM (Feb. 19, 2016), https://web.archive.org/web/20160219011903/http://www.rethinkppis.com/

VIII. Defendants Made Misrepresentations and Omissions In the Labeling and Marketing of Their Ranitidine-Containing Products

A. Defendants' Labels Were Misleading and Omitted Material Information and Warnings that Should Have Been Apparent to Them through Stability Testing

313. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[78] and to conform to requirements governing the appearance of the label.[79]

314. "Labeling" encompasses all written, printed, or graphic material accompanying the drug or device,[80] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

315. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the [FDCA] as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[81]

316. All drug manufacturers (brand and generic) are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[82] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and

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78 21 C.F.R. §201.5.

79 21 C.F.R. §801.15.

80 *Id.*; 65 Fed. Reg. 14286 (March 16, 2000).

81 *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

82 22 C.F.R. §211.166(a).

specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[83]

317. The purpose of stability testing is, in part, to determine "the appropriate storage conditions and expiration dates."[84] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[85] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."[86]

318. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[87]

319. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration

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[83] *Id.*

[84] *Id.*

[85] 21 C.F.R. §211.137(a).

[86] 21 C.F.R. §211.137(b).

[87] 43 Fed. Reg. 45059.

date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[88]

320. After a drug is approved, a manufacturer (brand or generic) can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§314.70 and 314.71.[89]

321. Some of the requirements in those regulations require a brand or generic manufacturer of an approved drug to obtain FDA approval before implementing a label change.[90]

322. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[91]

323. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[92] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[93]

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88 21 C.F.R. §211.166(b).

89 *See* 21 C.F.R. §§314.70, 314.97(a) (requiring generics to comply).

90 §314.70(b).

91 21 C.F.R. §314.70(c)(3), (c)(6).

92 21 C.F.R. §314.70(c)(6)(i).

93 65 Fed. Reg. 83042 (Dec. 29, 2000).

324. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use" or to ensure that the drug is shipped and stored under appropriate conditions. [94]

325. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to: "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under §201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."[95]

326. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. This includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[96]

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[94] 21 C.F.R. §211.137(a).

[95] 21 C.F.R. §§314.70(c)(6)(iii)(A), (C), (D).

[96] 21 C.F.R. §314.71(d)(2)(ix).

327. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."[97]

328. At no time did any Defendant attempt to include a warning about NDMA levels in ranitidine, and the FDA never rejected such a warning. Defendants holding the NDAs had the ability to unilaterally add an NDMA and/or cancer warning to the labels of Ranitidine-Containing Products without prior FDA approval pursuant to the CBE regulation. Had any such Defendant attempted to add an NDMA warning to the label of its Ranitidine-Containing Products, the FDA would not have rejected it.

329. At no time did any Defendant attempt to change its label to delete a false or misleading expiration date, to delete false or misleading shipping and storage conditions, to add a proper expiration date, or to add proper shipping and storage conditions, to ensure that the Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

330. Based on the public scientific information available starting in 1983 (or earlier), the Defendants knew or should have known that NDMA could form from ranitidine by exposure to heat and/or over time in storage.

331. At no time did any Defendant change its label to shorten the expiration date or alter the safe shipping and storage temperature of its ranitidine-containing product, and the FDA never rejected such changes. Both Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants had the ability to unilaterally make such label changes (for both prescription and OTC)

[97] *Id.* §314.71(d)(2)(vi).

without prior FDA approval pursuant to the CBE regulation. Had any Defendant attempted such label changes, the FDA would not have rejected them.

332. Because they failed to warn that Ranitidine-Containing Products contained or broke down into NDMA, Defendants made false statements in the labeling of their products and omitted material information regarding the drug's safety.

333. Because they failed to include appropriate expiration dates on their products, Defendants made false statements in the labeling of their products and omitted material information regarding the drug's safety.

334. Because they failed to include proper storage instructions on their products, Defendants made false statements in the labeling of their products and omitted material information regarding the drug's safety.

IX. Defendants' Ranitidine-Containing Products Are Misbranded and Adulterated Because They Contain Biologically Relevant Levels of NDMA

335. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[98]

336. The introduction into commerce of any misbranded or adulterated drug is also prohibited.[99]

337. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is unlawful.[100]

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[98] 21 U.S.C. §331(g).

[99] 21 U.S.C. §331(a).

[100] 21 U.S.C. §331(c).

338. Because Defendants did not disclose NDMA as an ingredient in the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

339. Because Defendants did not disclose the proper directions for storage of the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

340. Because Defendants did not disclose the proper directions for expiration of the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

341. It is unlawful to introduce a misbranded drug into interstate commerce. Thus, the Ranitidine-Containing Products Plaintiffs made payments or reimbursements for were unlawfully distributed and sold and is economically worthless.

X. Defendants Made and Breached Warranties to Plaintiffs and TPP Class Members

342. Each Defendant's Ranitidine-Containing Drug is accompanied by an FDA-approved label. By providing TPPs with an FDA-approved label, Defendants made representations and express or implied warranties to TPPs like Plaintiffs and TPP Class members that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded and therefore legal to sell.

343. In addition, each Brand-Name Manufacturer Defendant, and Generic Manufacturer Defendant affirmatively misrepresented and warranted to Plaintiffs, TPP Class members, PBMs utilized by Plaintiffs, consumers, and physicians, through their websites, brochures, dossiers, monographs, social media, and other marketing or informational materials, that their Ranitidine-Containing Products complied with cGMPs, were manufactured in such a way to assure that they were of proper identity, strength, quality and purity, and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

A. Defendant GSK's Warranties

344. GSK promises to "do the right thing" for patients and consumers and to "strive for the highest quality."[101] In its Code of Conduct, GSK states:

> We put [patients' and consumers'] safety first, provide them with clear, up-to-date information and promote our products appropriately and ethically.
>
> * * *
>
> Our promotional activities and materials conform to high ethical, medical and scientific standards. They are legal, industry-compliant and evidence based.
>
> * * *
>
> We provide complete, up-to-date and evidence based product information to healthcare professionals and consumers, wherever they are in the world.
>
> * * *
>
> We strive to assure the safety, quality and efficacy of our products for our patients and consumers by ensuring that our procedures comply with Good Practice regulations.

345. Throughout the almost 4 decades that Zantac has been marketed and sold in the United States by GSK, GSK has frequently represented itself as a company committed to manufacturing quality, and safe, products, repeatedly touting that its primary focus was to "improve the quality of human life." GSK touted oversight of "product quality across the supply chain, from suppliers and third party manufacturers through manufacturing to the supply operations that deliver products into the market."[102]

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[101] GSK, Living Our Values and Expectations, Our Code of Conduct, at 7, 12 https://www.gsk.com/media/4800/english-code-of-conduct.pdf (last accessed June 13, 2020).

[102] GSK, 2007 Annual Report http://www.annualreports.com/HostedData/AnnualReportArchive/g/LSE_GSK_2007.pdf (last accessed June 20, 2020).

346. This mantra was repeated throughout their annual reports when GSK represented that they were:

- "generat[ing] the right information about" about products to provide to TPPs including information about "safety, efficacy and quality." (2000)[103]
- "delivering quality products around the world" (2001)[104]
- "improving productivity in both quality and quantity" (2002)[105]
- "developing more high quality compounds than ever before" (2003)[106]
- focusing on securing a supply of "high quality products" that are "best in class" while being at the "leading edge of practices and performances." (2004) [107]
- having "[s]ophisticated quality assurance and quality control procedures in place" (2005)[108]

[103] GSK, 2000 Annual Report, https://www.gsk.com/media/4698/annual-report-2000.pdf (last accessed June 20, 2020).

[104] GSK, 2001 Annual Report, https://www.gsk.com/media/2659/annual-report-2001.pdf (last accessed June 20, 2020).

[105] GSK, 2002 Annual Report, https://www.sec.gov/Archives/edgar/data/1131399/000102123103000405/gsk_report.pdf (last accessed June 20, 2020).

[106] GSK, 2003 Annual Report, https://www.gsk.com/media/2669/annual-report-2003.pdf (last accessed June 20, 2020).

[107] GSK, 2004 Annual Report, https://www.sec.gov/Archives/edgar/data/1131399/000102123103000405/gsk_report.pdf (last accessed June 20, 2020).

[108] GSK, 2005 Annual Report, https://www.gsk.com/media/2676/annual-report-2005.pdf (last accessed June 20, 2020).

- having a "secure source of high quality products" (2006) [109]
- overseeing "product quality across the supply chain, from suppliers and third party manufacturers through manufacturing to the supply operations that deliver products into the market." (2007)[110]

347. However, a 2010 Settlement with the Department of Justice laid bare the truth of GSK's operations, which included a slew of compliance related issues, such as the distribution of ointments that contained microorganisms, sale of drugs that contained no active ingredient, contamination of sterile drugs, rendering them non-sterile, and the like. [111]

348. In a statement from July 2012, newly minted GSK CEO Sir Andrew Witty conceded that GSK had made "mistakes" and that there had been employees who had "engaged in misconduct," but that, as of 2012, GSK had a "clear priority to ingrain a culture of putting patients first, acting transparently, respecting people inside and outside the organization and displaying integrity in everything we do." [112]

[109] GSK, 2006 Annual Report, https://www.gsk.com/media/2679/annual-report-2006.pdf (last accessed June 20, 2020).

[110] GSK, 2007 Annual Report http://www.annualreports.com/HostedData/AnnualReportArchive/g/LSE_GSK_2007.pdf (last accessed June 20, 2020).

[111]https://www.justice.gov/archive/usao/ma/news/2010/October/GSK%20Settlement%20Agreement10_26.pdf (last accessed June 22, 2020).

[112] https://www.gsk.com/en-gb/media/press-releases/glaxosmithkline-concludes-previously-announced-agreement-in-principle-to-resolve-multiple-investigations-with-us-government-and-numerous-states/ (last accessed June 20, 2020).

Generic Manufacturer Defendants' Warranties

1. Amneal

349. Amneal states it "produce[s] quality generic, specialty and biosimilar medicines."[113] Amneal proudly proclaims that its "quality culture is one of the core pillars of our success." [114]

350. Amneal further touts its success in "consistently meet[ing] or exceed[ing] quality, industry and global regulatory standards."[115]

351. As part of their corporate "Purpose and Commitment," Amneal sets "a high bar for our products, pipeline, operations and service—always going the extra mile to exceed expectations and reliably execute in everything we do… because patients' lives depend on it." [116]

352. Amneal's SEC filings clearly acknowledge manufacturers are "required to comply with cGMP standards at all times during the production and processing of pharmaceuticals, and the FDA may inspect the manufacturer's sites at any time to ensure compliance."[117] Amneal further recognizes "its products must be made in a manner consistent with cGMP" in the United States

[113] Amneal, Products: Our Portfolio, https://www.amneal.com/products/our-portfolio/ (last accessed June 17, 2020).

[114] Amneal, Products: Quality, https://www.amneal.com/products/quality/ (last accessed June 17, 2020).

[115] Amneal, Products: Quality, https://www.amneal.com/products/quality/ (last accessed June 17, 2020).

[116] Amneal, About: Our Purpose, https://www.amneal.com/about/our-purpose-commitments/ (last accessed June 17, 2020).

[117] http://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_AMRX_2019.pdf

and around the globe and maintains it is "committed to continuing to improve [its] quality control and manufacturing practices."

1. Aurobindo

353. Aurobindo insists they are "committed to quality and safety."[118]

354. Further, Aurobindo "aspire[s] to emerge as a leading global player in high quality, innovative specialty generic formulations."[119]

355. Aurobindo asserts the following "Core Strengths" in "Formulations"[120]:

- Vertically integrated operations from conception to commercialization.
- Large manufacturing capabilities for a diversified product portfolio.
- Efficient regulatory affairs team ensuring market compliance.
- Dedicated R&D setup for finished dosages and active ingredients.
- Technology and expertise for specialty formulations.

356. As part of Aurobindo's "Research and Development" commitment, Aurobindo maintains that it meets federal requirements, and is "focused on the areas of organic synthesis, analytical research, dosage form development, pharmacology, bio-equivalence studies and drug delivery systems."[121]

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[118] Aurobindo, https://www.aurobindo.com/ (last accessed June 22, 2020).

[119] Aurobindo, https://www.aurobindo.com/about-us/business-units/formulations/ (last accessed June 17, 2020).

[120] Aurobindo, https://www.aurobindo.com/about-us/business-units/formulations/ (last accessed June 17, 2020).

[121] Aurobindo, https://www.aurobindo.com/about-us/business-units/rd/ (last accessed June 17, 2020).

357. Aurobindo further asserts a four-point "instrumentation and analytical knowledge base" that the company implements[122]:

- Complete impurity profiling in all products developed.
- Development of analytical methods and specifications from raw materials, to non-compendial finished products.
- In-house synthesis of reagents for analyzing organolithiums and noble metals.
- Accelerated and real-time stability studies.

2. Dr. Reddy's

358. Dr. Reddy's asserts that its "focus on quality helps ensure product safety and efficacy."[123]

359. As part of Dr. Reddy's manufacturing of generic drugs, Dr. Reddy's claims it "focuses on continual improvement aimed at optimizing processes and eliminating non-value-adding efforts in production. These efforts are primarily directed towards reducing variability in process and product quality characteristics." [124]

360. In order to "achieve" their "Quality Management System," Dr. Reddy's insists on the following four-step process: [125]

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[122] Aurobindo, About Us, https://www.aurobindo.com/about-us/business-units/rd/ (last accessed June 17, 2020).

[123] Dr. Reddy's, Our Products: Quality, https://www.drreddys.com/our-products/quality/ (last accessed June 17, 2020).

[124] Dr. Reddy's, Our Products: Quality, https://www.drreddys.com/our-products/quality/ (last accessed June 17, 2020).

[125] Dr. Reddy's, Our Products: Quality, https://www.drreddys.com/our-products/quality/ (last accessed June 17, 2020).

- Adopt Quality by Design (QbD) approach in Manufacturing and clearly identify sources of variability and minimize them on an ongoing basis.
- Be right the first time. Identify and eliminate defects. Improve efficiency.
- Undertake "risk-based" approach to manufacturing and mitigate risks wherever they are likely to impact quality
- Develop transparency in all areas of operations and build robust quality culture across the organization.

3. Glenmark

361. Glenmark claims to be a "global leader in the development and commercialization of generic drugs of the highest quality and value." [126]

362. As part of their "Operations", Glenmark asserts "[our] dedicated employees and state-of-the-art manufacturing centers help make our vision a reality… In a highly regulated environment, where quality and precision are critical, our manufacturing processes are as rigorous as our scientific research. Our state-of-the-art global facilities include all the processes needed to manufacture safe products for our consumers." [127]

4. Lannett

363. Lannett's "generic pharmaceutical products have consistently met the highest standards, and [its] track record for safety and quality is nearly unmatched." [128]

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[126] Glenmark, Products: Generics, https://glenmarkpharma-us.com/products/generics/ (last accessed June 17, 2020).

[127] Glenmark, Operations, https://glenmarkpharma-us.com/operations/ (last accessed June 17, 2020).

[128] Lannett, https://www.lannett.com/approach/ (last accessed June 17, 2020).

364. Lannett maintains that "customers may rest assured that generic pharmaceuticals are produced with the same active ingredients and attention to quality as branded versions." [129]

5. Sandoz

365. Sandoz insists that "quality is a key priority in every aspect of our work… We are committed to giving back more to society than we take. This makes it imperative that we meet and exceed regulatory expectations, embracing the highest standards of quality and integrity in our work, and ensuring that our decisions are guided always by what's best for our patients." [130]

366. Sandoz commits to delivering "the highest quality products" and that the "Sandoz brand is a seal of quality." [131]

6. Strides

367. Strides proudly asserts that its "presence" in the United States "enhances [their] ability to reach a larger base of customers and patients in need of quality treatment options." [132]

368. Strides is "led and driven by its expertise in Research and Development." [133]

369. Strides also brags about its resources, describing its "200 plus scientists, the R&D team offers solutions across the entire product development chain including strategic sourcing, IP

[129] Lannett, Patient Resources: FAQ, https://www.lannett.com/patient-resources/faq/ (last accessed June 17, 2020).

[130] Novartis, Our Company, Our Culture and Values: Quality Commitment, https://www.novartis.com/our-company/our-culture-and-values/novartis-quality-commitment (last accessed June 17, 2020).

[131] Sandoz, About Us: Who We Are, https://www.sandoz.com/about-us/who-we-are/innovation-quality-and-supply (last accessed June 18, 2020).

[132] Strides, http://www.strides.com/pharma-united-states.html (last accessed June 17, 2020).

[133] Strides, http://www.strides.com/corporate-rd.html (last accessed June 17, 2020).

management, formulation development, analytical method development and validation… bio-equivalence, toxicological studies, packaging development and global regulatory submissions."[134]

7. Teva

370. Teva proudly "strive[s] to deliver quality medicines to patients around the world with integrity and ethical business practices."[135]

371. Under its "Generic FAQs" webpage, Teva responds to the question "are generic drugs as safe" by maintaining that their generic drugs "meets…quality standards."[136]

372. Teva proudly proclaims it is "one of the few global pharmaceutical companies that has integrated scientific expertise across generic and specialty (branded) R&D capabilities." [137]

373. Teva goes on to insist its "world-class scientists and doctors focus on being first to market, while ensuring the quality and affordability of our treatments and medicines. Teva's R&D group has an exceptional track record in translating early drug opportunities into clinically-proven drug candidates by using cutting edge research in facilities that are fully equipped to support both good laboratory practice (GLP) and current good manufacturing practice (cGMP) regulations." [138]

374. Under the "Quality Products" webpage, Teva asserts the following:

> "We validate and continually monitor our manufacturing processes to ensure they perform as expected. Each of our products is tested to confirm compliance to Teva's

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[134] Strides, http://www.strides.com/corporate-rd.html (last accessed June 17, 2020).

[135] Teva, https://www.tevapharm.com/product-focus/generics/ (last accessed June 17, 2020).

[136] Teva, https://www.tevapharm.com/product-focus/generics/#item(164507) (last accessed June 17, 2020).

[137] Teva, https://www.tevapharm.com/product-focus/research/generics-r-d/ (last accessed June 17, 2020).

[138] Teva, https://www.tevapharm.com/product-focus/research/generics-r-d/ (last accessed June 17, 2020).

> quality specifications and compliance standards. Because Teva is vertically integrated, we supply a substantial amount of our own active pharmaceutical ingredients. That allows us to closely control product quality… As a result, we have an enviable record of Current Good Manufacturing Practice (cGMP) compliance."[139]

8. Wockhardt

375. Wockhardt claims it is a global pharmaceutical and biotechnology organization "providing affordable, high-quality medicines for a healthier world."[140]

376. Wockhardt achieves its "success" having built an "international manufacturing footprint" that has earned the reputation of a "world-class manufacturer."[141]

377. According to Wockhardt, its "core business is innovation." [142] The website goes on to proudly proclaim that it "Spearhead[s] Research & Development" and "uses science and technology to develop medicines and other products that improve the quality of millions of people's lives through better health." [143]

378. Wockhardt further asserts it "has proved its technical excellence by developing patented modified release formulations and recombinant biotechnology products. It has a multi-disciplinary R&D program with more than 607 scientists, including over 80 doctorates, in the areas of… Pharmaceutical Research" and "Active Pharmaceutical Ingredients Research." [144]

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[139] Teva, Products: Our Qualityhttps://www.tevapharm.com/product-focus/our-quality/ (last accessed June 17, 2020).

[140] http://www.wockhardt.com/who-we-are/manufacturing.aspx (last accessed June 17, 2020).

[141] http://www.wockhardt.com/who-we-are/manufacturing.aspx (last accessed June 17, 2020).

[142] http://www.wockhardt.com/who-we-are/overview.aspx (last accessed June 17, 2020).

[143] http://www.wockhardt.com/who-we-are/overview.aspx (last accessed June 17, 2020).

[144] http://www.wockhardt.com/who-we-are/overview.aspx (last accessed June 17, 2020).

379. The presence of NDMA in Defendants' Ranitidine-Containing Products results in the Ranitidine-Containing Products containing an ingredient that is not also listed on each Defendant's FDA-approved label, breaching warranties arising from such labels, including Defendants' express warranty of compliance. Defendants willfully, recklessly, or negligently failed to ensure their products' labels and other advertising or marketing statements accurately conveyed information about their products.

380. Defendants have also impliedly warranted that their Ranitidine-Containing Products were merchantable and fit for their ordinary purposes.

381. Due to its status as a probable human carcinogen as recognized by both the IARC and the EPA, NDMA is not an FDA-approved ingredient. The presence of NDMA in their Ranitidine-Containing Products means that Defendants violated implied warranties to Plaintiffs. The presence of NDMA in Defendants' Ranitidine-Containing Products results in their being non-merchantable and not fit for its ordinary purposes, breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

382. For these and other reasons, Defendants' Ranitidine-Containing Products are therefore adulterated and/or misbranded, and it was illegal for Defendants to have introduced such products for sale in the United States. *See* 21 U.S.C. §§331(a), 351(a)(2)(B), 331(g).

XI. Defendants Failed to Comply with Current Good Manufacturing Practices

383. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards.[145]

[145] 21 U.S.C. §351(a)(2)(B).

384. 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

385. Pursuant to 21 C.F.R**.** §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine.

386. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" and may not be distributed or sold in the United States.[146] State common law and statutory law mirror these federal standards.

387. As discussed, drugs that are adulterated and misbranded are illegal to sell in the United States.

A. GSK

388. In 2010, GSK signed a settlement plea agreement with the United States Department of Justice as part of an ongoing investigation into its compliance and quality control operations, including a willful and blatant disregard of the operations that are required under the

[146] 21 U.S.C. §§331(a), 351(a)(2)(B).

cGMPs and necessary to assure that all products manufactured are of appropriate safety, identity, purity and strength.

389. For example, the Department of Justice found that the Site Director at GSK's Cidra facility "interfered with" the functioning of the Quality Unit by "directing that no investigations into possible process deficiencies be opened without prior approval and challenging the content of investigative reports prepared by the Quality Unit. [147]

390. In a 2001 inspection the FDA likewise found that GSK was utilizing inadequate analytical methods to ensure that drug products could meet their purported shelf life. [148]

391. However, even when repeatedly presented with these shocking allegations by Global Quality Director, Cheryl Eckard, not only did GSK c-suite executives ignore her information, but Eckard was eventually made redundant and escorted from the premises.

392. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into the company's outrageous misbehavior,[149] GSK's actions resulted in a criminal investigation and

[147] http://lib.law.virginia.edu/Garrett/corporate-prosecution-registry/agreements/sbpharmco.pdf (last accessed on June 20, 2020).

[148] Eckard *Qui Tam* Complaint, http://s3.amazonaws.com/fcmd/documents/documents/000/002/093/original/glaxosmithkline-puerto-rico_complaint.pdf?1423022024 (last accessed on June 20, 2020).

[149] *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong.2d Sess. 1 (Comm. Print Jan. 2010).

the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data in the country's history.[150]

B. Generic Manufacturer Defendants

393. While generic manufacturers assure consumers that their products are just as effective as the RLD, anecdotal evidence suggests that the grossly inadequate manufacturing processes and non-compliance with cGMPs in generic manufacturing facilities, especially those generic manufacturers who utilize and/or rely on foreign plants are flagrantly violating and ignoring the cGMPs that are in place to assure that pharmaceutical drugs sold in the U.S. are not adulterated and/or misbranded.

394. Katherine Eban recently published a headline-grabbing book titled *Bottle of Lies: The Inside Story of the Generic Drug Boom*, which the New York Times recently described as an "invaluable expose" on the failings of the generic drug industry. In *Bottle of Lies*, Eban argues that now-routine misbranding of generic drugs has resulted in a general and justified untrustworthiness of the generic drug industry and of such drugs living up to their ANDAs submitted to the FDA. In short, the generic drug industry is plagued by what Eban describes as "substandard" drugs not of the same quality as what the company purports them to be in ANDA submissions to the FDA. Defendants' Ranitidine-Containing Products are a case in point, and indeed Eban documents grossly inadequate manufacturing processes in her book related to Wockhardt, discussed *infra*.

395. Indeed, for some time it has been well documented that generic drugs manufactured overseas, particularly in India, were found or suspected to be less safe and effective than their

[150] U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report (last accessed June 21, 2020).

domestically-made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

396. The Generic Manufacturer Defendants' manufacturing operations were no exception to this.

1. Amneal

397. Between November 17 and 24 of 2019, the FDA conducted inspections of Amneal's New York facility.[151] The FDA issued a Form 483 to Amneal on November 24, 2019 based on its observations citing multiple violations of cGMPs. Specifically, the inspections revealed Amneals's manufacturing equipment was unacceptable in facilitating operations for its intended use for Ranitidine-Containing Products. Amneal's equipment was not designed properly based on product characteristic resulting in ill-fitting processing, packaging of products conducive to stability issues and degradation.

398. During the FDA's inspections, the inspector observed the mandatory practices intended to prevent the packaging and labeling of defective products were not being documented at the time of performance in any packaging batch records. The FDA further found the responsibilities and procedures of Amneal's quality control unit were not being fully followed and failing to track and maintain change control files per Amneal's own Standard Operating Procedure ("SOP") relating to filing field alert reports for recalls closed on 10/15/09 and "setup and operation of . . Label Inspection System" closed on 10/22/09.

[151] FDA Form 483, *Amneal* (November 17, 2019).

2. Aurobindo

399. Aurobindo has an extensive history of deviations from FDA's cGMP standards, and has been inspected an astounding 29 times since 2011, each inspection resulting in a Form 483 finding of non-compliance with cGMPS.

400. After an inspection of a Hyderabad facility from June 27 to July 1, 2016, the FDA told Aurobindo that its "[i]nvestigations are inadequate." The FDA explained that Aurobindo failed to initiate stability testing, and "[t]he deviation record…requires previous deviations of the same product or deviation type to be reported, no previous deviations were reported in this field." Moreover, "[t]his is a repeat observation from the 2014 inspection." [152]

401. Three months later, the FDA returned to Aurobindo's Hyderabad facilities and found four noteworthy manufacturing problems. First, "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product." Second, "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform [sic] to appropriate standards of identity, strength, quality and purity." Third, "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Fourth, the "use of instruments and recording devices not meeting established specifications was observed."[153]

[152] FDA Form 483, *Aurobindo*, (June 27, 2016).

[153] FDA Form 483, *Aurobindo*, (September 16, 2016).

402. In October 2016, the FDA observed that Aurobindo's nearby Borpatla facility had inadequately validated equipment cleaning procedures. [154]

403. In April 2017, the FDA observed that the manufacturing equipment in Aurobindo's Hyderabad facilities "is not always maintained to achieve its intended purposes." "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." "Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit." "[C]orrective and preventative actions (CAPAs), identified and initiated because of out of specifications (OOS) laboratory investigations, do not correlate to the identified root cause. In certain cases, CAPAs are not initiated at all." "Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." "Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel." "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established." [155]

404. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Second, "[c]ontrol procedures are not established which validate the performance of those manufacturing processes

[154] FDA Form 483, *Aurobindo*, (October 25, 2016).

[155] FDA Form 483, *Aurobindo*, (April 18, 2017).

that may be responsible for causing variability in the characteristics of in-process material and the drug product."

405. In February 2018, the FDA made nine more disturbing observations at Aurobindo's Hyderabad facilities. First, "[a]septic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions." Second, "[e]quipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product." Third, "[e]quipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." Fourth, "[b]uildings used in manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds[,] insects, and other vermin." Fifth, "[p]rocedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance." Sixth, "[e]mployees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions." Seventh, the "statistical quality control criteria fail to include appropriate acceptance levels and rejection levels." Eighth, "[e]stablished laboratory control mechanisms are not followed and documented at the time of performance." Lastly, "[a]ppropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel." [156]

[156] FDA Form 483, *Aurobindo*, (February 20, 2018).

406. It is clear Aurobindo has made no efforts to correct any of the previously identified errors, and continues to engage in grossly inadequate manufacturing processes. During an inspection in May 2019, an investigator made note of a panoply of serious issues which continue to call the integrity of the manufacturing operations into question.

407. For example, in determining that the Medchal, Telangaga facility was not following quality control measures, and likewise did not have quality control procedures in place, the investigator observed "loose handwritten notebooks with what appears to be laboratory test data results." [157]

408. The investigator also found a slew of data integrity issues. The investigator observed "multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as "incomplete data." The testing systems also allowed certain employees to "verify incomplete data in raw data file." The investigator found that the quality control reviewers attested to practices which "contradict actual review practices performed by reviews." Were these baseline data issues not enough, the investigator also noted that the facility did not retain adequate backup of the data, other than the assorted loose notebooks found lying around the facility.

409. The investigator also noted that in addition to all of the gross processing and data integrity issues, even the building itself did not have the "suitable construction to facilitate cleaning, maintenance and proper operations." The investigator noted that in a stability sample storage room, they observed a "PVC pipe connected to an air conditioner unit on one end," and a

[157] FDA Form 483, *Aurobindo*, (May 24, 2019).

blue plastic bucket placed on the other end of the pipe with approximate 50% of the bucket filled with condensate water." There were four other similar setups in other critical rooms in the facility.

3. Dr. Reddy's

410. Dr. Reddy's blatant disregard for cGMPs runs deep, spanning the course of decades, with repeated FDA inspections revealing seriously flawed and unreliable manufacturing practices, systemic failures to investigate out of specification analyses, wholly inadequate validation testing and analytical methods, and a hopelessly out of order record system. Dr. Reddy's inadequacies and history of recurring and ongoing cGMP violations allowed for contamination, degradation and instability in its Ranitidine-Containing Products.

411. As early as 2000, Dr. Reddy's had already adopted manufacturing practices designed to turn a blind eye to failing test results and defective materials. On November 9, 2000, the FDA issued a Warning Letter to a Dr. Reddy's affiliate based on its November 7 to 9, 2000 inspections of its India based facilities regarding its woefully inadequate processes and policies in place related to investigations of Out-of-Trend ("OOT") and Out-of-Spec ("OOS") results, noting the "firm set a blanket policy of not employing the [OOS] procedure for batches of. . .raw material" with numerous out of specification results and ". . .have not conducted an investigation to evaluate the quality of lots" for failing results and OOT results close to the upper limits.[158] Contrary to its own SOPs and tenets of quality manufacturing, Dr. Reddy failed to qualify its suppliers and shunned its responsibilities to retest and/or investigate the causes or evaluate the frequency of failing test results. The FDA additionally observed that Dr. Reddy's quality control laboratory shockingly had no record receipt of or logging of samples tested or received, repeatedly failed to

[158] FDA Establishment and Inspection Report, *Cheminor Drugs Ltd. / Dr. Reddy's Laboratories*, (Nov. 9, 2000).

conduct periodic testing, failed to demonstrate that its testing meets EPA specifications, and had improper validation testing necessary for accurate testing.

412. On April 11, 2002, the FDA issued an Establishment Inspection Report outlining multiple cGMP deficiencies in Dr. Reddy's manufacturing including improper cleaning validation studies, failure to investigate content uniformity, failure of the packaging line to meet established acceptance criteria, and deficient calibration procedures.[159]

413. During its 2002 inspections, the FDA again observed Dr. Reddy's failing to properly investigate OOS results in stability testing for impurities and not following its own written procedures requiring "the completion of an Incident Report when incidents affecting the quality, purity and strength occur." Instead, documentation and conclusory statements as to operational qualification studies for ranitidine were detected during the inspection and Dr. Reddy's had failed to properly validate its software for the production line, a requirement of cGMPs, and a step necessary to insure uniformity and quality products. Dr. Reddy's again failed to follow-up to correct problems detected during manufacturing of ranitidine.[160] After receiving multiple complaints between January 2001 and January 2002 regarding physical defects with its Ranitidine-Containing Products, Dr. Reddy's failed to perform any investigation into problems with rejected batches - "[n]o attempts were made to determine the cause of the failures (physical defects)."

414. Rather than learn from its mistakes, Dr. Reddy's skirted its manufacturing obligations by not investigating the sources of problems and not taking corrective actions to avoid recurrence. On February 13, 2012, the FDA issued a Form 483 detailing Dr. Reddy's grossly

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[159] *Id.*

[160] FDA Establishment and Inspection Report, *Dr. Reddy's Laboratories Ltd.*, (April 11, 2002).

inadequate procedures and cGMP violations relating to the manufacturing of ranitidine based on its inspections from February 8 to 13, 2012 at a Dr. Reddy's Louisiana facility.[161] It was observed that Dr. Reddy's continued to have deficiencies in terms of routine calibration precluding assurance of proper performance. Specifically, Dr. Reddy's failed to monitor printing devices and labeling "to verify that labeled containers bearing erroneous expiration dating and lot numbering information will be rejected." And contrary to proper procedures for rejection of materials which requires an investigation into rejected materials after 45 days, multiple drums of ranitidine, rejected on 12/19/2011, were observed "still in the rejection cage on 2/10/2012" - months later and Dr. Reddy's had failed to initiate any investigation the observation.

415. Despite assurances to the FDA that it would fix issues observed in prior inspections, Dr. Reddy's continued to violate cGMPs without appropriately implementing corrective actions. After another FDA inspection of its Louisiana facility in late August of 2013, the FDA issued a Form 483 relating to the "observations of objectional conditions and practices" from Dr. Reddy's inspection, reported pursuant to Section 704(b) of the Federal Food Drug and Cosmetic Act (21 U.S.C. §374(b)), which requires a written report "setting forth any conditions or practices observed by him, which in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

416. Dr. Reddy's written records of investigations into failure to meet specifications do not include conclusions and follow-up. Between October 2012 and May 2013, Dr. Reddy's

[161] FDA Form 483, Dr. Reddy's Laboratories Louisiana, LLC, (Feb. 13, 2012).

received over 250 complaints regarding strange odor and/or taste with its products. However, Dr. Reddy's failed to keep records of all the complaints after May 2013. In August 2013 it was discovered "this was a result of patient conditioning and current…production practices, resulting in castor oil degradation." Dr. Reddy's investigations "do not address adverse events associated with complaints…no summary conclusions or closures are addressed."[162]

417. In 2017, Dr. Reddy's shoddy manufacturing practices resulted in a massive recall of over-the-counter famotidine after discovering impurities and degradation during routine stability testing. [163]

418. Inspections in March of 2020 year continued to demonstrate Dr Reddy's API manufacturing travesties. Dr. Reddy's failed to appropriately validate the effective shelf lives of reference standards provided by third-party suppliers, which are used for Quality Control ("QC") testing of API and API intermediates with "no validation studies" being performed to support such statements. The FDA inspector also noted that retest periods for reference standards used in QC laboratory analysis of API are not established with supporting analytical data. Failing to maintain lab equipment in analytical testing of API to ensure the equipment is suitable for execution in accepted USP monograph testing. [164]

419. Contrary to Dr. Reddy's repeated assurances to the FDA regarding its purported corrective and preventative actions taken over the years and its corporate brochures touting "state-of-the-art manufacturing facilities," "quality beyond compliance" and "uniform manufacturing

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[162] FDA Form 483, Dr. Reddy's Shreveport Inspection, September 6, 2013.

[163] https://www.fiercepharma.com/manufacturing/dr-reddy-s-fighting-to-recover-from-fda-warning-letter-recalls-500-000-heartburn (last accessed June 21, 2020).

[164] FDA Form 483, *Dr. Reddy's Rudraram Facility*, (March 5, 2020) .

and quality standards for all products, regardless of their market," Dr. Reddy's has consistently and repeatedly contravened the cornerstones of quality drug manufacturing, violating cGMPs and encouraging impurities, degradation and instability in its ranitidine containing products.

4. Glenmark

420. Glenmark's manufacturing facilities have been inspected an astounding 16 times since 2013. Even more incredible is the fact that *each and every* inspection resulted in a form 483, detailing serious and troubling cGMP violations.

421. More recently, in April of 2019, the FDA issued Glenmark a Warning Letter, its sternest admonition. A Warning Letter is usually the first step in a process of steps ultimately culminates in an import alert if the deficiencies are not immediately and extensively addressed and corrected. An import alert would prevent a foreign manufacturer, such as Glenmark, from importing any of its product manufactured abroad into the United States. [165]

422. In the Warning Letter, the FDA cited Glenmark for its failure to "adequately investigate multiple temperature excursions that occurred during the shipping" of their drug products. The FDA described inadequate investigations into temperature excursions as an "ongoing issue" that was cited during a previous inspection.

423. The FDA also found that Glenmark's quality system is "inadequate" and does not "ensure consistent production of safe and effective products." These findings were a result of Glenmark's repeated failure to "determine the root cause" of serious quality defects and "implement CAPA to prevent the recurrence of such defects."

[165] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/glenmark-pharmaceuticals-limited-582701-10032019 (last accessed June 21, 2020).

424. In a 12-day March 2017 inspection, the FDA found that Glenmark failed to demonstrate that its storage warehouse was kept under the "required controlled environmental condition" specifically with respect to humidity. The FDA specifically identified a warehouse Glenmark used to store "raw materials, primary packaging materials, and finished products." Glenmark had failed to record any humidity information whatsoever.

5. Mylan

425. Throughout 2014 and 2015, the FDA began seriously investigating Mylan's Indian manufacturing facilities, routinely uncovering a multitude of violations of the cGMPs, and finding that Mylan responded with letters that lacked corrective action. These violations included failure to establish and follow written procedures to prevent microbiological contamination of drug products, lack of assurance that the manufacturing facilities were sterile, and failures to thoroughly investigate unexplained discrepancies in batches or whether the components met specifications.[166]

426. In 2015, a former Mylan employee sat down with FDA employees and alleged that the research and development centers in Hyderabad had become a hub for data fraud.[167]

427. The Mylan whistleblower identified specific applications for drugs that were due to be launched into the American market, claiming that in order to generate passing results for some drug products, Mylan had manipulated the testing, by switching the tests from batch testing to pilot batches (which were easier to control, but not as reliable in ensuring the results as they were smaller in size).[168]

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[166] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mylan-laboratories-limited-464863-08062015 (last June 20, 2020).

[167] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 328.

[168] *Id*.

428. The Mylan whistleblower also claimed that the Mylan team had evolved its fraudulent methods to evade detection. For example, instead of deleting manipulated data from the plant's software systems, which would have left a trail of metadata that could be uncovered by the FDA, plant managers were deliberately corrupting the data they wanted to hide. [169]

429. In July of 2016, upset by the failure of the FDA to investigate, the Mylan whistleblower sent an email to FDA officials that said: "I learned that Mylan's strategy of providing employment to FDA members has been working very well…Perhaps the agency awaits a definitive tragedy to occur on U.S. soil due to sub-standard generic products not meeting the safety & efficacy standards." [170]

430. The email had the intended effect. Two months later, in September 2016, the FDA inspected the Mylan India facilities.[171]

431. Over the course of the week-long inspection, the FDA found evidence that the plant's software system was riddled with error messages showing "instrument malfunction," or "power loss," as though Mylan was literally pulling the plug from the wall to stop the creation of metadata showing failed testing.

432. In confidential correspondence with the FDA, Mylan tried to explain the high number of data error messages (42 over a seven-day period), but provided insufficient and illogical responses, arguing that there may have been accidental knocking of cables off of tables, or through electronic loss of signals. For another error that was observed (150 times over seven days), the

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169 *Id.*

170 *See* Katherine Eban, *Bottle of Lies* (2019) at p. 329.

171 *Id.*

partial explanation given by Mylan was that some software settings led to the "unintended consequence of a number of repetitive error messages." [172]

433. The FDA did not buy these excuses. In a stern Warning Letter sent to Mylan in April of 2017, the FDA effectively froze the site's applications until the company took corrective actions. The letter noted that Mylan's quality systems did not "adequately ensure the accuracy and integrity of the data." [173]

434. But Mylan's issues were not solely limited to its India operations. Several months after the April 2017 letter regarding the India operations, Mylan operations in West Virginia were under scrutiny. The allegations were that laboratory technicians had failed to investigate anomalous results and had instead falsified records to cover-up any anomalous results. Regulators were "stunned" by the lapses, finding the practices "egregious," and questioned whether Mylan was being "transparent at all of its sites." [174]

435. The inspectors also found bins full of shredded documents, including quality-control records, in parts of the factory where every piece of paper is supposed to be saved. [175]

436. The list of alleged infractions became so long that a fourth inspector was added. A Warning Letter, the FDA's strongest rebuke, was drafted. [176]

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[172] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 331.

[173] *Id*.

[174] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 332.

[175] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost (last accessed June 20, 2020).

[176] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost (last accessed June 20, 2020).

437. Ultimately, the FDA's director of the Office of Manufacturing Quality, Tom Cosgrove, made the controversial decision, over the strenuous objections of staff in two separate FDA divisions, to downgrade the investigators' negative findings at Morgantown, WV from Official Action Indicated to Voluntary Action Indicated. [177]

438. In an email to FDA colleagues, Cosgrove acknowledged their view that the company's practices were "more widespread and that Mylan's investigation was insufficient," but ultimately defended his decision and said that he had no reason to believe that Mylan would not "remediate voluntarily." [178]

439. However, while Mylan's Morgantown plant was no longer receiving intensive agency scrutiny, it did little to resolve the issues.

440. In early 2018, a whistleblower from inside the Morgantown plant reached out to the FDA to report deteriorating conditions, from understaffing to cleaning lapses. The whistleblower from inside the plant claimed that Mylan management was focused on creating a "façade of documents" to fend off the FDA, according to an agency memo that detailed the allegations. The whistleblower also notified the FDA that Mylan had brought in a team of employees from India to the Morgantown, WV facility, to rapidly close a backlog of company investigations, and that employees were instructed not to question their work.[179]

441. Consequently, the FDA inspected the Morgantown, WV facility again in March and April of 2018. The inspectors found a host of new violations, including that Mylan's

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[177] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 333.

[178] *Id.*

[179] *Id.*

manufacturing equipment was not cleaned at appropriate intervals to prevent contamination, and that Mylan's attempts to address the purported testing from the 2016 inspection was "not adequate." [180]

6. Teva

442. Teva has been the extensive subject of FDA investigations finding repeated failures to follow cGMP and the core tenets of quality manufacturing of drug products. The FDA has commonly observed systemic problems with Teva failing to extend investigations of questionable or failing results to other batches of the same drug and utilizing improper analytical methods in an attempt to justify results.

443. On August 26, 2010 the FDA issued a Form 483 to Teva based on its August 23 to 26, 2010 inspections and cGMP violations observed at its facilities located in Israel.[181] During the inspections the FDA found a complete lack of "established procedures to ensure water meets all WHO and EPA standards" and protect water used in its products from contamination. In its Form 483, the FDA notes that Teva's "SOP for monitoring water systems does not allow for full investigations of the water manufacturing process when water fails to meet established contaminant limits." The FDA's inspections also pulled the curtain back on Teva's lack of control procedures to "monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product." Specifically, process control parameters to ensure "an adequate and consistent seal in the drug container."

[180] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost (last accessed June 21, 2020).

[181] FDA Form 483, Teva Pharmaceutical Industries, Ltd., (August 26, 2010).

444. Shortly thereafter, from September 12 to 16, 2010, the FDA conducted inspections of another Teva facility located in Israel, finding serious deficiencies in laboratory control systems and failures to adequately investigate OOS results.[182] The FDA issued a Form 483 on September 16, 2010 citing Teva's cGMP violations, specifically noting Teva's SOP "*does not provide a scientific sound approach* nor pre-determine criteria for further *investigating OOS or questionable analytical results*." Instead of properly re-testing and re-confirming results of lots with questionable impurity assays, Teva employed a host of varying, unreliable and unpredictable analytic and stability testing methods. For example, Teva offered no justification for its decision to "prepare…a new sample composite and analyze it with the original sample composite" instead of following proper re-testing procedures. The FDA further found Teva had no logical rationale for its "decision…to perform a re-test using new tablets and not the original stock solution. . . [and] to use a different HPLC system, new standards, and solvent solutions" or conducting a re-test "with an average result" of percentages obtained. Such practices fly in the face of quality manufacturing and Teva's "investigation failed to address the analytical variability and document appropriate corrections actions (CAPA)."

445. During its September 2010 inspections, the FDA also noticed serious and significant deficiencies with Teva's manufacturing practices including improper handling of components and drug products in an inadequate manner and lack of documented assessments of defined areas and control systems necessary to avoid contamination of its drug products.

446. On June 6, 2012, the FDA issued yet another Form 483 to Teva based on its June 4 to 6, 2012 inspections of its facility located in India, citing cGMP violations in the manufacturing

[182] FDA Form 483, Teva Pharmaceutical Industries, Ltd., (September 16, 2010).

of API.[183] The FDA inspections revealed Teva's complete disregard for proper stability testing and validation reports imperative to "generate[] data to demonstrate the increase in batch size and change in impurity release specifications. . . for commercial manufacturing process." Sizing up from small lab batches to commercial production requires diligence along the way to ensure quality is not lost on quantity.

447. Critical operating parameters must be defined in the production process. To the contrary, the FDA found Teva's SOPs, initially approved in April of 2010, wholly inadequate in that it allows "a limited quantity to be ordered for conducting testing without defining sample size requirements." Under these standards "testing to approve a supplier is only required from a minimum of. . .production batches to qualify the new supplier of active raw materials." Perhaps most importantly, the SOP allows newly sourced raw materials to not be routinely placed on stability testing. Teva's SOP for stability testing was found lacking any clearly defining requirements. Its SOP simply stated "*stability tests will be performed in accordance with the QA manager*" without clearly defining a requirement (emphasis in original).

448. During its 2012 inspections of Teva's API facility, the FDA also discovered several examples of GMP related deficiencies where Teva made changes to its manufacturing process without documenting change controls. Specifically, Teva changed its sources of starting raw material, changed its release specification for impurity and changed its release specifications for API without documented change controls.

449. Teva's trend of ignoring crucial control procedures in its manufacturing practices is widespread. In early September of 2016, the FDA conducted inspections of a Teva facility

[183] FDA Form 483, *Teva API India, Ltd.*, (June 6, 2012).

located in India and again issued a Form 483 to Teva, revealing the absence of established control procedures "which monitor the output of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."[184]

450. As in prior FDA inspections, in 2016 the FDA again observed undocumented, unfinished and incomplete investigations of multiple Manufacturing Deviation Reports evidencing Teva's lack of in-process controls leading to failing results and defective products. For example, Teva's manufacturing lacked process controls to test the integrity of products and limit exposure to ambient humidity prior to use by consumers. After discovering the root cause dealt with pressure settings on equipment not able to detect compromised product with large holes, Teva looked back at 20 batches "that could potentially be affected by this issue." During the inspection, the FDA determined "that additional batches that were not considered in the investigation could have been affected by this issue."

451. FDA completed inspections in late September 2016 and issued a Form 483 to Teva's Chinese affiliate on September 29, 2016, after observing Teva's "manufacturing process is not in a state of control." The FDA specifically observed that after multiple OOS batches were produced with impurities, none of Teva's closed investigations "determined a root cause and no corrective actions were taken." And none of Teva's previous investigations identified effective corrective actions and Teva's "[a]ctions described during investigations were not implemented within the quality system in a timely manner." For example, after concluding a potential root cause for impurity could be the amount of a component added per batch and recommending a maximum

[184] FDA Form 483, *Teva Pharmaceutical Industries, Ltd.*, (Sept. 15, 2016).

amount per batch be use, Teva astonishingly did "not formally include[] in a change control, batch record update, or documented training."

452. Similarly, after Teva determined a high yield range of crude product in batches was discovered with 7 deviations for yield since September 2015 (a year earlier), the reason for variability was determined to be "human error." Teva did not document same and "no further action was taken to address this variability."

453. In its 2016 inspections, the FDA also determined Teva's compliance with cGMPs were deficient in the following manners:

- Teva failed to demonstrate that its manufacturing process "can …manufacture an API meeting its predetermined quality attributes";
- Teva failed to include expanded sampling to evaluate variability for specification at almost all steps after manufacturing resulted in 8 OOS and 12 OOT results for unspecified impurities during 2014.
- Teva failed to record data contemporaneously, and failure to prevent unauthorized access or changes to data and to provide adequate controls to prevent manipulation and omission of data – key principals in quality manufacturing; and
- Teva failed to perform a thorough review of data.

454. FDA's most recent inspections of Teva's India facilities occurred from April 8 to 16, of 2019. Based on its inspections, the FDA issued a Form 483 on April 16, 2019, citing multiple violations of cGMPs relating to risk assessments inadequacies and failure to evaluate all root causes for impurities. A FDA "For Cause" inspection of Teva affiliate from April 8 to 16, 2019 was initiated to investigate APIs "that are implicated for potential contamination with carcinogenic

and mutagenic impurities" and distributed in the U.S.[185] At the conclusion of the inspection, Teva was issued a Form 483 for "[i]nadequate risk assessment by the quality unit" for failing to "evaluate all potential root causes for contamination of [] APIs" and failing to "follow the responsibilities and procedures applicable to quality control unit."[186]

455. The FDA found Teva "did not thoroughly assess [key starting materials] KSMs for the potential contamination of genotoxic and suspected human carcinogenic. . .derivatives. . .and other. . .impurities," despite knowingly receiving multiple KSMs for APIs from a manufacturer of KSMs with processes identified as having a "high risk of forming. . . impurities." Even after detecting an impurity in February 2019, Teva failed to develop a formal process to assess raw materials for impurities. Teva did not take, test or consider any samples of key raw materials, but chose to conduct a wholly inappropriate "theoretical evaluation" in order to detect impurity pathways.

456. Additionally, Teva failed to re-assess its cleaning validation program of non-dedicated equipment. During its inspection, the FDA discovered unwrapped production equipment stored outside with "what appeared to be bird feces," in a manner wholly inadequate to "prevent contamination or carry-over material that would alter the quality" of the overall product.

7. Wockardt

457. The history and story of Wockhardt's cGMP violations were described in scintillating detail in *Bottle of Lies*.

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[185] FDA Establishment Inspection Report, *Teva API India Pvt. Ltd,* (April 8-16, 2019).

[186] FDA Form 483, *Teva API India Pvt. Ltd*., (April 16, 2019).

458. For example, on the first day of a March 2013 inspection of Wockhardt's Maharashtra, India facility, an FDA Inspector named Peter Baker observed an employee hurl a black garbage bag beneath a stairwell. Inside the bag were torn original records, which showed serious deficiencies with one of Wockhardt's products.[187]

459. Upon further inquiry into this document, Baker discovered that the records contained in the black garbage bag were batch records associated with a manufacturing line that Wockhardt had claimed did not exist, but, as it turned out, operated secretly within the plant.[188]

460. As the inspectors progressed, Baker and his team of FDA inspectors fell ill, and suspected they had been given unsealed water bottles that were contaminated to make them fall ill in order to cause the inspectors to shorten their inspection. [189]

461. Nevertheless, the Inspectors persisted with their duties.

462. However, they were met with obfuscation and obstruction on the part of Wockhardt executives and employees.

463. As documented in the Establishment Inspection Report[190] associated with the March 2013 inspection, FDA inspectors were lied to and/or mislead on at least 6 occasions:

- Wockhardt employees lied about the existence of additional records that had been placed in the trash area, claiming no further records existed. However, upon additional review, the inspector found more records set to be destroyed, including stability protocol records;

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[187] Katherine Eban, *Bottle of Lies* (2019) at p. 304.

[188] *Id*.

[189] *Id.* at p. 306.

[190] FDA Establishment Inspection Report, *Wockhardt*, (March 2013).

- When asked about the contents of partially labeled glass vials Baker observed strewn about, a Wockhardt employee began immediately dumping the contents of the vials into a drainage sink in front of Baker, destroying the evidence, and then declared that the content of the vials could not be determined;

- Wockhardt employees lied about the contents of certain forms used to record the visual inspection of products;

- Wockhardt executives lied about the existence of a second manufacturing facility, which they had previously denied ever existed, which was contaminating drugs with metal pieces. Despite this being a hidden manufacturing line, and lying about its existence to Baker and the other FDA inspectors, this line was manufacturing product being shipped into the US;

- Wockhardt employees lied about the destruction of samples, which were not recorded in the logbook; and

- Wockhardt lied about the company's system and controls in place to ensure the integrity of electronic data collected during testing, and company employees gave contradictory answers about who was qualified to run tests on the HPLC instrumentation.

464. On the final day and as part of the inspection's close out, Baker presented his findings to the company's vice president of manufacturing. After informing the Wockhardt official that he was reporting discrepancies between "unofficial" and "official" manufacturing batch records for product that was shipped to the United States, the executive threateningly demanded that Baker remove that observation from the report.[191]

465. After refusing to remove the observation from their report, and light of his suspicions he had been given poisoned water intended to make him sick, Baker felt unsafe at the facility. However, when another inspector wanted to mail back the evidence, Wockhardt

[191] *Id*. at p. 306.

executives changed their threatening demeanor, and offered to call DHL, the global shipping service, to arrange for the shipment. However, as the process to arrange for shipping unfolded, Baker suspected that the person was not a DHL employee, but was instead a Wockhardt facility employee seeking to retain possession of the records demonstrating Wockhardt's non-compliance with cGMPs. This suspicion proved to be correct.

466. The FDA inspectors were in fear of their own personal safety and they arranged for their own transportation back to their hotel.[192]

467. Baker would later go on to note in his inspection report that "[d]ue to the threatening behavior and personal safety concerns encountered during this inspection, it is suggested that an inspectional team perform the follow-up inspection with a clear emergency plan in place prior to arrival." [193]

468. Undeterred, and concerned for the safety of American patients, Baker and his team of FDA inspectors returned several months later to inspect another Wockhardt facility in July of 2013.

469. During that inspection, Baker painted an equally troubling pattern of elaborate fraud, extreme hazard, and filth by Wockhardt employees and executives.

470. Such shocking allegations detailed in the Form 483[194] included:

- Urinals that lacked adequate draining systems, leaving urine to "fall directly onto the floor" where it was collected in open drains;

[192] Katherine Eban, *Bottle of Lies* (2019) at p. 306.

[193] Katherine Eban, *Bottle of Lies* (2019) at p. 306.

[194] FDA Form 483, *Wockhardt's Aurangabad Facility*, (July 2013).

- Significant mold growth in storage areas, and finished product being stored in makeshift areas;

- No written controls or procedures associated with the cleaning or temperate controls for any storage areas;

- Failure to follow written stability program, as evidenced by open bottles missing pills that were in storage for stability testing; and

- No evidence that samples are taken according to sampling plans and/or procedures that are representative of the batch of material from when they are taken.

XII. The Truth Was Revealed When an Independent Pharmacy and Testing Laboratory Discovered NDMA in Defendants' Ranitidine-Containing Products, Leading Defendants No Choice but to Recall and Stop Selling

471. On September 9, 2019, Valisure filed its Citizen Petition calling for the recall of all Ranitidine-Containing Products due to exceedingly high levels of NDMA found in Ranitidine-Containing Products. The FDA and European regulators started immediately reviewing the safety of ranitidine with specific focus on the presence of NDMA.[195] This set off a cascade of recalls by the Brand Manufacturer Defendants, Generic Manufacturer Defendants, Retailers, and Repackagers.

472. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.[196]

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[195] FDA, FDA Updates and Press Announcements https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (last accessed June 19, 2020); European Medicines Agency, EMA to review ranitidine medicines following detection of NDMA (Sept. 13, 2019), https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma (last accessed June 19, 2020).

[196] https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine (last accessed June 19, 2020).

473. On September 24, 2019, Generic Manufacturer Defendant Novartis voluntarily recalled all of its Ranitidine-Containing Products due to concerns of a "nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine."[197]

474. On September 26, 2019, Generic Manufacturer Apotex and Retailers such as Walgreens, Walmart, and Rite Aid voluntarily recalled all of their Ranitidine-Containing Products and removed them from shelves.[198] Apotex issued a statement, noting that "Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)[.]"[199]

475. On September 28, 2019, CVS stated that it would stop selling Zantac and its CVS-repackaged ranitidine out of concern that they might contain a carcinogen.

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[197] U.S. Food & Drug Administration, *FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity* (Sept. 24, 2019), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity (last accessed June 19, 2020).

[198] FDA Updates and Press Announcements, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (last accessed June 21, 2020).

[199] U.S. Food & Drug Administration, Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All pack sizes and Formats) due to the potential for Detection of an Amount of Unexpected Impurity,N-nitrosodimethylamine (NDMA) Impurity in the product (Sept. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and (last accessed June 19, 2020).

476. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using an LC-HRMS testing protocol, which "does not use elevated temperature."[200]

477. On October 8, 2019, Brand-Name Manufacturer Defendant GSK voluntarily recalled all Ranitidine-Containing Products internationally.[201] As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GSK is continuing with investigations into the potential source of the NDMA."[202]

478. On October 18 and 23, 2019, Brand-Name Manufacturer Defendant Sanofi and Generic Manufacturer Dr. Reddy's voluntarily recalled all of their Ranitidine-Containing Products.[203]

479. On October 28, 2019, Generic Manufacturer Defendants Perrigo, Novitium, and Lannet voluntarily recalled all their Ranitidine-Containing Products.[204]

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[200] FDA, FDA Updates and Press Announcements. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (last accessed June 19, 2020).

[201] Medicines and Healthcare products Regulatory Agency, Press Release, *Zantac-MHRA drug alert issued as GlaxoSmithKline recalls all unexpired stock* (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock (last accessed June 19, 2020).

[202] Justin George Varghese, *GSK recalls popular heartburn drug Zantac globally after cancer scare*, REUTERS (Oct. 8, 2019), https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL (last accessed June 19, 2020).

[203] FDA, FDA Updates and Press Announcements, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (last accessed June 19, 2020).

[204] *Id*.

480. In its recall notice, Generic Manufacturer Defendant Perrigo stated, "[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall."[205]

481. Generic Manufacturer Defendant Lannett also acknowledged the presence of NDMA in the active pharmaceutical ingredient it used to manufacture ranitidine in its recall notice: "Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA."[206]

482. In each instance, the Brand-Name and Generic Manufacturer Defendants or retailers chose to recall or stop the sale of all Ranitidine-Containing Products because the problem was so pervasive none could be safely sold.

483. On November 1, 2019, the FDA announced the results of recent testing, finding "unacceptable levels" of NDMA in Ranitidine-Containing Products, and requested that drug

[205] U.S. Food & Drug Administration, Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n (last accessed June 21, 2020).

[206] FDA, Lannett Issues Voluntary Nationwide Recall. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lannett-issues-voluntary-nationwide-recall-ranitidine-syrup-ranitidine-oral-solution-usp-15mgml-due (last accessed June 19, 2020).

makers begin to voluntarily recall their Ranitidine-Containing Products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[207]

484. Between November 1, 2019 and February 27, 2020, the following Generic Manufacturers and Repackagers recalled their products from the market, citing NDMA concerns: Aurobindo, Amneal, American Health Packaging, GSMC, Precision Dose, Glenmark, Appco, and Denton Pharma.[208]

485. On January 2, 2020, research laboratory, Emery, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to label-compliant temperature ranges that would occur during normal transport and storage conditions.

486. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine in temperature-controlled vehicles.

487. In response,[209] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when

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[207] U.S. Food & Drug Administration, Laboratory Tests | Ranitidine, Laboratory analysis of ranitidine and nizatidine products, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (last accessed June 15, 2019).

[208] FDA, FDA Updates and Press Announcements, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine. (last accessed June 19, 2020).

[209] https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market (last accessed June 19, 2020).

those products present a danger to health."[210] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[211] The FDA found that the recall of all Ranitidine-Containing Products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk."[212] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[213]

488. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed NDMA levels were higher as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any Ranitidine-Containing Products could remain stable through its labeled expiration date. Consequently, the FDA withdrew the products from the market. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

489. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions took action to restrict or ban Ranitidine-Containing Products.[214]

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[210] *Id.* (*citing* 21 CFR 7.40(a)).

[211] *Id.*

[212] *Id.*

[213] *Id.* at 10.

[214] Margaret Newkirk and Susan Berfield, *FDA recalls are always voluntary and sometimes haphazard – and the agency doesn't want more authority to protect consumers*, Bloomberg Businessweek (Dec. 13, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/ (last accessed June 19, 2020).

490. The European Medicines Agency ("EMA"), the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[215]

XIII. Defendants' Conduct Caused Economic Injury to Plaintiffs and TPP Class Members

491. As a direct and proximate result of Defendants' breaches of express and implied warranties, wrongful acts, fraudulent misrepresentations and omissions, and negligence in connection with their development, design, manufacture, marketing, sale, handling, storage, distribution, and promotion of Ranitidine-Containing Products as detailed herein, Plaintiffs and TPP Class members suffered economic losses.

492. Plaintiffs and TPP Class members did not know that the drugs were not manufactured in such a manner to assure that the Ranitidine-Containing Products were of appropriate safety, quality, purity, identify and strength. This is evidenced by the fact that Defendants' Ranitidine-Containing Products contained NDMA, a known human carcinogen. Plaintiffs and TPP Class members reasonably and justifiably relied on Defendants'

[215] *European Medicines Agency, Suspension of ranitidine medicines in the EU* (Mar. 30, 2020), https://www.ema.europa.eu/en/medicines/human/referrals/ranitidine-containing-medicinal-products (last accessed June 15, 2020).

misrepresentations, omissions, concealments, and/or failure to disclose materials facts about the Ranitidine-Containing Products.

493. As a direct and proximate result of Defendants' breach of their express and implied warranties to consumers that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded; failure to manufacture, store, warehouse, and distribute their products in accordance with cGMPs; failure to adequately inspect/test the drugs during the manufacturing process; failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Products; breach of their duty to provide appropriate and accurate instructions regarding the proper storage and handling of Ranitidine-Containing Products; and breach of their duty of reasonable care and failure to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, Plaintiffs and TPP Class members suffered damages through their reimbursement for purchases of Ranitidine-Containing Products that were adulterated, misbranded, illegal to sell, and therefore economically worthless.

494. Had Plaintiffs and the TPP Class members known the drugs were manufactured in such a way that rendered them adulterated and misbranded, they would not have reimbursed for purchases of Ranitidine-Containing Products. Nor would they be required to reimburse for such products, as adulterated and misbranded products are illegal to sell and would not have been on the market, much less on a TPP's formulary.

495. Accordingly, Plaintiffs and TPP Class members have been injured because they paid reimbursements for an economically worthless drug they otherwise would not have been

obligated to pay, and suffered out-of-pocket loss. Thus, Plaintiffs and the TPP Class members have suffered concrete injury as a direct and proximate result of Defendants' wrongful conduct.

XIV. EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

A. Discovery-Rule Tolling

496. Within the period of any applicable statutes of limitation, Plaintiffs and members of the proposed TPP Class (defined below) could not have discovered through the exercise of reasonable diligence that Defendants were not disclosing the high levels of the carcinogen NDMA in their Ranitidine-Containing Products, rendering the drugs adulterated, misbranded and illegal to sell.

497. Plaintiffs and the other TPP Class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants did not disclose the high levels of NDMA contained in Ranitidine-Containing Products, including Zantac. The information linking ranitidine, including Zantac, to NDMA was contained exclusively in articles published in scientific journals and intended for the scientific audience. Defendants also sought to actively discredit such publications with publications of their own detailing the comparative safety of the drug.

498. Additionally, Plaintiffs and other TPP Class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants had not been complying with cGMPs with respect to their manufacturing practices and policies, as evidenced by the fact that Defendants' Ranitidine-Containing Drugs contained NDMA, a known human carcinogen.

499. Plaintiffs and TPP Class members could not have reasonably discovered the true extent of Defendants' deception with regard to the safety of Ranitidine-Containing Products, until

Valisure filed its citizen petition on September 9, 2019 disclosing the extremely high levels of NDMA produced by Ranitidine-Containing Products.

500. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent-Concealment Tolling

501. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment of the fact that Ranitidine-Containing Products had the capacity to degrade to NDMA with exposed to certain storage and containment situations.

502. Instead of disclosing the link between ranitidine, including Zantac, and the carcinogen NDMA, Defendants continued to manufacture and sell Ranitidine-Containing Products without disclosing this information on the drug's label or anywhere else.

C. Estoppel

503. Defendants were under a continuous duty to disclose to Plaintiffs and the other TPP Class members that they were manufacturing and selling Ranitidine-Containing Products that were adulterated and misbranded because they contained NDMA, a known human carcinogen.

504. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the truth about Ranitidine-Containing Products, that they were adulterated and misbranded because they contained NDMA, a known human carcinogen, and never updated the drug's label to disclose this risk.

505. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

XV. TPP CLASS ALLEGATIONS

506. Plaintiffs bring this suit as a Class action pursuant to Rule 23(b)(2), (b)(3) and (c)(4) of the Federal Rules of Civil Procedure on behalf of a Nationwide TPP Class consisting of:

> All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for prescription Zantac or the Generic Manufacturer Defendants' Ranitidine-Containing Products for purposes other than resale since their respective approval dates.

507. Excluded from the TPP Class are the Defendants and their officers, directors, employees, predecessors-in-interest, successors-in interest, assignees, affiliates and subsidiaries; all governmental entities, except for government funded employee, retiree and Medicare Part D plans provided through private insurance companies; all pharmaceutical wholesalers or distributors that purchased one or more of the Defendants' Ranitidine-Containing Products for purposes of resale; and PBMs.

508. As an alternative and/or in addition to Nationwide TPP Class, Plaintiffs bring this action in their individual capacities and on behalf of State Classes for all fifty states of the United States of America, the District of Columbia, and Puerto Rico pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **[State] TPP Class:** All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for prescription Zantac or the Generic Manufacturer Defendants' Ranitidine-Containing Products for purposes other than resale since their respective approval dates.

509. Excluded from the State Classes are Defendants and their officers, directors, employees, predecessors-in-interest, successors-in interest, assignees, affiliates and subsidiaries;

all governmental entities, except for government funded employee, retiree and Medicare Part D plans provided through private insurance companies; all pharmaceutical wholesalers or distributors that purchased one or more of the Defendants' Ranitidine-Containing Products for purposes of resale; and PBMs.

510. Plaintiffs reserve the right to modify or amend the definitions of State Classes, including to add one or more subclasses, after having the opportunity to conduct discovery.

511. The Nationwide TPP Class and the alternative State Classes are collectively referred to as the "TPP Class" or "Classes."

A. Fed. R. Civ. P. 23 Requirements

512. Each of the proposed TPP Classes meets the requirements of Federal Rules of Civil Procedure 23(a), (b)(2), (b)(3) and/or (c)(4).

513. ***Numerosity.*** The members of each class are so numerous that joinder is impracticable. There are thousands of TPPs, such as Plaintiffs, across the country.

514. ***Typicality.*** Plaintiffs' claims are typical of the claims of putative TPP Class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the claims of the other TPP Class members. Each Plaintiff, like each TPP Class member, reimbursed for Ranitidine-Containing Products, manufactured or sold by Defendants, which were adulterated, misbranded, illegal to sell and, thus, worthless. Plaintiffs, like each TPP Class member, were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the TPP Class members.

515. ***Adequacy.*** Plaintiffs will fairly and adequately protect the interests of the TPP Class members. Plaintiffs' interests and the interests of all other members of each respective TPP Class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will

fairly and adequately protect the TPP Class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

516. ***Commonality and Predominance.*** There are numerous questions of law and fact common to the TPP Class, and these common questions predominate over any issues affecting only individual TPP Class members. Questions common to the TPP Classes include, but are not limited to the following:

a. Whether Defendants knew or should have known that Ranitidine-Containing Products were manufactured in such a way that they contained unacceptable levels of NDMA which rendered their drugs adulterated, and/or misbranded, and therefore economically worthless;

b. Whether Defendants' marketing, advertising, or promotion of Ranitidine-Containing Products misrepresented the safety of Ranitidine-Containing Products, or failed to disclose that their Ranitidine-Containing Products were manufactured in such a way that they contained high levels of the carcinogen NDMA, which rendered their drugs adulterated, misbranded, and therefore economically worthless;

c. Whether Defendants breached express warranties;

d. Whether Defendants breached implied warranties;

e. Whether Defendants have been unjustly enriched;

f. Whether Defendants' conduct violated the Racketeering and Corrupt Organizations Act, 18 U.S.C. §1962(c)-(d);

g. Whether Defendants' conduct violated the Magnuson-Moss Warranty Act, 15 U.S.C. §§2301, *et seq.*;

h. Whether Plaintiffs and the TPP Class members are entitled to recover damages and the appropriate measure of those damages;

i. The appropriate measure of disgorgement; and

j. The type and format of injunctive relief that is appropriate.

517. ***Superiority.*** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered

in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not have the resources to mount such a litigation. Here, the economic losses suffered by Plaintiffs and the TPP Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendant, and thus, individual litigation to redress Defendant's wrongful conduct would be impracticable. Individual litigation by each TPP Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

518. Plaintiffs reserve the right to seek certification under Rule 23(c)(4) of common questions related to Defendants' knowledge, conduct, products, and duties.

CAUSES OF ACTION

COUNT 1
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1962(c)-(d)
(On Behalf of the TPP Class Against the RICO Defendants)

519. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

520. Plaintiffs bring this Count on behalf of the TPP Class against Defendants Sanofi BI, Pfizer, and GSK (for purpose of this Count, these Defendants are collectively referred to as "RICO Defendants").

521. Plaintiffs and other TPP Class members are "persons" within the meaning of 18 U.S.C. §1961(3), and each is a "person injured in his or her business or property" by reason of the Defendants' violation of RICO within the meaning of 18 U.S.C. §1964(c).

522. Plaintiffs and other TPP Class members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for Zantac that they otherwise would not have made had the RICO Defendants not engaged in their pattern of racketeering activities. Plaintiffs and the TPP Class members suffered direct, consequential and concrete financial loss flowing from the injury of their property by having paid for Zantac, which was adulterated and misbranded, illegal to sell and economically worthless, and thereby suffered out-of-pocket losses. But for the predicate acts committed or caused to be committed by RICO Defendants, Plaintiffs and the TPP Class members would not have suffered their RICO injuries.

523. At all relevant times, each RICO Defendant has been a "person" within the meaning of 18 U.S.C. §1961(3) because each was capable of holding "a legal or beneficial interest in property."

524. The RICO Defendants conduct their business—both legitimate and illegitimate—by and through various affiliates and subsidiaries, each of which is a separate legal entity. Boehringer Ingelheim operates by and through Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation, among others. Sanofi operates by and through Sanofi S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., and Chattem, Inc., among others. GSK operates by and through GlaxoSmithKline plc, GlaxoSmithKline LLC, and GlaxoSmithKline (America) Inc., among others. Pfizer also operated by and through various affiliates and subsidiaries at all

relevant times. Defendants have also formed joint ventures and other agreements between and among each other at various points in time during the scheme as detailed herein.

A. The Zantac RICO Enterprise

525. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

526. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. §1962(d).

527. Zantac, the trade name for ranitidine, was for years the world's top selling drug and the first to top $1 billion in annual sales. The unprecedented success of Zantac was not an accident. It was the direct result of aggressive marketing by the RICO Defendants and others that pushed Zantac as safe and effective for consumers. In their quest to reach ever new heights of sales and profits, the RICO Defendants recklessly continued to push Zantac as safe and effective knowing the NDMA risks associated with ranitidine.

528. Instead of pulling Zantac from the shelves or warning the public and regulators about its safety risks, the RICO Defendants hid the truth. To do so, each RICO Defendant was employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (defined below and referred to collectively as the "Zantac RICO Enterprise"), whose purpose was to conceal or downplay the safety risks of Zantac. The motivation was simple: to increase Defendants' revenues and profits and minimize their losses from the manufacture and sale of Zantac. As a direct and proximate result of their fraudulent scheme and common course of conduct, the RICO Defendants were able to extract billions of dollars from Plaintiffs and the TPP

Class. Until recently Zantac remained on retail and pharmacy shelves in the United States. The RICO Defendants' decades-long scheme violated Sections 1962(c) and (d) of the RICO statute.

529. At all relevant times, the RICO Defendants, along with other individuals and entities, including unknown third parties involved in the formulation, manufacture, and sale of Zantac, operated an association-in-fact enterprise, which was formed for the purpose of selling Zantac throughout the U.S. and through which enterprise(s) they conducted a pattern of racketeering activity under 18 U.S.C. §1961(4). The enterprise is referred to herein as the "Zantac RICO Enterprise."

530. At all relevant times, the Zantac RICO Enterprise constituted a single "enterprise" or multiple enterprises within the meaning of 18 U.S.C. §1961(4), as legal entities, as well as individuals and legal entities associated-in-fact for the common purpose of engaging in RICO Defendants' unlawful profit-making scheme.

531. The association-in-fact Zantac RICO Enterprise consisted of at least the following entities and individuals, and likely others:

a. Sanofi S.A. is a French multinational pharmaceutical company headquartered in Paris and listed on the NASDAQ. As of June 8, 2020, it had a market capitalization of $63.7 billion. The other Sanofi Defendants are not publicly traded and thus have no SEC reporting obligations, but they do have reporting obligations, protections and responsibilities unique to their respective home states.

b. BI is a German multinational company and one of the world's largest pharmaceutical companies and the largest private one. BI operates with 146 affiliates and is owned by the Boehringer, Liebrecht, and von Baumbach families.

c. GlaxoSmithKline plc is a British multinational pharmaceutical company headquartered in the United Kingdom and listed on the New York Stock Exchange. As of June 8, 2020, it had a market capitalization of $105 billion. The other GSK Defendants are not publicly traded and thus have no SEC reporting obligations, but do have reporting obligations, protections and responsibilities unique to their respective home states.

d. Pfizer is an American multinational pharmaceutical company headquartered in New York City and listed on the New York Stock Exchange. As of June 8, 2020, it had a market capitalization of $203 billion. Other Pfizer entities or divisions, such as Warner-Lambert Consumer Healthcare, are not publicly traded and thus have no SEC reporting obligations but do have reporting obligations, protections and responsibilities unique to their respective home states.

532. At all relevant times, the Zantac RICO Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Sanofi Defendants, the BI Defendants, the GSK Defendants, and Pfizer, and/or other entities and individuals associated for the common purpose of formulating, manufacturing, distributing, testing, and selling Zantac to Plaintiffs and the TPP Class by concealing safety risks and deriving profits and revenues therefrom.

533. Each member of the Zantac RICO Enterprise shared in the bounty generated by the enterprise, *i.e.*, by sharing the benefit derived from increased sales revenue generated by the scheme to defraud TPP Class members nationwide. If any member of the Zantac RICO Enterprise had publicly revealed the safety risks, all would lose their revenues and profits from Zantac. At various points in time, the RICO Defendants entered into joint ventures and/or other agreements concerning the rights to Zantac including for, example, the partnership between GSK and Warner-Lambert resulting in Warner-Lambert Consumer Healthcare; Pfizer's acquisition of Warner Lambert; BI's acquisition of the rights to OTC Zantac; and Sanofi's acquisition of the rights to OTC Zantac.

534. The Zantac RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce, because it involved commercial activities across both state and national

boundaries, such as the marketing, promotion, advertisement, distribution, and sale of Zantac throughout the country and beyond, and the receipt of monies from the sale of the same.

535. Within the Zantac RICO Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis. The enterprise used this common communication network for the purpose of formulating, manufacturing, marketing, distributing, and selling Zantac nationwide.

536. Each participant in the Zantac RICO Enterprise had a systematic linkage to others through corporate ties, contractual relationships, financial ties, and continuing coordination of activities. Through the Zantac RICO Enterprise, the RICO Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their profits and revenues, as well as minimizing their losses.

537. The RICO Defendants participated in the operation and management of the Zantac RICO Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

538. Each of the RICO Defendants exerted substantial control over the Zantac RICO Enterprise, and participated in, operated and/or directed the enterprise, by:

a. concealing or downplaying safety risks from the public, TPPs, PBMs, and regulators;

b. misleading the public, TPPs, PBMs, and regulators as to the nature and safe use of Zantac;

c. formulating, manufacturing, distributing, promoting, and/or selling Zantac;

d. misrepresenting or omitting safety risks (or causing such misrepresentations and omissions to be made) in promotional materials or advertisements, or materials provided to TPPs and PBMs to gain access to their formularies;

e. concealing or downplaying safety risks in scientific studies;

f. misrepresenting or omitting (or causing such misrepresentations and omissions to be made) safety risks on FDA applications and other communications with regulators;

g. introducing Zantac into the stream of U.S. commerce with concealed safety risks;

h. entering into joint ventures or agreements concerning the rights to Zantac;

i. persisting in the manufacturing, distribution, and sale of Zantac even after questions were raised about safety risks;

j. collecting revenues and profits in connection with the sale of Zantac; and/or

k. ensuring that the other RICO Defendants and unnamed co-conspirators complied with the scheme or common course of conduct.

539. Without the RICO Defendants' willing participation, the Zantac RICO Enterprise's years-long scheme and common course of conduct would have been unsuccessful.

540. The RICO Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiffs cannot fully know at present, because such information lies in Defendants' and others' hands. Similarly, because the Defendants often refer to themselves as a group (*i.e.*, "Sanofi," "Boehringer Ingelheim," "GSK," etc.), Plaintiffs cannot fully know the full extent of each individual corporate entity's involvement in the wrongdoing prior to having access to discovery.

B. Mail and Wire Fraud

541. To carry out, or attempt to carry out the scheme to defraud, the RICO Defendants, each of whom is a person associated-in-fact with the Zantac RICO Enterprise, did knowingly conduct or participate, directly or indirectly, in the conduct of the affairs of the Zantac RICO

Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

542. Specifically, as alleged herein, the RICO Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§1341 and 1343). The multiple acts of racketeering activity that the RICO Defendants committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the RICO Defendants in the Zantac RICO Enterprise. The RICO Defendants participated in the scheme to defraud by using e-mail, mail, telephone, facsimile, TV, radio, and the Internet to transmit mailings and wires in interstate or foreign commerce.

543. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions.

544. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and the TPP Class or to obtain money from them by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

545. The RICO Defendants' predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing their unlawful scheme to manufacture, market, and sell Zantac by concealing or downplaying its safety risks.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money by concealing or downplaying the safety risks of Zantac.

546. The RICO Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery, or shipment of the following, which were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme:

a. Zantac tablets, capsules, injections, syrup, and/or granules;

b. False or misleading websites;

c. False or misleading industry publications and/or studies;

d. False or misleading sales and marketing materials, including websites, ads, and brochures concealing the true nature of Zantac, such as the multi-media "Captain Zantac" campaign;

e. False or misleading product packaging and labels;

f. False or misleading AMCP dossiers, monographs, or TPP/PBM marketing materials;

g. False or misleading FDA applications and other government communications;

h. False or misleading communications intended to lull the public and regulators from discovering the true nature of Zantac;

i. Documents and communications that facilitated the scheme, including but not limited to invoices, shipping records, reports, and correspondence;

j. Millions of dollars in compensation to company executives;

k. Deposits of proceeds; and/or

l. Other documents and things.

547. The RICO Defendants (or their agents), for the purpose of executing the illegal scheme, transmitted (or caused to be transmitted) in interstate commerce by means of wire communications, certain writings, signs, signals and sounds, including the items described above and the following discussed below.

548. The RICO Defendants used the internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants omitted safety risks of Zantac on websites, YouTube, Facebook, Twitter, and other online advertising, all of which were intended to mislead the public and regulators.

From	**To**	**Date**	**Description**
Sanofi subsidiary, Chattem Inc., Chattenooga, Tennessee	Twitter, San Francisco, California	September 3, 2019	Twitter feed: "The Captain likes his wings 4-alarm spicy."
Sanofi subsidiary, Chattem Inc., Chattenooga, Tennessee	YouTube, San Mateo, California	July 3, 2019	Online Video Ad: "S. O. Neal: No Mess Fast Relief Heart Burn Night"
Sanofi subsidiary, Chattem Inc., Chattenooga, Tennessee	YouTube, San Mateo, California	March 14, 2019	Zantac TV Commercial, "Family Taco Night"
GSK, United Kingdom	US Healthcare Professionals via GSK Direct website	Throughout 2018	Zantac 150 Tablets 500's product description for US Healthcare professionals online
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	YouTube, San Mateo, California	March 7, 2017	Online Video Ad: "Releases Cooling Sensation in Mouth and Throat"
Boehringer Ingelheim Pharmaceuticals,	Sanofi US, Bridgewater, New Jersey	February 24, 2017	Transfer of domain ownership of "RethinkPPIs.com" website claiming that non-prescription

From	To	Date	Description
Inc., Ridgefield, Connecticut			Zantac has "no long-term safety concerns."
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	PR Newswire, New York, New York	September 9, 2013	Press release re: launch of "Captain Zantac™" 360-degree brand equity campaign with national TV ads, print, online, and retail advertising
Pfizer, New York, New York	Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	October 13, 2006	Agreements and related correspondence re: BI acquisition of OTC rights to Zantac from Pfizer

549. The RICO Defendants (or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of Zantac drugs, and related documents by mail or a private carrier affecting interstate commerce, including the items described above and the following examples:

From	To	Date	Description
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut	ESPN Magazine	March 2, 2015	Print Ad: "CAPTAIN Zantac IN HEARTBURN RESCUE: Stop! That heartburn pill can take 24 hours to work! Zantac is different! Zantac rushes relief in as little as 30 minutes. Zantac. No pill relieves heartburn faster!"
GlaxoSmithKline, Research Triangle Park, North Carolina	U.S. Food & Drug Administration, Silver Spring, Maryland	September 4, 2009	Zantac FDA Label
Pfizer Consumer Healthcare, Richmond, Virginia	Madison Wisconsin State Journal	November 2, 2003	Print Ad: "Zantac 75 relieves heartburn fast, right when you need it. Prilosec OTC doesn't."
U.S. Patent & Trademark Office, Alexandria, Virginia	Warner-Lambert Company	February 2, 1996	Trademark statement of use processing complete

550. The RICO Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various other affiliates, regional offices, divisions, dealerships and other third-party entities in furtherance of the scheme.

551. The mail and wire transmissions described herein were made in furtherance of the RICO Defendants' scheme and common course of conduct to sell Zantac, which Defendants knew or recklessly disregarded as forming NDMA in the body.

552. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

553. The RICO Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d), the RICO Defendants conspired to violate 18 U.S.C. §1962(c), as described herein. Various other persons, firms and corporations, including third-party entities and individuals not currently named as defendants, have participated as co-conspirators with the RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the RICO Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

554. The RICO Defendants had knowledge of the fraud and aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

555. To achieve their common goals, the RICO Defendants hid or downplayed the dangers of Zantac and obfuscated its true nature even after regulators and others raised concerns. The RICO Defendants suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the safety risks of Zantac.

556. The RICO Defendants and each member of the conspiracy, with knowledge and intent, have agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud in formulating, manufacturing, distributing, marketing, and/or selling Zantac.

557. Indeed, for the conspiracy to succeed each of the RICO Defendants and their co-conspirators had to agree to implement and use the similar devices and fraudulent tactics—specifically concealing or downplaying the safety risks of Zantac's NDMA.

558. The RICO Defendants knew and intended that the public and regulators would rely on their material omissions. The RICO Defendants knew and intended that Plaintiffs and the TPP Class would incur costs as a result. In fact, Plaintiffs, along with the TPPs, the public, and others across the country, relied upon the concealment of material facts caused by them. Plaintiffs' reliance is made obvious by the fact that they reimbursed for drugs that were not safe for use and never should have been introduced into the U.S. stream of commerce as made plain by the fact that they have been pulled from the shelves now.

559. Unbeknownst to Plaintiffs and the TPP Class, the RICO Defendants engaged in a pattern of related and continuous predicate acts for many years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiffs and TPP Class members based on the concealment of the truth, while providing Zantac drugs that were worth significantly less than the purchase price paid.

The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

560. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants (and minimizing their losses) at the expense of Plaintiffs and TPP Class members. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Zantac RICO Enterprise and in furtherance of the scheme, and were interrelated in that they involved obtaining Plaintiffs' and TPP Class members' funds and avoiding the expenses and loss of revenues associated with recalling the drugs.

561. During the formulation, manufacture, marketing, and sale of Zantac, the RICO Defendants came across and/or shared information about the risk that ranitidine was being manufactured in such a way that it was becoming contaminated with NDMA, a known human carcinogen. Nevertheless, the RICO Defendants shared and/or disseminated information that misrepresented Zantac as safe while concealing its risks.

562. By reason of, and as a result of the conduct of the RICO Defendants, and in particular, their pattern of racketeering activity, Plaintiffs and TPP Class members have been injured in their business and/or property in multiple ways, including but not limited to:

a. Reimbursements for the purchase price of Zantac;

b. Other out-of-pocket expenses.

563. The RICO Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiffs and TPP Class members. Plaintiffs and TPP Class members are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c).

COUNT 2
BREACH OF EXPRESS WARRANTIES
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

564. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

565. This cause of action is alleged on behalf of TPP Class members against Defendant GSK and Generic Manufacturer Defendants (described herein as "Defendants"), and to the extent applicable law permits non-consumers reimbursing for consumer purchases to assert this cause of action.

566. Defendants are, and at all relevant times were, "merchants" and/or "sellers" with respect to Ranitidine-Containing Products.

567. TPP Class members are, and at all relevant times were, "buyers" or "purchasers" of Ranitidine-Containing Products.

568. In connection with their sale of Ranitidine-Containing Products, by and through statements in labels, publications, package inserts, and other written materials intended for TPPs and the general public, Defendants made certain express affirmations of fact and/or promises relating to the Ranitidine-Containing Products to Plaintiffs and the TPP Class members, as alleged herein, including that such drugs were safe for human consumption and fit to be used for their intended purpose. These express affirmations of fact and/or promises include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Ranitidine-Containing Products.

569. Each Defendant expressly warranted that its Ranitidine-Containing Products were fit for their ordinary use, i.e., as an FDA-approved generic pharmaceutical product and that such drugs were safe for human consumption and fit to be used for their intended purpose.

570. Each Defendant sold Ranitidine-Containing Products that they expressly warranted were compliant with cGMPs and/or not adulterated and/or misbranded.

571. Defendants advertised, labeled, marketed, and promoted Ranitidine-Containing Products with such express affirmations of fact and/or promises in such a way as to induce their purchase or use by through reimbursement or payment for some of the purchase price by Plaintiffs and TPP Class members, thereby making an express warranty that Ranitidine-Containing Products would conform to the representations.

572. Defendants affirmations of fact and/or promises about Ranitidine-Containing Products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

573. Despite the express warranties Defendants created with respect to Ranitidine-Drugs, Defendants' Ranitidine-Containing Products did not conform to Defendants' express warranties in that such drugs were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the express warranties in the following ways:

> (i) Defendants represented through their labeling, advertising, and marketing materials that Ranitidine-Containing Products were manufactured, stored, and distributed in such a way that would assure the identity, strength, quality, and purity of the Ranitidine-Containing Products.

(ii) Defendants represented through their labeling, advertising, and marketing materials that they were complying with cGMPs to assure proper design, monitoring, and control of the manufacturing processes, quality assurance measures and at their facilities used in the manufacture of their Ranitidine-Containing Products.

574. Each Defendant's Ranitidine-Containing Drug did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMPs and was adulterated and misbranded which is evidenced by the fact that it contained NDMA, a known human carcinogen.

575. At all times relevant, all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code §7-2-313; Alaska Stat. §45.02.313; Ariz. Rev. Stat. Ann. §47-2313; Ark. Code. Ann. §4-2-313; Cal. Com. Code §2313; Colo. Rev. Stat. §4-2-313; Conn. Gen. Stat. Ann. §42a-2-313; 6 Del. Code. §2-313; D.C. Code. §28:2-313; Fla. Stat. Ann. §672.313; Ga. Code. Ann. §11-2-313; Haw. Rev. Stat. §490:2-313; Idaho Code §28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. §26-1-2-313; Kan. Stat. Ann. §84-2-313; Ky. Rev. Stat. Ann. §355.2-313; 11 Me. Rev. Stat. Ann. §2-313; Md. Code. Ann. §2-313; Mass. Gen. Law Ch. 106 §2-313; Mich. Comp. Laws Ann. §440.2313; Minn. Stat. Ann. §336.2-313; Miss. Code Ann. §75-2-313; Mo. Rev. Stat. §400.2-313; Mont. Code Ann. §30-2-313; Nev. Rev. Stat. U.C.C. §104.2313; N.H. Rev. Ann. §382-A:2-313; N.J. Stat. Ann. §12A:2-313; N.M. Stat. Ann. §55-2-313; N.Y. U.C.C. Law §2-313; N.C. Gen. Stat. Ann. §25-2-313; N.D. Stat. §41-02-313; Ohio Rev. Code Ann. §1302.26; Okla. Stat. tit. 12A §2-313; Or. Rev. Stat. §72.3130; 13 Pa. C.S. §2313; P.R. Laws. Ann. Tit. 31, §3841, et seq.; R.I. Gen. Laws §6A-2-313; S.C. Code Ann. §36-2-313; S.D. Stat. §57A-2-313; Tenn. Code Ann. §47-2-313; Tex. Bus. & Com. Code Ann. §2-313; Utah Code Ann. §70A-2-313; Va. Code §8.2-313; Vt.

Stat. Ann. 9A §2-313; W. Va. Code §46-2-313; Wash. Rev. Code §62A 2-313; Wis. Stat. Ann. §402.313 and Wyo. Stat. §34.1-2-313.

576. Each Defendant breached its express warranties with respect to its Ranitidine-Containing Products as they were not of merchantable quality, were not fit for their ordinary purpose, did not comply with cGMPs and were adulterated, misbranded and illegal to sell.

577. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other TPP Class members have been injured and suffered damages, in that the Ranitidine-Containing Products they made payments or reimbursements for were so inherently flawed, unfit, or unmerchantable as to have no intrinsic market value.

COUNT 3
BREACH OF IMPLIED WARRANTIES
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

578. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

579. This cause of action is alleged on behalf of the TPP Class against Defendant GSK and the Generic Manufacturer Defendants (described herein as "Defendants"), and to the extent applicable law permits non-consumers to assert this cause of action.

580. At all times relevant, all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code §7-2-314; Alaska Stat. §45.02.314; Ariz. Rev. Stat. Ann. §47-2314; Ark. Code. Ann. §4-2-314; Cal. Com. Code §2314; Colo. Rev. Stat. §4-2-314; Conn. Gen. Stat. Ann. §42a-2-314; 6 Del. Code. §2-314; D.C. Code. §28:2-314; Fla. Stat. Ann. §672.314; Ga. Code. Ann. §11-2-314; Haw. Rev. Stat. §490:2-314;

Idaho Code §28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. §84-2-314; Ky. Rev. Stat. Ann. §355.2-314; La. Civ. Code Ann. Art. §2520; 11 Me. Rev. Stat. Ann. §2-314; Md. Code. Ann. §2-314; Mass. Gen. Law Ch. 106 §2-314; Mich. Comp. Laws Ann. §440.2314; Minn. Stat. Ann. §336.2-314; Miss. Code Ann. §75-2-314; Mo. Rev. Stat. §400.2-314; Mont. Code Ann. §30-2-314; Nev. Rev. Stat. U.C.C. §104.2314; N.H. Rev. Ann. §382-A:2-314; N.J. Stat. Ann. §12A:2-314; N.M. Stat. Ann. §55-2-314; N.Y. U.C.C. Law §2-314; N.C. Gen. Stat. Ann. §25-2-314; N.D. Stat. §41-02-314; Ohio Rev. Code Ann. §1302.27; Okla. Stat. tit. 12A §2-314; Or. Rev. Stat. §72.3140; 13 Pa. C.S. §2314; P.R. Laws. Ann. Tit. 31, §3841, et seq.; R.I. Gen. Laws §6A-2-314; S.C. Code Ann. §36-2-314; S.D. Stat. §57A-2-314; Tenn. Code Ann. §47-2-314; Tex. Bus. & Com. Code Ann. §2-314; Utah Code Ann. §70A-2-314; Va. Code §8.2-314; Vt. Stat. Ann. 9A §2-314; W. Va. Code §46-2-314; Wash. Rev. Code §62A 2-314; Wis. Stat. Ann. §402.314 and Wyo. Stat. §34.1-2-314.

581. Each Defendant was a merchant within the meaning of the above statutes.

582. Each Defendant's Ranitidine-Containing Products constituted "goods" or the equivalent within the meaning of the above statutes.

583. Each Defendant was obligated to provide Plaintiffs and other TPP Class members reasonably fit Ranitidine-Containing Products for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

584. Each Defendant knew or should have known that its Ranitidine-Containing Products were being manufactured and sold for the intended purpose of human consumption and impliedly warranted that same was of merchantable quality and fit for that purpose.

585. Each Defendant breached its implied warranty because each Defendant's Ranitidine-Containing Products were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods. Rather, Defendants' Ranitidine-Containing Products were of a substandard quality, adulterated and/or misbranded as evidenced by the fact that they contained NDMA, a known human carcinogen.

586. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other TPP Class members have been injured and suffered damages, in that Defendants' Ranitidine-Containing Products that Plaintiffs and the TPP Class members made payments or reimbursements for were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

587. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the TPP Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 4
VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. §2301, *et seq.*
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

588. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

589. This cause of action is pleaded on behalf of all Plaintiffs and the TPP Class against Defendant GSK and the Generic Manufacturer Defendants (described herein as "Defendants"), and to the extent applicable law permits non-consumers to assert this cause of action.

590. Plaintiffs and members of the TPP Class are "consumers" within the meaning of 15 U.S.C. §2301(3).

591. Each Defendant is a "supplier" and "warrantor" within the meaning of 15 U.S.C. §2301(4) and (5), respectively.

592. The Ranitidine-Containing Products paid or reimbursed for by Plaintiffs and members of the TPP Class are "consumer products" within the meaning of 15 U.S.C §2301(1).

593. 15 U.S.C. §2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a supplier or warrantor to comply with a written or implied warranty.

594. The amount in controversy of Plaintiffs' individual claims meets or exceeds $25.00 in value. In addition, the amount in controversy meets or exceeds $50,000 in value (exclusive of interest and/or costs) on the basis of all claims to be determined in this lawsuit.

595. At all relevant times, the Defendants expressly represented and warranted to the purchasers of their products, by and through statements in labels, publications, package inserts, and other written materials intended for Plaintiffs and the general public, that Ranitidine-Containing Products were safe for human consumption and fit to be used for their intended purpose. The Defendants advertised, labeled, marketed, promoted and sold Ranitidine-Containing Products, representing the quality to Plaintiffs, TPP Class members and the public in such a way as to induce their purchase or use, thereby making an express warranty that Ranitidine-Containing Products would conform to the Defendants' representations.

596. Defendants represented to Plaintiffs and members of the TPP Class via media, advertising, packaging, labeling, and promotions that:

a. Ranitidine-Containing Products were manufactured in such a way that they could assure the safety, efficacy, purity, identity and quality for lifetime of

the product, when in fact, they contain unsafe levels of NDMA – far exceeding the 96 ng limit – and which increase as the product ages; and

b. Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew or should have known they were unsafe for their intended purpose.

597. The representations about Ranitidine-Containing Products, as alleged herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

598. Defendants breached these express warranties because, among other things, Ranitidine-Containing Products were defective, dangerous, were not merchantable or safe for their intended use, were not manufactured in compliance with cGMPs, and were adulterated and/or misbranded.

599. Under state law, a warranty that goods shall be merchantable is implied in every contract for the sale of goods by a merchant that deals in such goods. Before Plaintiffs' and TPP Class members' payment or reimbursement for Defendants' Ranitidine-Containing Products, the Defendants impliedly warranted to Plaintiffs and the TPP Class, that Ranitidine-Containing Products were of merchantable quality, safe and fit for their intended use, manufactured in compliance with cGMPs , and were not adulterated or misbranded.

600. Plaintiffs and the TPP Class were the intended third-party beneficiaries of the implied warranties made by Defendants to purchasers of their Ranitidine-Containing Products.

601. Plaintiffs and the TPP Class have had sufficient direct dealings with Defendants or their agents (including distributors, and dealers) to establish privity of contract between Defendants, on the one hand, and Plaintiffs and each member of the TPP Class, on the other hand.

602. Defendants breached their implied warranty to Plaintiffs and the TPP Class in that Ranitidine-Containing Products were not of merchantable quality, safe, nor fit for their intended use. Ranitidine-Containing Products have dangerous propensities in that they have a propensity to degrade into NDMA, a known human carcinogen.

603. As a direct and proximate result of Defendants' breach of the written and implied warranties, Plaintiffs and members of the TPP Class have suffered damages. Plaintiffs would not have been obligated to reimburse for the purchase of Ranitidine-Containing Products and suffered economic injury.

604. No Defendant has acted upon the opportunity to cure its failure to uphold its express and implied warranties concerning the Ranitidine-Containing Products.

605. As a result of Defendants' breaches of express and implied warranties, as alleged herein, Plaintiffs and the TPP Class members seek an order awarding compensatory and punitive damages, attorneys' fees and expenses pursuant to 15 U.S.C. §2310(d)(2), and any other legal equitable relief available under the law.

COUNT 5
FRAUD
(Affirmative Misrepresentation, Omission, and Concealment)
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

606. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

607. Plaintiffs bring this cause of action on behalf of themselves and the members of the TPP Class under the common law of fraud against Defendant GSK, and the Generic Manufacturer Defendants (described herein as "Defendants").

608. Defendants falsely or misleading represented to Plaintiffs and members of the TPP Class, and PBMs via media, dossiers, advertising, marketing, websites, social media, packaging, labeling, and promotions that:

a. Ranitidine-Containing Products were manufactured in such a way that they could assure the safety, efficacy, purity, identity and quality for lifetime of the product, when in fact, they contain NDMA, a known human carcinogen – and which increases in concentration as the product ages;

b. Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew or should have known they were unsafe for their intended purpose.

609. Defendants' statements were false or misleading at the time they were made. Due to the unsafe levels of NDMA they contain, Defendants' Ranitidine-Containing Products were adulterated, misbranded, unsafe for their intended purpose, and not manufactured in compliance with cGMPs. In fact, Ranitidine-Containing Products are so adulterated and unsafe for their intended purpose that the FDA was compelled to order the immediate withdrawl of all Ranitidine-Containing Products on April 1, 2020.

610. Defendants also omitted, concealed, and failed to disclose material facts regarding the Ranitidine-Containing Products – most importantly, the fact that they were manufactured in such a way that they could not assure that their Ranitidine-Containing Products were of appropriate identity, strength, quality, and purity. This was evidenced by the fact that Defendants' Ranitidine-Containing Products contained unacceptable levels of NDMA, a known human carcinogen, which rendered them unfit for human consumption.

611. Defendants had a duty to disclose the fact that Ranitidine-Containing Products contained elevated levels of NDMA that rendered them unsafe for human consumption because they:

a. had exclusive and/or far superior knowledge and access to the facts regarding the defects associated with the Ranitidine-Containing Products than Plaintiffs and members of the TPP Class, and Defendants knew the facts regarding defects associated with the Ranitidine-Containing Products were not known to, or reasonably discoverable by, Plaintiffs and members of the TPP Class;

b. intentionally concealed the foregoing from Plaintiffs and members of the TPP Class; and

c. knew that the defects associated with the Ranitidine-Containing Products were facts basic to the transaction that Plaintiffs and TPP Class members would reasonably expect to be disclosed, and knew that Plaintiffs or the TPP Class would pay or reimburse for the Ranitidine-Containing Products under the mistaken belief that they were safe for human consumption, and manufactured in such a way to assure that they were of appropriate identity, strength, quality, and purity.

612. These misrepresented, omitted, concealed, and undisclosed facts were material because Defendants knew, or reasonably should have known, that their misrepresentations were would induce and/or require Plaintiffs and the TPP Class to pay for some or all of the cost of Defendants' Ranitidine-Containing Products.

613. To the extent applicable, Defendants intended their misrepresentations and omissions to induce and/or require Plaintiffs and other TPP Class members to reimburse for purchases of Defendants' Ranitidine-Containing Products.

614. Defendants misrepresented, omitted, actively concealed, and/or failed to disclose these material facts, in whole or in part, to protect their profits and to avoid recalls that would hurt their brands' images and cost the Defendants money. In doing so, Defendants acted in bad faith at the expense of Plaintiffs and members of the TPP Class.

615. A reasonable TPP would not have expected that the Ranitidine-Containing Products would be manufactured in such a noncompliant manner that the prescription drugs contained

elevated levels of NDMA, a known human carcinogen, which rendered them misbranded, adulterated, illegal to sell and therefore economically worthless.

616. Moreover, Plaintiffs and members of the TPP Class did not, and could not, unravel the deception on their own. Plaintiffs and members of the TPP Class were unaware of these misrepresented, omitted, concealed, and undisclosed material facts and reasonably and justifiably relied on them. If they had known the truth, Plaintiffs and members of the TPP Class would not have paid or reimbursed for Defendants' Ranitidine-Containing Products.

617. As a direct and proximate result of Defendants' misrepresentation, concealment, omission, and/or failure to disclose material facts, Plaintiffs and the members of the TPP Class suffered damages through their payment or reimbursement for Defendants' Ranitidine-Containing Products that are adulterated and misbranded because they contain NDMA, a known human carcinogen. Had Defendants not misrepresented, omitted, concealed, and/or failed to disclose material facts as alleged herein, Plaintiffs would not have paid or reimbursed for Defendants' Ranitidine-Containing Products.

618. As a result of Defendants' fraudulent conduct, Plaintiffs and members of the TPP Class have been injured because they paid or reimbursed for Defendants' Ranitidine-Containing Products for which they otherwise would not have been obligated to pay, and suffered out-of-pocket loss for these reimbursements.

619. Defendants' acts were done knowingly, willfully, maliciously, oppressively, deliberately, with intent to defraud, in reckless disregard of Plaintiffs' and the TPP Class members' rights and well-being, and with the aim of enriching Defendants. Defendants' conduct, which exhibits the highest degree of reprehensibility, being intentional, continuous, placing others at risk of death and injury, and affecting public safety, warrants an assessment of punitive damages in an

amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

COUNT 6
NEGLIGENT MISREPRESENTATION AND OMISSION

(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

620. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

621. This cause of action is alleged on behalf of TPP Class members against Defendant GSK and the Generic Manufacturer Defendants (described herein as "Defendants"), and to the extent applicable law permits non-consumers to assert this cause of action.

622. Each Defendant had or undertook a duty to accurately and truthfully represent the quality, nature, and characteristics of its Ranitidine-Containing Products.

623. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its Ranitidine-Containing Products.

624. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its Ranitidine-Containing Products.

625. Each Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were made).

626. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its

misrepresentations and omissions would induce and/or require TPP Class members to make payments or reimburse for Defendants' Ranitidine-Containing Products.

627. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other TPP Class members have suffered harm, and will continue to do so.

628. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other TPP Class members to reimburse or make payments for Ranitidine-Containing Products.

629. Each Defendant intended its misrepresentations or omissions to induce and/or require Plaintiffs and the TPP Class to pay or reimburse for Defendants' Ranitidine-Containing Products or had reckless disregard for whether they would do so.

630. But for these misrepresentations (or omissions), Plaintiffs and other TPP Class members would not have paid or reimbursed for purchase of Defendants' Ranitidine-Containing Products.

631. Plaintiffs and other TPP Class members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each TPP Class Member.

632. Plaintiffs and other TPP Class members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

COUNT 7
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

633. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

634. This cause of action is alleged on behalf of TPP Class members against Defendant GSK and the Generic Defendants (described herein as "Defendants"), and to the extent applicable law permits non-consumers to assert this cause of action for the reimbursement of all or a portion of the cost of purchases for which Plaintiffs and TPP Class members reimbursed.

635. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code §8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. §44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code §4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code §17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§17500, *et seq.*

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. §6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code §28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code §48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. §24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. §714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. §50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. §367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. §51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. §207, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code §13-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. §445.901, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §325F.67, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Rev. Stat. §407.0 10, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code §30-14-101, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §59-1601, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. §598.0903, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. §358-A:1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. §56:8-1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §57-12-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §349, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §350, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §51-15-01, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 §751, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. §646.605, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. §201-1, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws §39-5-10, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws §37-24-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code §47-18-101, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code §17.41, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. §13-11-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, §2451, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code §59.1-196, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code §19.86.010, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. §40-12-100, *et seq.*; and

636. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

637. Each Plaintiff and other TPP Class Member is a consumer or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

638. Specifically by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were adulterated, misbranded, defective, and not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by the above statutes, including:

a. representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

b. representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

c. advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

d. using exaggeration and/or failing to state the material facts concerning the Ranitidine-Containing Products in a manner that tended to deceive;

e. acting in a manner that resulted in a gross disparity between the true value of the Ranitidine-Containing Products (worthless) and the price paid; and

f. engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

639. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in Plaintiffs' minds, and were likely to and, in fact, did deceive reasonable TPPs, including Plaintiffs and the TPP Class members, about the worthlessness of Defendants' Ranitidine-Containing Products.

640. Defendants' misrepresentations and omissions regarding the inherently worthless and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the TPP Class members in a uniform manner.

641. The facts regarding Ranitidine-Containing Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by Plaintiffs and the TPP Class members, (and, in fact, were material to Plaintiffs and TPP Class members), who consider such facts to be important to their reimbursement decisions with respect to Ranitidine-Containing Products.

642. Plaintiffs and TPP Class members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants had concealed or failed to disclose. Plaintiffs and TPP Class members did not, and could not, unravel Defendants' deception on their own.

643. Defendants had an ongoing duty to Plaintiffs and the TPP Class members to refrain from unfair or deceptive practices. Specifically, Defendants owed Plaintiffs and TPP Class members a duty to disclose all the material facts concerning the dangers of Ranitidine-Containing

Products because they possessed exclusive knowledge that the drugs were being manufactured in such a manner as to render the Ranitidine-Containing Products adulterated and misbranded, and therefore illegal to sell and economically worthless.

644. Plaintiffs and TPP Class members were aggrieved by Defendants' violations of the above statutes because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, including that such drugs were adulterated and misbranded, and therefore illegal to sell and economically worthless.

645. Specifically, Plaintiffs and the TPP Class members reimbursed for purchases of Ranitidine-Containing Products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, implying they were not adulterated and/or misbranded, when in fact they were adulterated, misbranded, contained a known human carcinogen and were therefore illegal to sell. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and TPP Class members would not have paid or reimbursed for Defendants' Ranitidine-Containing Products (nor could they have so done), and, thus, they suffered out-of-pocket loss.

646. Defendants' violations presented risk to the general public, and thus the unlawful acts and practices complained of herein affect the public interest.

COUNT 8
UNJUST ENRICHMENT
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

647. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

648. This cause of action is alleged on behalf of Plaintiffs and the TPP Class members against Defendant GSK and the Generic Manufacturer Defendants (referred to in this section as "Defendants"), and to the extent applicable law permits non-consumers to assert this cause of action.

649. Plaintiffs and TPP Class members conferred a benefit on Defendants in the form of payment or reimbursement of monies for worthless Ranitidine-Containing Products containing dangerously high levels of NDMA, which rendered the drugs misbranded and adulterated, and therefore unfit for their intended purpose and illegal to sell, and economically worthless.

650. As a result of the Defendants' misrepresentations and omissions, Plaintiffs and TPP Class members were not aware of the true facts concerning the Ranitidine-Containing Products and did not benefit from the Defendants' misconduct.

651. The Defendants readily accepted and retained these benefits from Plaintiffs and TPP Class members and knowingly benefitted from their unjust conduct – at Plaintiffs' and the TPP Class members' expense – by selling worthless Ranitidine-Containing Products that were misbranded and adulterated, and therefore unfit for their intended purpose and illegal to sell, and economically worthless.

652. It is inequitable and unconscionable for the Defendants to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and members of the TPP Class, who would not have paid or reimbursed for the medications at all, but for the Defendants' misrepresentations and omissions. Additionally, the Defendants' distribution and sale of Ranitidine-Containing Products in the United States was illegal because they were adulterated, misbranded, and unfit for human consumption.

653. Plaintiffs and other TPP Class members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

COUNT 9
NEGLIGENCE
(On Behalf of the TPP Class Against Defendant GSK and the Generic Manufacturer Defendants)

654. Plaintiffs incorporate the preceding allegations in paragraphs 1 through 519 as though fully set forth herein.

655. This cause of action is alleged on behalf of Plaintiffs and the TPP Class members against Defendant GSK and the Generic Manufacturer Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

656. Defendants directly caused Ranitidine-Containing Products to be sold, distributed, marketed, promoted, and/or reimbursed by Plaintiffs and members of the TPP Class.

657. At all relevant times, Defendants had a duty to exercise reasonable care in the design, research, manufacture, labeling, testing, marketing, advertisement, supply, promotion, packaging, warning, sale, storage, handling, and distribution of Ranitidine-Containing Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not adulterated and/or misbranded.

658. At all relevant times, Defendants had a duty to exercise reasonable care in the marketing, advertisement, and sale of Ranitidine-Containing Products. Defendants' duty of care owed to Plaintiffs, TPP Class members, (and their PBMs) included providing accurate, true, and correct information concerning the risks of using Ranitidine-Containing Products and appropriate,

complete, and accurate warnings concerning the potential adverse effects of Ranitidine-Containing Products – in particular, their ability to transform into the carcinogenic compound, NDMA.

659. At all relevant times, Defendants knew – or in the exercise of reasonable care, should have known – of the hazards and dangers associated with the manufacture of Ranitidine-Containing Products. Specifically, Defendants knew or should have known of the potential for the Ranitidine-Containing Products to degrade into NDMA during the manufacture, transport and storage of Ranitidine-Containing Products, which rendered the drugs adulterated and misbranded and therefore economically worthless.

660. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, labeling, marketing, supply, promotion, advertisement, packaging, warning, sale, and distribution of Ranitidine-Containing Products, in that Defendants manufactured and produced defective Ranitidine-Containing Products, which carry the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their product and knew or had reason to know that drugs containing NDMA were adulterated, misbranded and therefore illegal to sell.

661. Outside of the labeling context, Defendants were negligent in their promotion of Ranitidine-Containing Products by failing to disclose material risk information as part of their promotion and marketing of Ranitidine-Containing Products through the mediums of internet, television, print advertisements, etc. Nothing prevented Defendants from presenting the truth concerning the risks associated with use of Ranitidine-Containing Products in their promotional efforts. Indeed, Defendants had a duty to disclose the truth regarding those risks, outside of the context of labeling.

662. Despite their ability and ample means to investigate, study, and test their products and provide adequate warnings, Defendants failed to do so. Instead, Defendants wrongfully concealed information and made further false and/or misleading statements concerning the safety and use of Ranitidine-Containing Products

663. Defendants' acts of negligence included:

a. Manufacturing, producing, formulating, creating, developing, designing, selling, and/or distributing Ranitidine-Containing Products without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Ranitidine-Containing Products while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Ranitidine-Containing Products;

c. Failing to design and manufacture Ranitidine-Containing Products so as to ensure they were of proper identity, strength, quality, and purity;

d. Representing that their Ranitidine-Containing Products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose because they were manufactured in such a way that Defendants could not assure that their Ranitidine-Containing Products were not adulterated and/or misbranded (and were in fact adulterated and misbranded, as evidenced by the fact that they contained NDMA, a known human carcinogen); and

e. Continuing the manufacture and sale of Ranitidine-Containing Products despite having the knowledge that they could not assure that their Ranitidine-Containing Products were not adulterated and/or misbranded, as evidenced by the fact that the Ranitidine-Containing Products they did manufacture contained NDMA, a known human carcinogen.

664. Defendants knew – or in the exercise of reasonable care, should have known – that it was foreseeable that TPPs such as Plaintiffs and members of the TPP Class would suffer economic injuries through the payment or reimbursement for Defendants' Ranitidine-Containing Products as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Ranitidine-Containing Products.

665. But for Defendants' negligent acts, Plaintiffs and members of the TPP Class would not have made payments or reimbursements for Defendants' Ranitidine-Containing Products.

666. Manufacturer Defendants owed a duty to Plaintiffs and members of the TPP Class to ensure that their Ranitidine-Containing Products sold in the United States complied with current cGMPs in order to ensure they met safety, quality, purity, identity, and strength standards in violation of 21 U.S.C. §351(a)(2)(B) and the following parallel state statutes:

- Alabama Code §§20-1-24 and -27(1);
- Alaska Statutes §17.20.290(a)(1);
- Arizona Statutes §§32-1965(1), (2) and -1966(3);
- Arkansas Code §20-56-215(1);
- California Health and Safety Code §§111295 and 111400;
- Colorado Statutes §§25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§3302 and 3303(2);
- District of Columbia Code §48-702(2);
- Florida Statutes §§499.005(1) and .006(3);
- Georgia Code §26-3-3(1);
- Hawaii Revised Statutes §§328-6(1) and -14(1)(B)(ii);
- Idaho Code §37-115(a);
- Chapter 410, Illinois Statutes §§620/3.1 and /14(a)(2)(B);
- Iowa Code §§126.3(1) and .9(1)(c);
- Kentucky Statutes §217.175(1);
- Maryland Code, Health–General §§21-216(c)(5)(2) and -256(1);

- Massachusetts General Laws chapter 94 §§186 and 190;
- Minnesota Statutes §§151.34(1) and .35(1);
- Missouri Statutes §196.015(1);
- Montana Code §§§50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§71-2461(2) and -2481;
- Nevada Statutes §585.520(1);
- New Hampshire Revised Statutes §§146:1(I) and :4(V);
- New Mexico Statutes §§26-1-3(A) and -10(A);
- New York Education Law §6811;
- North Dakota Century Code §§19-02.1-02(1) and .1-13(3);
- Ohio Code §3715.52(A)(1);
- Oklahoma Statutes title 63 §1-1402(a);
- Title 35, Pennsylvania Statutes §780-113(a)(1);
- Title 21, Rhode Island General Laws §21-3-3(1);
- South Carolina Code §§39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§39-15-3 and -10;
- Title 18, Vermont Statutes §4052(1);
- Virginia Code §54.1-3457(1);
- West Virginia Code §§16-7-1 and -2(a)(3); and
- Wyoming Statutes §§35-7-111(a)(i)–(iv), (vi) and -116.

667. 21 C.F.R. §211.142(b) states that the cGMPs required that warehousing of drug products shall be performed to provide for "[s]torage of drug products under appropriate conditions

of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse Ranitidine-Containing Products.

668. Testing conducted by the FDA, which led to the agency's withdrawal of Ranitidine-Containing Products, confirms that improper storage of Ranitidine-Containing Products has resulted in extremely high levels of NDMA. The FDA has also concluded that NDMA can increase in Ranitidine-Containing Products even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers. FDA's testing also showed that as Ranitidine-Containing Products age the level of NDMA in the product increases.

669. The FDA concluded that these defects raised the level of NDMA in Ranitidine-Containing Products above the acceptable daily intake limit to the point that the drugs had to be withdrawn from the market.

670. As such, Defendants owed these duties to Plaintiffs and members of the TPP Class under 21 C.F.R. §211.142(b) and the following parallel state statutes:

- Alabama Code §§20-1-20(13) and -27(1);
- Alaska Statutes §§17.20.090(1), (10) and .290(a)(1);
- Arizona Statutes §§32-1965(1), (2) and -1967(1), (12);
- Arkansas Code §§20-56-211(1), (10) and -215(1);
- California Health and Safety Code §§111295, 11330, and 111440;
- Colorado Statutes §§25-5-403(1)(a), (b) and -415(1)(a), (j);
- Title 16, Delaware Code §§3302 and 3308(3);

- District of Columbia Code §48-702(2);
- Florida Statutes §§499.005(1) and .007(1), (10);
- Georgia Code §§26-3-3(1) and -8(a)(1), (10);
- Hawaii Revised Statutes §§328-6(1) and -15(1), (10);
- Idaho Code §§37-115(a) and -127(a), (j);
- Chapter 410, Illinois Statutes §§620/3.1 and /15(a), (j);
- Iowa Code §§126.3(1) and .10(1)(a), (j);
- Kentucky Statutes §§217.065(1), (10) and 217.175(1);
- Maryland Code, Health–General §§21-217(b)(1), (6) and -256(1);
- Massachusetts General Laws chapter 94 §§187 and 190;
- Minnesota Statutes §§151.34(1) and .36(1);
- Missouri Statutes §§196.100(1) and .015(1);
- Montana Code §§50-31-306(1)(a), (l) and -501(1);
- Nebraska Revised Statutes §§71-2470(1) and -2481;
- Nevada Statutes §§585.410, .470, and .520(1);
- New Hampshire Revised Statutes §§146:1(I) and :6(I), (X);
- New Mexico Statutes §§26-1-3(A) and -11(A)(1), (G);
- New York Education Law §§6811 and 6815;
- North Dakota Century Code §§19-02.1-02(1) and .1-14(1), (11);
- Ohio Code §§3715.52(A)(1) and 3715.64(A)(1), (11);
- Oklahoma Statutes title 63 §§1-1402(a) and 1-1409(a), (j);
- Title 35, Pennsylvania Statutes §§780-108(1), (10) and 780-113(a)(1);

- Title 21, Rhode Island General Laws §§21-3-3(1) and -15(a)(1), (10);
- South Carolina Code §§39-23-40(a), (j) and -80(A)(1);
- South Dakota Code §§39-15-5 and -10;
- Title 18, Vermont Statutes §§4052(1) and 4064(1), (10);
- Virginia Code §§54.1-3457(1) and -3462(1), (8);
- West Virginia Code §16-7-1; and
- Wyoming Statutes §§35-7-111(a)(i)–(iv), (vi) and -116.

671. Manufacturer Defendants have failed to comply with federal cGMPs and federal adulteration standards as well as the below parallel state statutes:

- Alabama Code §§20-1-24 and -27(1);
- Alaska Statutes §17.20.290(a)(1);
- Arizona Statutes §§32-1965(1), (2) and -1966(3);
- Arkansas Code §20-56-215(1);
- California Health and Safety Code §§111295 and 111400;
- Colorado Statutes §§25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§3302 and 3303(2);
- District of Columbia Code §48-702(2);
- Florida Statutes §§499.005(1) and .006(3);
- Georgia Code §26-3-3(1);
- Hawaii Revised Statutes §§328-6(1) and -14(1)(B)(ii);
- Idaho Code §37-115(a);
- Chapter 410, Illinois Statutes §§620/3.1 and /14(a)(2)(B);

- Iowa Code §§126.3(1) and .9(1)(c);
- Kentucky Statutes §217.175(1);
- Maryland Code, Health–General §§21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§186 and 190;
- Minnesota Statutes §§151.34(1) and .35(1);
- Missouri Statutes §196.015(1);
- Montana Code §§§50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§71-2461(2) and -2481;
- Nevada Statutes §585.520(1);
- New Hampshire Revised Statutes §§146:1(I) and :4(V);
- New Mexico Statutes §§26-1-3(A) and -10(A);
- New York Education Law §6811;
- North Dakota Century Code §§19-02.1-02(1) and .1-13(3);
- Ohio Code §3715.52(A)(1);
- Oklahoma Statutes title 63 §1-1402(a);
- Title 35, Pennsylvania Statutes §780-113(a)(1);
- Title 21, Rhode Island General Laws §21-3-3(1);
- South Carolina Code §§39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§39-15-3 and -10;
- Title 18, Vermont Statutes §4052(1);
- Virginia Code §54.1-3457(1);
- West Virginia Code §§16-7-1 and -2(a)(3); and

- Wyoming Statutes §§35-7-111(a)(i)–(iv), (vi) and -116.

672. As a result of Defendants' failures to do so, Defendants' own actions and inactions created a foreseeable risk of harm to Plaintiffs and members of the TPP Class.

673. Plaintiffs and members of the TPP Class, as entities reimbursing for purchases of Ranitidine-Containing Products, are within the class which 21 U.S.C. §351(a)(2)(B) and 21 C.F.R. §211.142(b) (and the related state statutes) were designed to protect, and the harm to Plaintiffs and members of the TPP Class is of the nature these statutes were designed to prevent.

674. Defendants' negligence was a substantial factor in causing Plaintiffs' and TPP Class members' economic injuries. Had Defendants disclosed and not concealed the risks associated with the use of Ranitidine-Containing Products, Plaintiffs and members of the TPP Class would not have made payments or reimbursements for Defendants' Ranitidine-Containing Products, and therefore would have avoided economic injury.

675. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and members of the TPP Class have been injured. They paid or reimbursed for Ranitidine-Containing Products that were adulterated and misbranded, and therefore illegal to sell and economically worthless as a result of Defendants' misrepresentation, omission, and concealment of, and/or failure to timely disclose, the safety and quality issues associated with Ranitidine-Containing Products caused by Defendants' conduct. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the TPP Class members would not have made payments or reimbursements for Defendants' Ranitidine-Containing Products.

676. As a direct and proximate result of Defendants' negligent conduct, Plaintiffs and members of the TPP Class have been injured because they made payments or reimbursements for

a drug for which they otherwise would not have paid or reimbursed, and suffered out-of-pocket loss.

677. Plaintiffs seek compensatory damages on behalf of themselves and the TPP Class, all attorneys' fees, costs, interest, and such further relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court grant the following relief:

A. Determine that this action may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), (b)(3), and/or (c)(4), direct that reasonable notice of this action be given to the classes, appoint Plaintiffs as named representatives of the classes, and appoint Plaintiffs' counsel as class counsel;

B. Enter judgment against Defendants and in favor of Plaintiffs and the classes;

C. Award damages (including actual, nominal, presumed, statutory, punitive, and treble damages as provided by law) and restitution to the classes in an amount to be determined at trial, plus interest, in accordance with law;

D. Order disgorgement of Defendants' profits;

E. Order any and all appropriate preliminary and/or final injunctive or equitable relief against the against the conduct of Defendants described herein;

F. Award Plaintiffs and the TPP Class members their costs of suit, including reasonable attorneys' fees as provided by law;

G. Award such further and additional relief as is necessary to redress the harm caused by Defendants' unlawful conduct and as the Court may deem just and proper under the circumstances; and

H. Award any other relief that is deemed just and proper.

JURY DEMAND

Plaintiffs demand trial by jury.

Dated: June 22, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2020, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/ *Robert C. Gilbert*
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