IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, and WASHINGTON; the Commonwealths of MASSACHUSETTS and VIRGINIA; and the DISTRICT OF COLUMBIA; *ex rel.* VALISURE LLC, Plaintiffs and Relator, v. GLAXOSMITHKLINE, plc, and GLAXOSMITHKLINE, LLC, Defendants.	Case No. 2:19-cv-04239-JP **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT
PURSUANT TO THE FEDERAL FALSE CLAIMS ACT
AND SUPPLEMENTAL STATE FALSE CLAIMS ACTS

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I. INTRODUCTION

1. For nearly four decades, Defendants GlaxoSmithKline, LLC and GlaxoSmithKline, plc (collectively, "GSK") lied to the U.S. Food and Drug Administration ("FDA"), the government, the medical and scientific communities, and consumers about the stability of the drug ranitidine (brand name Zantac). In 1981, GSK conducted experiments on ranitidine, showing that it could react to form a dangerous carcinogen: N-Nitrosodimethylamine ("NDMA"). When the FDA ordered GSK to disclose all its data about this issue due to the FDA's concerns about the chemical structure of the ranitidine molecule, GSK concealed its data. In fact, GSK fabricated a different study, designed to conceal any NDMA connection, and then used that study to mislead the FDA and other independent researchers. GSK knowingly and deliberately lied to the FDA and the government so that it could get ranitidine approved.

2. Ranitidine would not have received FDA approval if GSK did not commit the acts of fraud described herein, including, but not limited to, the concealment of the ranitidine-NDMA data, fabrication and submission of false and misleading data as part of ranitidine's approval, submission of a false product labels and summary basis of approvals, submission of false and misleading supplemental applications for approval without concealing the NDMA issue, and repeated interactions with the FDA and medical community that failed to disclose

the NDMA link that, under federal law, GSK was required to disclose.

3. The fraud worked. In 1983, the FDA approved the drug, citing the false data submitted by GSK. And, for nearly forty years, GSK was able to conceal the connection between ranitidine and NDMA, even after repeatedly seeing ranitidine product discolor into a yellow oily substance (NDMA is a yellow oily substance) when exposed to any heat or humidity. Even after studies emerged—including secret clinical trials—showing that people using ranitidine had higher levels of NDMA in their stomach fluid and were developing cancer at an alarming rate, GSK just kept lying to the FDA and government about the safety and stability of ranitidine.

4. The ranitidine molecule begins to decompose into NDMA from the point of manufacture until it is consumed, exacerbated by heat and humidity. Every dose of ranitidine, thus, is contaminated with NDMA, render the drug adulterated, misbranded, worthless, and unfit for human consumption. GSK knew this before ranitidine was every approved, and concealed this fact from the federal government.

5. Through that fraud GSK made billions. Ranitidine, a drug that provides no unique benefit as compared to other similar H2-blocker drugs on the market, like Tagamet (cimetidine), became one of the bestselling drugs in history, catapulting GSK from a small British pharmaceutical laboratory to one of the most

powerful drug companies in the world. Riding ranitidine's success, GSK would go on to make and sell more blockbusters—leading to criminal convictions and multi-billion-dollar fines for defrauding the government —but its fraudulent conduct related to ranitidine remained buried until 2019.

6. Everything changed in 2019, when a small laboratory in Connecticut—the Relator Valisure, LLC—tested ranitidine pills for the presence of NDMA. Indeed, Relator conducted the standard tests for nitrosamine formation that GSK had done in 1981, and observed the same results. Ranitidine was unstable and formed NDMA. However, unlike GSK, who buried the data and lied to the world about it—Relator disclosed their alarming results to the FDA. Within months, in response to the very experiments that GSK lied about in 1981, the FDA investigated and on April 1, 2020 ordered the immediate removal of all ranitidine products from the market, citing Relator's experiments. FDA specifically stated that ranitidine decomposed into NDMA, under regular transport and storage, and that it would expose users to unsafe levels of NDMA. FDA ordered all products off the market and that any remaining products left on the market to be destroyed immediately. No ranitidine has since been permitted for sale in the United States.

7. Taxpayers spent billions paying for ranitidine products, even though those products were not fit for human consumption and exposed users to NDMA. The FDA would never have permitted ranitidine to be sold—a fact borne out by

the FDA's reaction to learning the truth from Relator—and GSK would never have been able to bilk government-funded programs of billions of dollars in ranitidine product purchases and reimbursements.

8. Specifically, GSK caused numerous false claims to be submitted for payment from various government-funded programs, like Medicare and Medicaid, starting in 1983. Every time a government-funded program paid a claim for a ranitidine product, the claim was false; whether that product was brand name or generic.

9. Factually, each claim submitted to a government-funded program was false: when claimants requested payment or reimbursement for a ranitidine product, the drug that was ultimately delivered was not what it purported to be. The ranitidine products were not safe, effective, or medically reasonable drugs; they were adulterated, misbranded, and unfit for human consumption (a fact underscored by the FDA ordering all ranitidine products destroyed once the truth was exposed by Relator).

10. Legally, each claim submitted to a government-funded program was false because they were premised on express and/or implied false certifications: when claimants requested payment or reimbursement for a ranitidine product, they certified that the ranitidine product subject to the payment or reimbursement was, in fact, an FDA-approved medication (which it was not because it was adulterated,

misbranded, worthless, and unfit for human consumption), and that the ranitidine product being purchase was medically reasonable (which it was not because the drug exposed patients to the dangerous NDMA carcinogen).

11. GSK caused each false claims to be submitted by medical providers, pharmacies, and patients for payment from government-funded programs. But for GSK's fraud in concealing the NDMA issue from the federal government, government-funded programs would never have reimbursed or paid for a single ranitidine product. This point is underscored by the FDA removing ranitidine from the market in 2020, after learning the truth from Relator.

12. Relator Valisure LLC, on behalf of the United States of America and the above-captioned Plaintiff States,[1] brings this action against Defendants for violations of the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and

[1] "Plaintiff States" as used herein collectively refers to: The State of California, The State of Colorado, The State of Connecticut, The State of Delaware, The State of Florida, The State of Georgia, The State of Hawaii, The State of Illinois, The State of Indiana, The State of Iowa, The State of Louisiana, The Commonwealth of Massachusetts, The State of Michigan, The State of Minnesota, The State of Montana, The State of Nevada, The State of New Jersey, The State of New Mexico, The State of New York, The State of North Carolina, The State of Oklahoma, The State of Rhode Island and Providence Plantations (the "State of Rhode Island"), The State of Tennessee, The State of Texas, The Commonwealth of Virginia, The State of Washington, and The District of Columbia. "Government Plaintiffs" as used herein collectively refers to the United States and the Plaintiff States.

of the Plaintiff States' counterpart false claims statutes.[2]

13. This case seeks to hold GSK accountable for defrauding taxpayers for nearly four decades. Drug companies cannot be permitted to lie and cheat the FDA, the governments, and the medical and scientific communities, and make jaw-dropping profit from doing so. There are consequences when a company, through

[2] These statutes, collectively referred to herein as the "State False Claims Acts," are: the California False Claims Act, Cal. Gov't Code § 12650 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. Ann. § 4-274 *et seq.*; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.*; the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*; the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*; the Iowa False Claims Act, Iowa Code § 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5A *et seq.*; the Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.005 *et seq.*; the District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq.*

fraud, steals billions of taxpayer dollars.

14. This case is not about whether the NDMA in ranitidine causes cancer. That issue is at the heart of personal injury lawsuits related to ranitidine causing individual consumer's cancer—an issue that has little to do with this lawsuit. This lawsuit is about GSK's fraud on the federal and state governments and the money spent on ranitidine products by governments because of that fraud. Whether ranitidine increases the risk of cancer in humans is immaterial to this lawsuit.

II. JURISDICTION AND VENUE

15. This Court has original subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, as the case asserts a federal question.

16. This Court has general personal jurisdiction of this action pursuant to 31 U.S.C. § 3732(a) because Defendants have transacted business in the Eastern District of Pennsylvania and most of the alleged fraudulent conduct occurred in this district, including the acts designed to deceive governmental regulators regarding the ability of ranitidine to form NDMA.

17. The Court has personal jurisdiction over Defendants, and venue is proper in this district, because the False Claims Act provides for service of process anywhere in the United States, and because Defendants transact business in this district, and because one or more of the acts committed by Defendants and proscribed by 31 U.S.C. § 3729 *et seq.* occurred in this district. 31 U.S.C. §

3732(a).

18. This Court also has general personal jurisdiction over Defendants because each Defendant has consented to personal jurisdiction in the State of Pennsylvania by registering to do business within this state. *See Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122 (2023).

19. This Court also has specific personal jurisdiction over the Defendants because many of the actions and decisions made by Defendants within the State of Pennsylvania give rise and relate to the claims asserted in this complaint.

20. This Court has supplemental jurisdiction of the State False Claims Acts claims pursuant to 28 U.S.C. § 1367.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 31 U.S.C.§ 3732, because Defendants transact business in this District, including with respect to ranitidine. Ranitidine products have been (1) supplied to Government Health Care Program recipients, including Medicare and Medicaid recipients, and (2) the subject of claims for reimbursement by health care providers to Government Health Care Programs.

22. A copy of this Complaint and written disclosures of substantially all material evidence and information in Relator's possession were served on the Government pursuant to Rule 4 of the Federal Rules of Civil Procedure. In addition, the same has been delivered to the attorneys general (or relevant

official(s)) of each of the Plaintiff States.

23. Relator has direct and independent knowledge on which the allegations are based, is an original source of this information to the United States, and has voluntarily provided the information to the United States before filing this action based on the information.

24. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure, Relator is an original source under 31 U.S.C. § 3730(e)(4)(B).

25. Relator Valisure is an "original source" of the information pursuant to 31 U.S.C. § 3730(e)(4)(B) because Valisure voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based prior to public disclosure.

III. THE PARTIES

26. Relator Valisure LLC is a New Haven, Connecticut-based technology company that provides independent certification using chemical analysis of a product's supply chain. Valisure is incorporated in the State of Delaware. Thus, Valisure is a citizen of Connecticut and Delaware, and not of any other state.

27. Defendant GlaxoSmithKline plc is a public limited company organized under British law and is headquartered in London, England. It is the

parent company of Defendants' interconnected corporate structure. It was formed by the merger of Glaxo Wellcome plc and SmithKline Beecham plc, in 2000.

28. GlaxoSmithKline plc, along with its various subsidiaries, is a continuation of Glaxo Wellcome plc and SmithKline Beecham plc and the various subsidiaries thereof, and is a successor to the interests and liabilities of these. Both Glaxo Wellcome plc and SmithKline Beecham plc previously had succeeded to earlier corporate interests and liabilities, including without limitation those of: Glaxo plc and Wellcome plc, which merged to form Glaxo Wellcome plc in 1995; and SmithKline Corp. and Beecham Group plc, which merged to form SmithKline Beecham plc in 1989.

29. Defendant GlaxoSmithKline LLC is a Delaware limited liability company and has headquarters in Philadelphia, Pennsylvania and Research Triangle Park, North Carolina. GlaxoSmithKline LLC operates as the United States subsidiary of GlaxoSmithKline plc. Defendant GlaxoSmithKline, LLC is a citizen of Delaware, Pennsylvania, and North Carolina. Upon information and belief, GlaxoSmithKline LLC, in its role as United States subsidiary, has succeeded to business activities previously performed by various entities incorporated under United States law, some now no longer in existence, including without limitation Glaxo Inc. and Glaxo Wellcome Inc.

30. As used herein, the terms "GSK" and "Defendants" collectively refer

to: (1) GlaxoSmithKline plc and its subsidiaries, including without limitation GlaxoSmithKline LLC; (2) said entities' predecessors and successors in interest and liability, including without limitation any such entities specifically identified herein; and (3) any affiliates of these, including without limitation entities specifically identified herein that have been involved in the testing, development, manufacture, marketing, sale, and/or distribution of ranitidine.[3]

31. Together, the entities comprising GSK are in the business of, among other endeavors, manufacturing, marketing, importing, preparing, and selling pharmaceutical products distributed throughout the United States, including the Plaintiff States. These business activities specifically include ranitidine sales that resulted in prescriptions of ranitidine and, in turn, claims to the Government Health Care Programs for costs of ranitidine.

32. The real parties in interest to the claims in this action are the Government Plaintiffs, i.e., the United States and its agencies and instrumentalities, and the Plaintiff States.

33. The United States is a Plaintiff to this action. The United States' interest in this action results from damages that Defendants caused to, among other

[3] Such subsidiaries, predecessors, successors, and affiliates include, in addition to those already identified above: Glaxo Group Research Limited, Glaxo Research and Development Limited, Matburn Research Limited, Glaxo Wellcome Manufacturing Pte. Ltd., Glaxo Group Limited, Glaxo Holdings plc, and GlaxoSmithKline Services Unlimited, among other entities.

federal entities, the federal Department of Health and Human Services ("DHHS") and Centers for Medicare and Medicaid Services ("CMS"), which administer the Government Health Care Programs known as Medicare and Medicaid, and the Veterans Administration.

34. Each of the Plaintiff States is a Plaintiff to this action. At all times relevant here, ranitidine products were provided to Medicaid recipients in each Plaintiff State, and were covered Medicaid benefits under each Plaintiff State's Medicaid program (or analog thereof). Such products were also provided to Medicare recipients in each Plaintiff State, and were covered by taxpayer moneys administered through CMS.

IV. BACKGROUND

A. Ranitidine Product History

35. Zantac (ranitidine) was originally discovered and developed by scientist John Bradshaw on behalf of GSK[4] in 1976.

36. The drug 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.

[4] Dr. Bradshaw was working for Glaxo Inc. at the time. Glaxo Inc. later merged with the Wellcome Foundation in 1995 to become Glaxo Wellcome plc. Then, in 2000, Glaxo Wellcome plc merged with Smithkline Beecham plc to form GlaxoSmithKline plc.

37. In 1977, Smith, Kline, and French ("SKF") launched cimetidine (Tagamet)—the first histamine 2 receptor blocker ("H2RA")—and it was a tremendous success.

38. Eager to get into the lucrative H2RA market, Glaxo (the predecessor to GSK) rushed Zantac's approval through the U.S. Food and Drug Administration ("FDA")—starting with investigation approval in December 1979, and final submission of the new drug application (NDA) by February 1982.

39. To say that Zantac was an important product for GSK (then Glaxo) would be an understatement. As one GSK executive put it in 1983:

> [T]he sheer size of this opportunity and the potential rewards from it dwarf anything we've done so far. *It's not just that Zantac is bigger than all our other products put together...it's bigger than the whole company.* You've all heard the numbers. *My mind finds it difficult to absorb all those zeroes...especially when I'm salivating so hard.*
>
> (LAUGHTER)

40. Zantac was approved by the FDA, pursuant to the NDA process in 1983 (NDA 18-703) and, quickly, became one of GSK's most successful products, being the first prescription drug in history to reach $1 billion in sales, which in the pharmaceutical industry is referred to as a "Blockbuster."

41. In 1993, GSK entered into a joint venture with Pfizer[5] to develop an over-the-counter ("OTC") version of Zantac. That joint venture led to FDA

[5] The joint venture was between Glaxo Wellcome plc and Warner–Lambert, Inc. Warner-Lambert was later acquired by Pfizer, Inc. in 2000. For the purposes of this Complaint, Warner-Lambert will be referred to as Pfizer.

approval of a 75 mg OTC version of Zantac in December 1995. Zantac 75 OTC was approved through an NDA process (NDA 20-520).

42. In 1997, GSK's patent on ranitidine expired, and generic ranitidine-containing drugs entered the market. Despite generic entry, however, brand name prescription and OTC Zantac continued to be sold. Although sales of brand-name Zantac declined as a result of generic and alternative products, ranitidine-containing drug sales remained strong over time, including purchases made by the United States and Plaintiff States. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year.

43. In December 1998, the joint venture between GSK and Pfizer dissolved. As part of the separation, GSK retained the rights to sell all forms of Zantac internationally and prescription Zantac in the U.S., while Pfizer retained the rights to sell OTC Zantac domestically and retained ownership over the Zantac trademark. Under this agreement, GSK retained control and responsibility over the prescription Zantac NDA and Pfizer retained control and responsibility over the OTC Zantac NDA.

44. As part of this agreement, Pfizer agreed to pay GSK annual royalties on OTC sales in excess of $130 million. Thus, GSK continued to have a financial interest in the sale of OTC Zantac. Additionally, GSK continued to manufacture

the ranitidine drug substance, also known as active pharmaceutical ingredient ("API"), for all Pfizer OTC Zantac products.

45. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA approved NDA 21-698 OTC Zantac 150 mg on August 31, 2004.

46. In 2004, in addition to GSK, Pfizer began also using ranitidine API manufactured by Uquifa, located in Barcelona, Spain.

47. In December 2006, Pfizer through a divestiture agreement of its consumer healthcare products to Johnson & Johnson, ultimately 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, and customer and supply contracts—to Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI" or "Boehringer"). As part of this deal, Boehringer obtained control and responsibility over all the Zantac OTC NDAs.

48. The royalty agreement for GSK was transferred to Boehringer, which continued to make royalty payments to GSK for OTC sales.

49. BIPI also continued to make purchases of API from GSK for it is OTC products, which lasted until 2010.

50. In November 2017, GSK ceased marketing prescription Zantac in the

U.S., with the last product still in the U.S. set to expire in November 2018. However, GSK still retains control over the prescription Zantac NDAs.

51. As of January 1, 2017, Boehringer sold the rights of OTC Zantac to Sanofi. As part of this deal, Sanofi obtained control and responsibility over the OTC NDA and currently retains that control and responsibility.

52. To date, the FDA has approved numerous generic manufacturers for the sale of prescription and OTC ranitidine-containing products through an Abbreviated New Drug Application ("ANDA") process. That process relies on the data presented in the original NDAs submitted by GSK to the FDA. But-for FDA's approval of Zantac, no OTC ranitidine or generic prescription ranitidine products would have been available for purchase in the United States.

B. NDMA Is a Dangerous Carcinogen

53. NDMA is a yellow oily substance that is part of the N-nitrosamine chemical family.

54. Before 1976, NDMA was primarily used in the production of rocket fuel, rubber, and copolymers. However, in 1976, NDMA was banned, and now it is only used in research, specifically, to induce genetic damage and cancer in laboratory experiments as a positive control.

55. NDMA is considered the most well-studied chemical in the N-nitrosamine family.

56. It is generally accepted that NDMA is a carcinogen. In 1978, IARC reviewed NDMA and classified it as "probable human carcinogen." IARC based its conclusion on the overwhelming evidence of animal and cell data (including human cell data). While there was no human epidemiology for NDMA at that time, IARC stated that NDMA "should be regarded for practical purposes as if it were carcinogenic to humans." IARC has not re-reviewed NDMA since, although its official listing under the modern IARC classification occurred in 1987. IARC does not re-review its classifications unless the carcinogen has been nominated and a committee recommends review. This is a function of IARC focusing on unknown carcinogens; not well-established carcinogens like NDMA. As NDMA has been known as a carcinogen for fifty years, and with every regulatory agency treating it as such, IARC has not re-reviewed NDMA or amended its position that NDMA should be treated as a human carcinogen.

57. Both the FDA and the Environmental Protection Agency ("EPA") consider NDMA to be a "probable human carcinogen" in accordance with IARC.

58. The Department of Health and Human Service's Report on Carcinogens ("ROC") states that NDMA is "reasonably anticipated to be a human carcinogen[.]"

59. In 1989, the U.S. Department of Health and Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") assessed the

carcinogenicity of NDMA and concluded: "it is reasonable to anticipate that NDMA will be carcinogenic in humans. It is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." The ATSDR further explained that "it is reasonable to expect that exposure to NDMA by eating, drinking, or breathing could cause cancer in humans."

60. Recently, in 2023, the ATSDR revised its toxicological profile on NDMA, systematically reviewing data on NDMA. Although the ATSDR no longer makes classifications, it noted "NDMA's carcinogenicity is widely recognized."

61. In 2002, the World Health Organization ("WHO"), of which IARC is part, issued a chemical assessment document for NDMA, and stated (emphasis added):

> Based upon laboratory studies in which tumours have been induced in all species examined at relatively low doses, ***NDMA is clearly carcinogenic.*** There is overwhelming evidence that NDMA is mutagenic and clastogenic. …. Qualitatively, the metabolism of NDMA appears to be similar in humans and animals; as a result, it is ***considered highly likely that NDMA is carcinogenic to humans, potentially at relatively low levels of exposure***.

62. In 2002, Canadian regulators concluded that "owing to the considerable evidence of carcinogenicity of NDMA in laboratory species, evidence of direct interaction with DNA consistent with tumour formation, as well as the

apparent lack of qualitative species-specific differences in the metabolism of this substance, NDMA is highly likely to be carcinogenic to humans."

63. In 2020, when the FDA ordered the immediate withdrawal of all ranitidine from the market due to finding NDMA, the FDA stated that "NDMA is a probable human carcinogen (a substance that could cause cancer)." The FDA specifically explained that "sustained higher levels of exposure may increase the risk of cancer in humans."

64. The dangers of NDMA are recognized by the Defendants. On September 25, 2019, GSK's occupational toxicologists prepared a Hazard Assessment Report on NDMA. This document was created "to protect the scientists and anybody handling" NDMA in the laboratory. GSK's scientists reviewed the literature on NDMA and repeatedly indicated that NDMA is a human carcinogen:

> There appear to be no qualitative differences in metabolism of NDMA between humans and laboratory animals, and there is no reason to believe that humans would respond qualitatively differently.
>
> N-Nitrosodimethylamine (NDMA) is reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in experimental animals.
> …
>
> There is overwhelming evidence that NDMA is mutagenic and clastogenic. … Positive results have been observed in human as well as rodent cells.
> …

> Qualitatively, the metabolism of NDMA appears to be similar in humans and animals; as a result, it is considered highly likely that NDMA is carcinogenic to humans, potentially at relatively low levels of exposure.
> …
>
> NDMA is a genotoxic carcinogen, and exposure should be reduced to the extent possible.

65. GSK has specifically used NDMA to induce tumors in laboratory animals. In an effort to test whether a specific testing method was capable of detecting liver tumors, GSK researchers used NDMA as a positive control, noting that "[p]reliminary work using … N-nitrosodimethylamine (NDMA) as hepatotoxins generated progressive liver lesions of varying severity in a dose-dependent manner."[6] Thus, even GSK used NDMA as part of its own method development because it was such a potent carcinogen.

66. Because NDMA has been studied for so long, it is also understood how NDMA, mechanistically, causes cancer in cells. Unmetabolized NDMA is, itself, harmless. However, in the body, NDMA is quickly metabolized by an enzyme called cytochrome p450. As the NDMA molecule breaks down, it creates formaldehyde and a "methyldiazonium ion." Both of these metabolites are genotoxic, especially the methyldiazonium ion, which is known to cause DNA

[6] Giffen P.S., et al., *Alpha-glutathione S-transferase in the assessment of hepatotoxicity--its diagnostic utility in comparison with other recognized markers in the Wistar Han rat*, 30 TOXICOL PATHOL. 3, 365–372 (2002).

adducts, i.e., bind to genetic material and cause mutations.

67. When NDMA is ingested by humans, nearly all of it is metabolized and converted into its genotoxic metabolites. Although human experimentation with NDMA is considered unethical, one experiment was done in the 1980s to confirm the rapid and near-complete metabolization of NDMA. In the Spiegelhalder study, researchers noted: "[i]t is well accepted that exposure to nitrosamines must be considered to be a cancer risk. To calculate this risk it is necessary to estimate total exposure."[7] To explore human metabolism of NDMA, volunteers ingested beer, orange juice, and orange juice with 6% alcohol that were spiked with known quantities of NDMA. When urine was collected, the subjects who consumed the NDMA-spiked orange juice without alcohol had no detectable NDMA in the urine, indicating that all the NDMA had been metabolized. Conversely, 0.5 – 2.5% of the NDMA was recovered in the urine of volunteers that consumed alcohol. This makes sense as alcohol (ethanol) is known to competitively inhibit the cytochrome p450 enzyme that is also used to metabolize NDMA.

68. The absorption and metabolism of NDMA is well studied, and its mechanism of causing DNA damage is well characterized. NDMA is mutagenic

[7] Spiegelhalder, B, et al., *Urinary Excretion of N-Nitrosamines in Rats and Humans*, 41 IARC SCI. PUB. 443-449 (1982).

and/or genotoxic (depending on the assay used) in virtually all systems tested. Indeed, NDMA is so effective and consistent in causing genetic damage that it is routinely used as a positive control in genotoxicity studies.

69. In *every* study, in *every* species, and in *every* sex, NDMA caused tumors to develop.

70. Numerous human epidemiological studies have been conducted involving both occupational and dietary exposure to NDMA. And, the greater weight of the evidence is clear: NDMA exposure causes cancer in humans:

A. De Stefani, et al., *Dietary Nitrosodimethylamine and the Risk of Lung Cancer: A Case-Control Study from Uruguay*, 5 CANCER EPI. BIOMARKERS & PREVENTION 679, 679–682 (1996).

B. Goodman, et al., *High-Fat Foods and the Risk of Lung Cancer*, 3 EPI. 4, 288-299 (1992).

C. Hidajat, et al., *Lifetime exposure to rubber dusts, fumes and N-nitrosamines and cancer mortality in a cohort of British rubber workers with 49 years follow-up*, 76 OCCUP. ENV. MED. BRIT. MED. J., 250, 250–258 (2019).

D. Jakszyn, et al., *Endogenous versus exogenous exposure to N-nitroso compounds and gastric cancer risk in the European Prospective Investigation into Cancer and Nutrition (EPIC-EURGAST) study*, 27

CARCINOGENESIS 7, 1497–1501 (2006)

E. Jakszyn, et al., *Red Meat, Dietary Nitrosamines, and Heme Iron and Risk of Bladder Cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC)*, 20 CANCER EPI. BIOMARKER & PREVENTION 3, 555–559 (2011).

F. Jakszyn, et al., *Nitrosamines and Heme Iron and Risk of Prostate Cancer in the European Prospective Investigation into Cancer and Nutrition*, 21 CANCER EPI. BIOMARKER & PREVENTION 3, 547–551 (2012).

G. Keszei, et al., *Dietary N-nitroso compounds, endogenous nitrosation, and the risk of esophageal and gastric cancer subtypes in the Netherlands Cohort Study*, 97 AMER. J. CLIN. NUTRITION 135, 135–46 (2013).

H. Knekt, et al., *Risk of Colorectal Cancer and Gastro-Intestinal Cancers After Exposure to Nitrate, Nitrite, and N-Nitroso Compounds: A Follow Up Study*, 80 INT. J. CANCER 852, 852–856 (1999).

I. Larsson, et al., *Processed meat consumption, dietary nitrosamines and stomach cancer risk in a cohort of Swedish women*, 119 INT. J. CANCER 915, 915–919 (2006).

J. La Vecchia, et al., *Nitrosamine intake and gastric cancer risk*, 4 EUR. J. CANCER PREV. 461, 461–474 (1995).

K. Loh, et al., *N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 AMER. J. CLIN. NUTRITION 1053, 1053–61 (2011).

L. Palli, et al., *Dietary patterns, nutrient intake and gastric cancer in a high-risk area of Italy*, 12 CANCER CAUSES AND CONTROL 163, 163–172 (2001).

M. Pobel, et al., *Nitrosamine, nitrate and nitrite in relation to gastric cancer: A case-control study in Marseille, France*, 11 EUR. J. EPI. 67, 67–73 (1995).

N. Rogers, et al., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cancer*, 4 CANCER EPI. BIOMARKER & PREVENTION 29, 29–36 (1995).

O. Ronco, et al., *Meat Consumption, Animal Products, and the Risk of Bladder Cancer: A Case-Control Study in Uruguayan Men*, 15 ASIAN PAC. J. OF CANCER PREVENTION 5805, 5805–5809 (2014).

P. Seyyedsalehi, et al., *Association of Dietary Nitrate, Nitrite, and N-Nitroso Compounds Intake and Gastrointestinal Cancers: A Systematic Review and Meta-Analysis*, 11 TOXICS 190, 1-13 (2023).

Q. Song, et al., *Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric Cancer: A Meta-Analysis*, 7 Nutrients 9872, 9872–9895 (2015).

R. Zheng, et al., *Dietary N-Nitroso Compounds and Risk of Hepatocellular Carcinoma: A USA-Based Study*, 74 HEPATOLOGY 6, 3161–3173 (2021).

S. Zhu, et al., *Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada*, 111 BRIT. J. NUTRITION 6, 1109–1117 (2014).

71. The World Health Organization has recommended that long-term total daily ingested NDMA amounts from all sources in an average male adult should be less than 200 ng, because of a 70-year estimated risk of cancer increase.

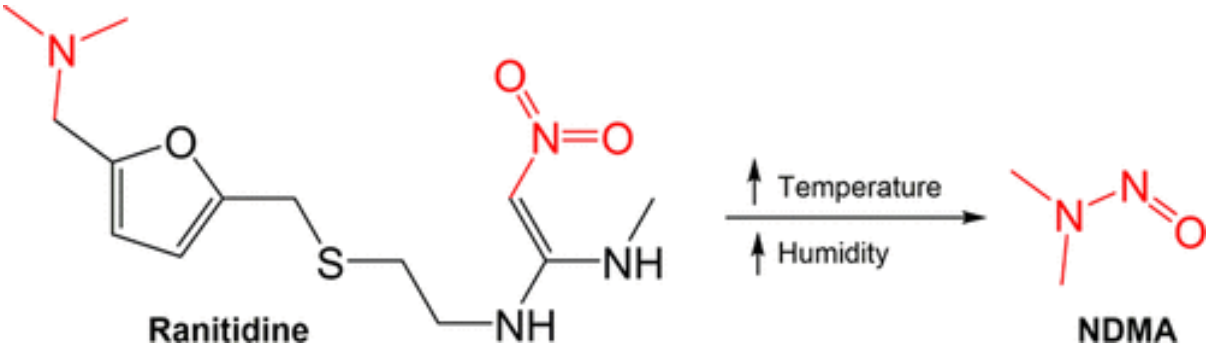
72. It is estimated that the average adult consumes 100 to 110 ng of NDMA daily in the water and food supply. This means that ingesting more than 100 ng of NDMA daily from prescription drugs (either from contaminated product ingestion or conversion in the stomach) would bring the daily ingested amount of NDMA to above 200 ng and significantly increase the risk of cancer.

73. FDA guidelines limit NDMA exposure from daily medications to no

more than 96 ngs.[8]

C. Ranitidine Is an Unstable Molecule and Will Naturally Degrade in NDMA, Accelerated by Heat and Humidity, Exposing Users to Illegal Levels of NDMA Upon Ingestion

74. Ranitidine, is an amine-based pharmaceutical, that has been shown to decompose to N-nitrosodimethylamine (NDMA):



75. The ranitidine molecule contains the necessary tertiary amine group and a nitrosation source (both highlighted in red in Figure above) to form NDMA.[9] Using suitably isotopically labeled ranitidine hydrochloride, GSK researchers have confirmed the formation of NDMA solely from an intermolecular reaction of ranitidine hydrochloride without involvement of impurities. They also identified factors that influence the rate of degradation to include heat and humidity.

76. Testing done by GSK on both ranitidine drug substance batches

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[8] U.S. Food & Drug Administration, *M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk, Guidance for Industry* (March 2018).

[9] King, et al., *Ranitidine Investigations into the Root Cause for the Presence of N-Nitroso-N,N-dimethylamine in Ranitidine Hydrochloride Drug Substances and Associated Drug Products*, ORG. PROCESS RES. DEV., A-L (Oct. 2021).

manufactured by different suppliers, including GSK, and various finished ranitidine products, show high levels of NDMA.[10] For the ranitidine drug substance, they observed NDMA levels of up to greater than 40 mcg/g (40 ppm). To put this in context, each 150 mg ranitidine pill contains 168 mg of ranitidine hydrochloride drug substance, and each 300 mg pill contains 336 mg of ranitidine hydrochloride drug substance. If the underlying drug substance contained 40 ppm of NDMA (as observed in GSK testing), a 150 mg ranitidine pill would contain 6,720 ngs of NDMA. And a 300 mg pills would contain 13,440 ngs of NDMA. This is 140 times the FDA limit of NDMA. For finished drug product, GSK observed up to 7.6 mcg/g (7.6 ppm) in film coated tablets, which equals 2.28 mcg of NDMA in a 300 mg pill, or 2,280 nanograms. That would be 23 times the FDA limit. GSK tested 221 tablets. Of these, 209 (94.6%) contained NDMA levels in excess of the FDA's acceptable daily limit.

77. The FDA published testing results for pills that had been submitted by drug sponsors for testing.[11] FDA tested 29 tablets and observed NDMA up to 2.85 ppm, or 855 nanograms in a 300 mg pill. Overall, 12 of 29 (41%) of the tested pills were above the acceptable daily limit.

78. The Therapeutic Goods Administration (TGA) of the Australian

[10] *Id.*
[11] U.S. Food & Drug Administration, *Laboratory Tests: Ranitidine* (Nov. 2019).

government tested 135 batch samples of ranitidine.[12] The TGA found NDMA levels up to 14 ppm, or 4,200 nanograms in a 300 mg dose. Of the batches, 109 of 135 (89%) were in excess of the FDA's acceptable daily limit.

79. The South Korean Ministry of Food and Drug Safety tested 269 ranitidine products in 2019. They observed seven products with NDMA levels as high as 53.50 ppm.[13] With a maximal daily dose of ranitidine in Korea of 600 mg, at 53.5 ppm, that means daily use of ranitidine products could expose patients to 32,100 ngs of NDMA in a single day—334 times the FDA's acceptable daily limit.

80. The European Medicines Agency ("EMA") issued an Assessment Report in September 2020. The EMA did not, itself, test any finished product, but indicated that various drug makers had submitted testing results. According to the EMA, "[a]lmost for all drug products tested so far, NDMA has been identified in levels above the current limit of 0.16 ppm[.]" The EMA confirmed that this degradation was accelerated by heat and humidity.

81. Emery Pharma, a research and development laboratory in Alameda, California, conducted the most robust testing of finished ranitidine product. A total of 761 pills were tested. There were only 4 batches with NDMA levels that

[12] Australian Government, Therapeutic Goods Administration, *Contamination of ranitidine medicines with the nitrosamine NDMA* (Sept. 2019).
[13] Kim, et al., *Effect of Ranitidine Intake on the Risk of Gastric Cancer Development*, 9 HEALTHCARE 1071, 1–9 (2021).

were lower than the FDA's NDMA acceptable daily intake of 96 nanograms. For unexpired tablets produced by drug makers, including GSK, the mean NDMA level for a 150 mg dose was 1,576.3 nanograms. For expired tablets produced by drug makers, including GSK, and tested by Emery, the mean NDMA level for a 150 mg dose was 2,374.3 nanograms. For all tablets, the mean NDMA level for a 150 mg dose was 1,954.2 nanograms. The range of average NDMA levels found in the tablets was from 49.3 nanograms/150 mg to 28,052.8 nanograms/150 mg. This range is consistent with testing done by GSK on ranitidine drug substance and finished product.

82. Abe Y, et al., (2020) stored commercially available ranitidine reagent powders and formulations under various conditions.[14] When ranitidine tablets from two different brands were stored under accelerated condition (40˚C with 75% relative humidity) for up to 8 weeks, the amount of NDMA in them substantially increased from 0.19 to 116 ppm (57 ng to 34,800 ng in 300 mg dose) and from 2.89 to 18 ppm (867 ng to 5,400 ng in 300 mg dose), respectively.

D. Ranitidine Breaks Down into NDMA in the Stomach, Exposing Users to Endogenously Generated NDMA

83. There is also substantial evidence that ranitidine use leads to

[14] Abe, et al., *Temperature-Dependent Formation of N-Nitrosodimethylamine during the Storage of Ranitidine Reagent Powders and Tablets*, 68 CHEM. PHARM. BULLETIN 10, 1008–1012 (2020).

endogenous formation of NDMA. Animal, human, and *in vitro* studies have demonstrated that ranitidine interacts with sodium nitrate in gastric fluid, leading to the formation of up to hundreds of thousands of ngs of NDMA. Although such endogenous formation is difficult to quantify, its occurrence in humans is well established by a robust record of scientific evidence spanning four decades.

84. Numerous scientific studies have been conducted to assess the association of ranitidine with cancer. Those studies, however, have not be able to specifically quantify the amount of NDMA exposure and, thus, have limitations. Nonetheless, numerous reliable human epidemiological studies have shown a clear association between use of ranitidine and the development of bladder, breast, colorectal, esophageal, liver, lung, pancreatic, prostate, and stomach/gastric cancer.

E. For Nearly Four Decades GSK Concealed the Link Between Ranitidine and NDMA, Until Relator Valisure Blew the Whistle and the FDA Pulled Ranitidine Off the Market

85. From the very outset of ranitidine development, GSK was aware that ranitidine was an unstable molecule that could degrade into NDMA. GSK concealed that fact, which was not revealed to the world until Relator published its testing data in September 2019 (after first disclosing this information to the United States earlier in 2019). Within months of Relator's disclosure, the FDA investigated the issue and ordered all ranitidine products off the market. The following paragraphs detail how GSK committed this fraud, caused millions of

Americans to be exposed to a genotoxic carcinogen without their consent, leading the United States and the Plaintiff States to pay billions for ranitidine products that, absent the fraud, should never have been on the market and were, as marketed, adulterated, misbranded, and worthless.

1. In the 1970s, the Scientific Community Grew Increasingly Concerned with the Ability of Pharmaceutical Compounds to Nitrosate and Form into NDMA, Leading to Recalls of Drugs

86. Methapyrilene is an antihistamine that was developed in the 1950s that was effective at causing drowsiness—it was used to treat insomnia. In the 1970s, it was discovered that the drug caused liver tumors in rats. Researchers realized that the drug, due to its amine chemical structure, was capable of interacting with a nitosating agent, like sodium nitrite (commonly found in the human stomach), to form NDMA. The FDA pulled the drug off the market in 1978 following these discoveries. This prompted researchers to begin studying how secondary and tertiary amine drug products could form nitrosamines, especially in the presence of a nitro group like sodium nitrite.[15]

[15] William Lijinsky, et al., *Carcinogen Dimethylnitrosamine Produced In Vivo from Nitrite and Aminopyrine*, 236 NATURE NEW BIOL. 177, 177–78 (1972); William Lijinsky et al., *Carcinogenic Nitrosamines Formed by Drug/Nitrite Interactions*, 239 NATURE 165, 165–67 (1972); G.S. Rao et al., *Drug-Nitrite Interactions: Formation of N-Nitroso, C-Nitroso, and Nitro Compounds from Sodium Nitrite and Various Drugs Under Physiological Conditions*, 64 J. PHARM. SCI. 9, 1579–1581 (1975); *see also* A. Sakai et al., *Formation of Volatile Nitrosamines by Drug-Nitrite Interactions Under Physiological Conditions*, 75 JAPAN J. CANCER RES. 245, 245–52 (1984).

87. In 1980, IARC published a monograph where it raised serious concerns about the ability of nitrosatable drugs to form nitrosamines, including NDMA: "The formation of N-nitroso compounds is theoretically possible with all compounds that contain amino groups. Secondary amines react directly; tertiary and, in some cases, primary amines may react by more complicated mechanisms." IARC explained that because the "formation of N-nitroso compounds from nitrosatable amine precursors and nitrosating agents, such as nitrite or nitrous gases, is not usually taken into account in carcinogenicity tests of the parent compound, additional investigations are necessary to evaluate this possible hazard." IARC explained that "If valid comparisons are to be made, the reactions must be carried out under standard conditions for set times, and the identity and yield of N-nitroso compounds established by mass spectrometry or other appropriate methods. The WHO Expert Group recommended a 'Nitrosation Assay Procedure' (NAP test)," which would help elucidate the ability of drug compounds to react and form nitrosamines.

88. The NAP test has since become the standard method for assessing a molecule's affinity to nitrosate and form NDMA.

2. In the 1980s, before Ranitidine Was Approved, FDA Raised Concerns about the Ability of Ranitidine to Nitrosate and Form Nitrosamines

89. Shortly after the FDA gave investigational approval, concerns arose

about the possibility of ranitidine being carcinogenic due to nitrosation.

90. On May 2, 1980, GSK scientists met with the FDA. During the meeting, the "FDA voiced their concern about the nitrosation potential of ranitidine." And even after GSK provided background information about the work it had done in this regard, it "did not allay the FDA's concern." Instead, FDA "urged that a comprehensive description be sent to the FDA describing the exact details and conditions under which the experiments were carried out and this would be a factual report without editorialization." GSK agreed to provide that data.

91. A few months later, concerns about nitrosation and ranitidine also increased among investors. On November 1, 1980, a stockbroker issued a "Special Report" titled "Ranitidine – Cause for Concern?" The Special Report began by discussing how ranitidine would take on "considerable importance in determining Glaxo's future revenue, especially in the key US market." The Special Report noted that cimetidine and ranitidine were chemically similar, and that "cimetidine is capable of being nitrosated by nitrites under the acidic conditions of the stomach and nitroso compounds (especially N-nitroso compounds) are known to be carcinogenic[.]" It also noted that long-term use "leads to change in the types of bacteria which colonize the gut" specifically, an increase in "certain bacteria which reduce nitrate … to nitrite, thus leading to an increased likelihood of nitrosation."

The Special Report notes that ranitidine "is very easily nitrosated but forms C-nitroso compound which is not suspected of carcinogenic potential. However, under forcing conditions a second nitroso group can be inserted into the ranitidine" that "could be potentially harmful[.]" The Special Report finishes with a "cause for concern" about whether concerns about the carcinogenicity of ranitidine "could affect sales of ranitidine once it is marketed."

92. In response to this Special Report, GSK's public relations executives stated "it would be unwise to at this stage to over-react to this particular circular … we will take every opportunity to put the company's view to media and analysts. Group PR … will be watching the situation very closely with a view to proposing rapid defensive action should the position deteriorate." Glaxo's Drs. R. T. Brittain and D. Jack (important later) were specifically copied on the memo.

93. Thus, in the span of a few months, both the FDA and the investment market had taken notice of a potential issue with ranitidine to nitrosate and form a nitrosamine. And, GSK committed to providing all data about its findings to the FDA, but as alleged herein, deliberately failed to do so.

3. In Early 1980s, Scientists Raise Concern about the Ability of Cimetidine to Nitrosate Into Nitrosamines

94. The similarities between cimetidine and ranitidine are not by accident. Cimetidine works by physically blocking the H_2 receptors found in gastric parietal cells, which then prevents its activation. This, in turn, prevents the production of

stomach acid. Because the drug works structurally, Glaxo was able to develop ranitidine by mimicking cimetidine's molecular structure. Glaxo refined the cimetidine model by replacing the imidazole ring of cimetidine with a furan ring with a nitrogen-containing substituent. This is why, chemically, cimetidine and ranitidine are very similar.

95. Both molecules have a dimethylamine ("DMA") component in them. This means, when given an external source of nitro, it can react to form a nitrosamine. However, ranitidine, unlike cimetidine, also has a nitro group in the molecule itself. This is why ranitidine, as opposed to cimetidine, will form NDMA on standing, through an intermolecular interaction, without any addition of an external nitro source.

96. Before the approval of ranitidine, research on cimetidine had already revealed the danger of N-nitrosamine formation. In 1981, a study by a team of British researchers published in *The Lancet* found that people who took cimetidine had significantly higher levels of nitrosamines in their gastric juice.[16] The researchers believed this was a function of the ability of long-term use of cimetidine to impact the PH levels in the stomach which, in turn, allows the growth of specific bacteria that convert nitrates into nitrites. This greater amount of

[16] Reed et al., *Effect of Cimetidine on Gastric Juice N-Nitrosamine Concentration*, 318 LANCET 8246, 553–556 (1981).

stomach nitrite levels could then interact with cimetidine, leading to the formation of carcinogenic nitrosamines.

4. In 1981, GSK's Experiments Reveal that Ranitidine forms NDMA

97. In the first half of 1981, GSK specifically acknowledged the risk of nitrosation and cancer *internally*. Dr. L.E. Martin sent a report, covering six months prior to June 1981, to Dr. Brittain (copying various GSK scientists including Drs. M. Harris and D. Poynter). Dr. Martin was the "Head" of GSK's "Biochemical Pharmacology Department" with over 30 researchers reporting to him (including, among others, Dr. R. Tanner). In this report, Dr. Martin noted that "[c]oncern is still expressed by some physicians as to whether treatment with H2 receptor antagonists for long periods may increase the incidence of stomach cancer. It has been suggested that this increase in stomach cancer may be caused by N-nitroso compounds." This "concern" mirrors the issues being raised concerning ranitidine's close chemical relative, cimetidine. The report stated "Smith, Kline & French" which made cimetidine "and ourselves are having to give considerable through to evaluating the role of nitrite in the diet….A study is in progress in which the *in vitro* nitrosation of ranitidine and cimetidine are being compared in human gastric juice." The results were reported in the next six-month internal report, circulated amoung GSK executives in December 1981—eighteen months years before any FDA approval of ranitidine.

98. Specifically, Dr. Martin reported to Dr. Brittain (also copying Drs. M. Harris and Poynter) about a study titled "Formation of N-Nitrosodimethylamine [NDMA] from Ranitidine." Dr. Martin notes that "SKF reported to [GSK] that they had observed the formation of N-nitrosodimethylamine [NDMA] from ranitidine." He explained, drawing on well-established principles of organic chemistry, that "[r]anitidine is a tertiary amine and therefore when incubated under strongly acid conditions with high concentrations of sodium nitrite could react with the formation of N-nitrosodimethylamine." So, "a study was undertaken on the formation of N-nitrosodimethylamine [NDMA] under the WHO (NAP) conditions." GSK, using gas chromatography / mass spectrometry, performed the NAP test, using 10 mmol of ranitidine and 40mmol of nitrite and "found that about 2% of the ranitidine present [] was converted into N-nitrosodimethylamine." The experiment yielded 144 µgs of NDMA, or 144,000 ngs, from only 31.5 mg of ranitidine. When done with lower levels of nitrite, they did not see NDMA. This summary of the experiment was not shared with the FDA, even though FDA had already urged, and GSK agreed, to provide "a comprehensive description … describing the exact details and conditions under which the experiments were carried out" as it relates to the nitrosation of ranitidine into nitrosamines.

99. To put this result in context, this percent yield of NDMA formation was 25 times greater than methapyrilene (which had a yield of 0.08% under the

NAP test), which had three years prior, been pulled off the market out of concern of NDMA formation under the same conditions of experiment.

5. Independent Researchers Raise Concern about Nitrosation of Ranitidine and GSK Misleads Them

100. In October 1981, GSK coordinated an event called the "Second International Symposium on Ranitidine," which included presentations of fifty-four different research papers from hundreds of doctors and scientists around the world. The event was an opportunity for GSK to frame the safety debate concerning ranitidine, including reinforcing its narratives that NDMA formation was impossible, to frustrate any direct search for nitrosamine formation.

101. At the event, GSK presented an article authored by a group of its scientists that set forth the bases for its theory of how ranitidine metabolizes in the body—however, this theory concealed any mention of NDMA formation, even though GSK's recent experiments specifically identified NDMA formation.

102. GSK scientists also presented a paper[17] in which GSK set forth its defense on why researchers should not bother to study nitrosation concerns:

> The possibility of nitrosation reactions being of potential significance in terms of the formation of a carcinogen has been considered. It is important to realize that the rodents used were known to have nitrate-reducing bacteria in their stomachs and that they were ingesting large quantities of nitrate and nitrite known to be comparable to those ingested by man. Conditions of rodent stomach were therefore such that nitrosation reactions were possible.

[17] Poynter, D. et al., *Evaluation of Ranitidine Safety*, PROC. OF 2D INT'L SYMP. ON RANITIDINE, 56 (Kenneth G. Wormsley et al. eds., 1981).

> …
>
> Ranitidine, the metabolites formed from it in man and the products that might be formed by its interaction with nitrous acid under physiological conditions in man have all been investigated in a variety of tests. **There is no reason to suppose that ranitidine in itself or the products formed from it in man will present a carcinogenic risk.**

103. This statement was materially false and misleading when stated, because GSK knew that there was a real danger of NDMA formation. GSK intended for its statement to cut off debate and prevent investigation of the issue.

104. This, however, did not stop independent researchers from raising alarm about the potential nitrosation of ranitidine. In September 1981, Italian researchers Dr. De Flora and Dr. Brambilla, reached out to GSK about experiments they were conducting regarding the nitrosation of ranitidine. It is unknown if GSK immediately responded to them.

105. Then, on October 31, 1981, Dr. De Flora, published an abstract in *the Lancet*, titled "Cimetidine, Ranitidine, and their Mutagenic Nitroso Derivatives."[18] Dr. De Flora reported on experiments with ranitidine, that showed "preincubation with nitrite in human gastric juice from untreated individuals (60min at 37°C) or simply acidification of nitrite-ranitidine mixtures results in toxic and mutagenic effects in bacteria." Dr. De Flora explains that "ranitidine reacts with nitrite at

[18] De Flora, et al., *Cimetidine, ranitidine, and their mutagenic nitroso derivatives*, 2 LANCET 8253, 993–994 (1981).

lower doses than cimetidine[.]" This, chemically, makes sense, because ranitidine contains its own nitro group within the molecule. He goes on to state that these experiments were only *in vitro* but that "the predictive value of these *in vitro* tests is recognized and it would seem prudent to avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals, or by giving inhibitors of nitrosation such as ascorbic acid." Dr. De Flora explained that nitrosated ranitidine was mutagenic because it was converting into a nitrosamine, but had not yet identified what that specific nitrosamine was, i.e., NDMA.

106. Dr. Brittain, who not only had been put on notice of the potential impact to sales of ranitidine if it were shown that it could nitrosate into a nitrosamine like NDMA just a year prior, but was aware of GSK's nitrosation studies with ranitidine and the link to NDMA, published a response two weeks later (Drs. Martin, Harris, and Poynter were co-authors).[19] This study allowed GSK to deflect any concerns about nitrosation and NDMA and derail the FDA and independent researchers from making the connection.

107. In the response to Dr. De Flora, GSK indicated that its "detailed investigations can, we believe, place in perspective [Dr. De Flora's] findings in terms of the safety of ranitidine in man." GSK stated that "we were obviously

[19] Brittain, R.T., et al., *Safety of ranitidine*. 2 LANCET 8255, 1119 (1981).

concerned as to whether or not a mutagenic N-nitroso derivative of ranitidine could be formed in the stomach." And, they explained that "if the concentration of sodium nitrite was increased to 40mmol/1 a further reaction occurred whereby an N-nitroso nitrolic acid derivative was formed (figure). This latter product was mutagenic" and "is unstable and rapidly reverts to the non-mutagenic nitrolic acid derivative except in the presence of excess nitrous acid." Importantly, GSK makes no mention of NDMA, which they knew, based on their own experiments, would form under these *exact* conditions, which they had already studied. Thus, GSK explained, "[t]here can be little doubt that the product formed under the conditions of De Flora's experiment … is the N-nitroso nitrolic acid derivative of ranitidine." Even through Drs. Brittain, Martin, Harris, and Poynter knew that ranitidine could react with high levels of nitrite (specifically at 40 mmol) under the NAP test to form high levels of NDMA, GSK did not mention NDMA. This is remarkable considering how well-established it was that NDMA was a genotoxic and mutagenic nitrosamine. Failing to disclose this information to Dr. De Flora and the rest of the medical community was misleading. Indeed, they specifically stated that mutagenic compound formed in Dr. De Flora's experiment was, with "little doubt," a N-nitroso nitrolic acid derivative that quickly reverts to non-mutagenic nitrolic acid. GSK deliberately misled the public about their findings, diverting concerns regarding nitrosation away from NDMA and toward a N-nitroso

nitrolic acid derivative.

108. The results of the Brittain "N-nitroso nitrolic acid derivative" experiments were conveyed to the FDA as part of the original NDA for ranitidine prior to any FDA approval. However, GSK deliberately did not share the NDMA study or data related to NDMA.

109. Internal documents confirm that Dr. Brittian deliberately withheld information in his response to Dr. De Flora and did not identify all the resulting products formed by nitrosating ranitidine.

110. In December 1981, GSK finally decided to respond to the inquiries from Drs. De Flora and Brambilla. The researchers requested samples of the supposed nitrosation compounds that GSK has claimed to have isolated. However, Dr. Brittian cautioned that he did not want to disclose the products that were formed by nitrosated ranitidine to the researchers and, instead, work to convince them of ranitidine safety. He indicated that his colleagues, Drs. Jack and Poynter would/should handle. At no time did GSK tell these researchers about the NDMA data.

6. GSK Published a Nitrosamine Testing Assay Designed to Conceal the Instability of Ranitidine

111. In early 1981, GSK developed and published a standard assay

technique for ranitidine.[20] Glaxo selected a radioimmunoassay for the detection of ranitidine, even though the industry standard for decades had been chromatography mass spectrometry. Industry standard tests could have revealed the instability of ranitidine. As compared to the industry standard tests, GSK's chemically gentle assay was significantly less specific—its only advantage is it conceals ranitidine's molecular instability and does not show or test for small polar molecules like NDMA.

112. GSK's publication states up front that the radioimmunoassay contains "cross reactivity" with other ranitidine metabolites, making it significantly inferior to industry-standard chromatography mass spectrometry ("MS") tests that easily separate metabolites:

> The development of a radioimmunoassay for ranitidine in biological fluids is described. The sensitivity of the method is 2 ng/ml in human serum using a 0.1 ml sample. *The cross reactivity of the antiserum with synthetic standards of ranitidine metabolites is <1%, 22% and 11% for ranitidine N-oxide, ranitidine sulphoxide and desmethyl ranitidine respectively.* The latter two substances are minor metabolites in man, and do not affect the measurement of ranitidine in clinical samples. It was possible to produce a much higher titre antiserum by immunising the sheep instead of the rabbit.

113. Immunoassays involve the use of antibodies which require very gentle chemical conditions so as not to disturb their complex protein structure. GSK knew that in such conditions—which lack elevated temperatures, low pH, and

[20] William N. Jenner et al., *The Development of a Radioimmunoassay for Ranitidine in Biological Fluids*, 28 LIFE SCI. 1323, 1323–29 (1981).

oxidative environments—it would be able to conceal ranitidine degradation.

114. The development of a radioimmunoassay is very expensive and extremely technically challenging. It requires the handling of radioactive materials and the use of live lab animals, including rabbits and sheep, to biologically manufacture the required antibodies. The development of GSK's radioimmunoassay was much more expensive than industry-standard mass spectrometry, which does not require radioactivity, lab animals, or any biological processes. The significant time, expense, and developmental resources spent developing GSK's radioimmunoassay appear to have no justification other than to conceal ranitidine degradation concerns.

7. GSK Burries the NDMA Data and Lies to the FDA

115. On April 6, 1982, GSK's Dr. Tanner finalized the NDMA study titled, "The Determination of N-Nitrosodimethylamine [NDMA] formed by the Reaction of Ranitidine Hydrochloride with Sodium Nitrite." The report was circulated internally at GSK to Dr. Martin, and Dr. Brittain was specifically copied. Dr. Tanner noted that "molecules with tertiary amines," like ranitidine, can "react with nitrite under certain conditions to yield N-nitrosodimethylamine (NDMA)." This is consistent with the IARC literature. "[T]herefore experiments were carried out to determine whether NDMA could be formed from the drug in the presence of nitrite." Dr. Tanner used "conditions similar to those described for the WHO

…NAP test" and under a simulation of "the human stomach after ingestion of a nitrite rich meal[.]" Using "gas chromatography mass spectrometry" Dr. Tanner observed "under the conditions of the WHO NAP test (Experiment 3) 232µg [232,000 ngs] NDMA were formed … equivalent to 3.1% yield based on ranitidine." "A similar quantity of NDMA, 219µg [219,000 ngs], was formed in a 10ml incubation mixture when the ranitidine concentration was raised to that of nitrite (40mM)." This result was one of the highest NDMA conversion rates observed of a drug compound. It was 39 times greater than the 0.08% observed for the recalled drug methapyrilene pursuant to the NAP test. For the high nitrite-meal simulation experiment, it "gave a weak signal similar to that observed from a control incubation." Dr. Tanner however, did not provide the actual results of the NDMA formed to reach a "weak signal" despite the high temperatures used in the GCMS, which are known to cause NDMA formation.[21] Regardless, however, that ranitidine was giving any signal at all indicates that GSK specifically knew and understood the fundamental instability of the ranitidine molecule.

116. 108. GSK admits it did not share the Tanner study with the FDA or

[21] This point is critical. Valisure and other scientists have confirmed that when ranitidine is exposed to the high temperatures in gas chromatography, it will form high levels of NDMA—into the millions of nanograms. If GSK were looking for NDMA, they should have observed extremely high levels. That they failed to report this data is suspicious. GSK has since destroyed the data, so there is no way to know what the testing showed.

otherwise ever inform the FDA about NDMA prior to the drug being approved by the FDA or even while the drug was on the market. The Tanner study was only disclosed to the FDA in December 2019, a few months before the FDA recalled ranitidine from the market, and GSK only disclosed it after repeated requests by the FDA, having initially concealed it and lying to the FDA in August 2019 that no such study existed.

117. On May 13, 1982, GSK presented before the FDA's Scientific Advisory Panel to specifically discuss the science and safety of ranitidine. Dr. Poynter specifically presented to the FDA on ranitidine's "mutagenicity" and "nitrosation." Dr. Jack, however, who was originally copied on the Special Report (discussed above), set the stage:

> [W]e want to focus only on the part which raises the real problem in some people's mind, namely, *the possibility of carcinogenesis with drugs of this kind*. That possibility was first raised in people's mind when Elder and his colleagues from Manchester reported that they had some patients who developed cancer of the stomach within a few months of treatment with cimetidine. Of course, any such effect must be the effect of a very potent and highly specific carcinogen, and *the mechanism they proposed was that cimetidine in the body might be nitrosated to this N-nitroso derivative*… So what one is saying, very simply, that even if the hypothesis about cimetidine were right, it would not apply to ranitidine, because ranitidine behaves very differently towards nitrous acid. Instead of nitrosating on nitrogen, it nitrosates on carbon, this carbon. What is formed is a nitrolic acid.

118. Then, in introducing Dr. Poynter, Dr. Jack noted that he would present data "known to be sensitive to carcinogens and *in particular to nitrosamines*, under conditions which foster the production of these substances[.]" However, when Dr. Poynter presented to the FDA, he *did not disclose the NDMA data* nor any of

GSK's tests showing NDMA formation, including the recently completed Tanner Study. This, despite the FDA specifically raising concerns about the nitrosation of ranitidine in May 1980. Dr. Poynter referenced nitrosation and even the potential interaction of ranitidine with nitrite, but he deliberately omitted any reference to NDMA. Considering the importance Dr. Jack placed on presenting issues surrounding the nitrosation and formation of N-nitroso compounds, this omission was *intentional*.

119. Dr. Poynter focused on the rodent carcinogenicity studies done on ranitidine and explained that there was "no evidence of ranitidine being itself carcinogenic either in the stomach or for that matter anywhere else[.]" But, in GSK's first long-term mouse study, they specifically observed "a statistically significant positive dose-response trend in tumor rates for pulmonary tumors in female mice" and that there was only 1 liver tumor in the control group, versus seven liver tumors in mice treated with ranitidine. To state that there was "no evidence" is, at best, an exaggeration and, at worst, a falsehood. In the face of Dr. Poynter's presentation, unsurprisingly, the Committee voted to approve ranitidine.

120. A few months later, on August 10, 1982, GSK submitted a proposed Summary Basis for Approval ("SBA")—a document that the FDA issues summarizing its approval of any new drug. In the SBA, GSK specifically discusses the potential for nitrosamine formation, but limits its discussion to the N-

nitroso nitrolic acid derivative experiments by Brittain et al., and *makes no mention of NDMA* or their NDMA experiments. It states that "[a]lthough N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine. An unrealistic large amount of nitrite needs to be present to form and maintain the nitrosamine." By not submitting the Martin or Tanner data, and by providing an explanation for the observed mutagenic effects as being a "N-nitroso-nitrolic acid," GSK was able to avoid any suspicion that ranitidine, in the presence of nitrite, could form NDMA.

121. In 1983, the FDA approved ranitidine for the short-term treatment of ulcers. However, in the final SBA issued by the FDA, they repeated, verbatim, GSK's discussion of the N-nitroso nitrolic acid derivative. The FDA, however, did note that long-term use of ranitidine could result in a balance of bacteria in the gut that would lead to elevated levels of nitrite. FDA noted, which was not in the draft submitted by GSK in August 1982, that "[t]he importance of this finding is not clear. *High levels of nitrite could react with certain organic compounds to form nitrosamines*, *which are known carcinogens*. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies." But, GSK specifically had that evidence, i.e., that ranitidine and nitrite could react to form NDMA in human gastric fluid, a well-established and potent nitrosamine—evidence that the FDA

had *specifically* requested. By concealing this information from the FDA, the Agency concluded that because "[r]anitidine is recommended only for short-term use" the "carcinogenic risk, if any, should thus be minimized."

122. Even more alarming, however, is the fact that the FDA dismissed this concern regarding cancer because Zantac would only be used for short periods of time (two weeks) and GSK, at that time, knew that patients would use Zantac for longer periods of time. They specifically banked on this fact: "Zantac will be launched with indications for short-term duodenal ulcer … our major competitor, Tagamet, has broader indications … for long-term maintenance therapy... At first glance this may appear to be a limitation to Zantac. In reality, it is no limitation at all. … many physicians will, or their own accord, use Zantac in the same manner in which cimetidine is used." GSK knew that "the carcinogenic risk, if any" would not "be minimized" but it did not care—it needed to dominate the market. ("[W]e're out to dominate the entire product category.") (emphasis in original). In fact, GSK's marketing efforts, from day one, specifically focused on the off-label promotion of Zantac for long-term use, despite the drug's approved indication for short-term use and despite the potential risk of carcinogenicity stemming from long-term use.

123. In 1985, GSK hosted a "International Teaching Day" where GSK-sponsored a scientist to present to the British Society of Gastroenterology and

Nutrition Society on "Nutrition and nitrosamine formation."[22] The presentation begins with simple, generally-accepted truth: "N-nitroso compounds are an important group of chemical carcinogens that could be involved in human cancer." The authors explain that "suitable precursors are common dietary constituents … and the mildly acidic conditions of the stomach are favourable for their formation." Indeed, Dr. Challis explained that "[o]ver 90% of the N-nitroso compounds tested have proven to be carcinogenic, some in as many as thirty species ranging from mice to primates" and "[m]any are organ-specific carcinogens, producing tumours remote from the site of their administration." In this article, Dr. Challis openly admits that gastric nitrosation of nitrite with a tertiary amine (of which ranitidine is one), can lead to the formation of nitrosamines in the human stomach. This is further evidence that GSK was aware of the issues of nitrite interacting with a chemical with a tertiary amine, and the relevance of their own data showing this reaction specifically with ranitidine to form NDMA. That GSK concealed it from the FDA is inexcusable.

8. GSK Designed Ranitidine's Monograph Dissolution Test to Hide Ranitidine's Toxicity from the FDA and Medical Community

124. The United States Pharmacopeial Convention ("USP") is a non-governmental organization that issues a compendium of drug standards for use in

[22] Brian C. Challis, *Nutrition and Nitrosamine Formation*, 44 PROC. OF NUTRITION SOC'Y 95, 95–100 (1985).

the pharmaceutical industry. Although USP is not a governmental body, federal law specifically incorporates its standards. *See* 21 U.S.C. §§ 351(a)–(b), 352(e)–(g), 355(u)(3)(A). The FDA regularly consults USP standards as a reference point when issuing its own pharmaceutical standards.

125. USP issues "monographs" for specific drug compounds; these "monographs" list tests, procedures, and acceptance criteria related to the quality, purity, strength, and consistency standards for the pharmaceutical ingredients in an approved drug.

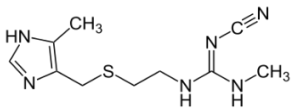
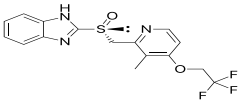
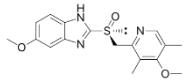
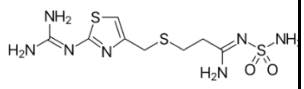
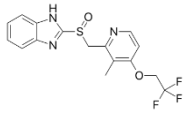
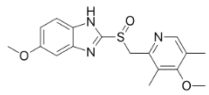
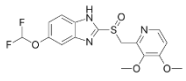
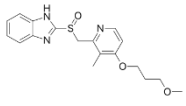
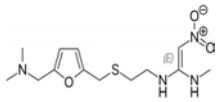
126. The process by which a monograph is created involves the manufacturer recommending its own monographs for approval, with substantial deference given to the manufacturer, as they have specialized knowledge in the art. Upon information and belief, GSK would have submitted its monograph to USP on or before May 12, 1983.

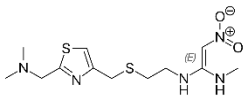
127. GSK selected an unusual monograph test for ranitidine dissolution that differs from the industry-standard dissolution tests used by its competitors across the histamine receptor-2 antagonist, or H2 blocker, and proton pump inhibitor, or PPI, classes. Ranitidine's purpose, as described in its own FDA-submitted-and-approved product insert, is to block secretion of acid in the stomach.

128. Ranitidine's key competitors in the H2 blocker class are Pepcid, Tagamet, and Nizatidine. H2 blockers also compete with PPIs like Prilosec,

Prevacid, Protonix, Aciphex, and Nexium. PPIs reduce acid in the stomach through a different mechanism of action.

129. The below chart describes the dissolution solution recommended by each of the monographs for these classes of drugs:

Brand Name	**Generic**	**Structure**	**Delivery**	**USP Dissolution Solvent**
Cimetidine	Tagamet		Tablet	$Acid^{+}$
Dexlansoprazole	Dexilant		Capsule DR, Tablet DR*	$Acid^{+}$
Esomeprazole	Nexium		Capsule	$Acid^{+,-}$
Famotidine	Pepcid		Tablet	$Acid^{-}$
Lansoprazole	Prevacid		Capsule DR	$Acid^{+,-}$
Omeprazole	Prilosec		Capsule	$Acid^{+,-}$
Pantoprazole	Protonix		Tablet DR	$Acid^{-}$
Rabeprazole	AcipHex		Capsule, Tablet*	$Acid^{+,-}$
Ranitidine	**Zantac**		**Tablet**	**Water**

Nizatidine	Axid		Capsule	Water

** From FDA, otherwise from USP41-NF36 2S current April 12, 2019*
+ HCl
- Phosphate buffer
DR: Delayed Release

130. GSK abandoned industry-standard acid to instead select water to test ranitidine, because GSK knew that an acidic environment renders ranitidine susceptible to breaking down into NDMA and may potentially reveal ranitidine's unstable and toxic nature in the actual stomach environment.

131. Other evidence supports the inference that GSK's selection of water as a solvent was designed to conceal degradation concerns about ranitidine. Curiously, Nizatidine, the only other drug of these classes to have its manufacturer not select an acid solvent, is chemically similar to ranitidine. Ranitidine and nizatidine are the only molecules in these classes with terminal DMA and nitrite groups, with substantial NDMA detected in Relator's testing, and that are known in the literature to form NDMA under acidic conditions. Additionally, the FDA specifically noted the ability of nizatidine to decompose into NDMA, like ranitidine. Thus, it is clear that the use of water in nizatidine was aimed to cover up the same instability issues that GSK observed in ranitidine.

9. GSK's Deception and Concealment of the NDMA Data Derailed Independent Researchers from Making the Connection to NDMA

132. GSK's deception also impacted researchers who were, at this time,

specifically investigating the nitrosation of ranitidine and potential nitrosamine formation. Following Dr. De Flora's original abstract, he and several other researchers published studies, after being misled by GSK.

133. In Maura (1983), researchers demonstrated that ranitidine, in the presence of nitrite, yielded "a nitroso derivative capable of inducing a dose-dependent DNA fragmentation in cultured Chinese hamster ovary cells."[23] When they evaluated the yellow oily substance created by the nitrosated ranitidine (which is exactly what NDMA looks like), the researchers assumed "the N-nitroso compound obtained was likely to be the N-nitroso nitrolic acid derivative … previously identified by Brittain." Indeed, the researchers specifically noted that "[b]ecause of the presence in ranitidine molecule of a dimethylamine group, in analogy with the nitrosation pattern of other tertiary amines [NDMA] formation should be also expected." But they dismissed that possibility, however, because "Brittain et al. showed that … if the concentration of [nitrite] was increased to 40 mmol, a further reaction occurred whereby an N-nitroso nitrolic acid derivative was formed" and "chromatography revealed only one major nitroso-derivative spot[.]" In other words, even though they expected NDMA to form, because they only observed one N-Nitroso compound, they assumed it was the compound

[23] Maura, et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOX. LETTERS 97, 87-102 (1983).

presented by Brittain.

134. In another example, Dr. De Flora published his full study in 1983, where he concludes "there seems to be no doubt about the possibility of formation of genotoxic derivatives from ranitidine and an excess nitrite under in vitro conditions[.]"[24] However, in discussing what may have been causing the genotoxicity, Dr. De Flora specifically noted that the way nitrosated ranitidine caused genetic damage is similar to NDMA. But, because Maura ruled it out, so did Dr. De Flora. Indeed, Dr. De Flora deferred to Brittain regarding the chemical makeup (as did Maura) of nitrosated ranitidine, concluding that "[o]ur findings seem to be consistent[.]"

135. In yet another study, Brambilla (1983), published the same year as Maura and De Flora, researchers specifically studied whether ranitidine and nitrite could induce genetic damage in a living animal.[25] And, once again, the researchers concluded, "[o]ur experimental findings have shown that simultaneous oral administration in rats of high doses of ranitidine and NaNO2 can produce DNA fragmentation either in liver or in gastric mucosa. However, this effect was found to be dependent on both gastric pH and molar ratio drug/nitrite." Remarkably, the

[24] De Flora, et al., *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255–260 (1983).
[25] Brambilla, et al., *Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite*, 4 CARCINOGENESIS 10, 1281–1285 (1983).

researchers used NDMA as a positive control, showing nearly identical levels of genetic damage in animals exposed to NDMA and nitrosated ranitidine. But, in discussing what was chemically causing the genetic damage, the researchers once again relied on Brittain: "the major (or the only) nitrosation product is likely to be the mutagenic N-nitroso nitrolic acid derivative obtained by Brittain et al. (34) by reacting ranitidine with a large excess of nitrite." The NDMA connection was never made because they were misled by Brittain's published letter and their direct interactions with GSK.

136. In another example, in Martelli (1983), researchers showed that nitrosated ranitidine, using nitrite, caused unscheduled DNA synthesis in rodent hepatocytes.[26] The researchers compared nitrosated ranitidine directly with NDMA to see how they induced mutations. The data showed the same effect on DNA synthesis. Citing the De Flora and Brambilla studies discussed above, the authors warned that a "more extensive assessment of its possible formation and genotoxicity in humans" was needed.

10. GSK Manipulated the Only *In Vivo* Study on Humans that Attempted to Measure N-Nitroso Compound Formation While Taking Ranitidine

137. In 1987, GSK co-authored a study designed to conceal the NDMA-

[26] Martelli, A., et al., *Unscheduled DNA synthesis induced by nitrosated ranitidine in primary cultures of rat hepatocyctes*, 122 Mutation Res. 373, 373–376 (1983).

formation that occurs within hours of consuming ranitidine ("GSK's One Year Study").[27] GSK's One Year Study concluded that ranitidine does not create N-nitroso compounds:

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

138. GSK's One Year Study suffered from serious flaws that were curious for an investigation of N-nitroso compound formation. For starters, the study had unorthodox testing protocols, which departed from the accepted science at the time. Instead of using an industry-standard GC/MS which could test for specific nitrosamines like NDMA, GSK's One Year Study engaged a method that only measured total nitrosamines:

> After preliminary dilution, if necessary, to 5-0 ml with distilled water, homogenised gastric juice samples were titrated (if pH<4) to pH 4-0 with molar sodium hydroxide and hydrazine sulphate (0-26M) was added to destroy any nitrite present, before freezing to - 10°C for later assay using the method of Walters *et al.* This method responds sensitively to all types of N-nitroso compounds tested to date: it involves the controlled evolution of nitrogen oxide sequentially from a range of compounds present in gastric juice when refluxed with ethyl acetate. After the addition of acetic acid, nitrogen oxide is liberated initially from nitrate and other compounds derived from it, such as the pseudonitrosites, and finally, when hydrogen bromide is added, denitrosation occurs yielding nitrogen oxide from N-nitroso compounds. Thus, nitrogen oxide originating from other types of compounds is eliminated before it is evolved from N-nitroso compounds. Nitrogen oxide was determined using a chemiluminescence analyser by the light emitted in the far visible and near infrared regions after its reaction with ozone. The lower limit of detection was approximately 5 nmol/l. *Id.* at 730.

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[27] J. Meyrick Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 28 GUT 726, 726–27 (1987).

139. This statement was false and misleading because the pretextual purpose of using this method, that it "responds sensitively to all types of N-nitroso compounds," is of little relevance considering the known connection of ranitidine to NDMA formation specifically due to the presence of DMA in the ranitidine molecule itself.

140. Adoption of the "Walters *et al.*" method appears to have no purpose other than to frustrate the test, which should be searching for *volatile* nitrosamines like NDMA. As Dr. Walters and colleagues explained in their underlying 1978 article,[28] their method was designed to search for non-volatile N-nitrosamines and for use in food:

> While volatile N-nitrosamines can be separated readily from a biological matrix by distillation in steam, no similar separation procedure applicable to all non-volatile N-nitrosamines is available, some compounds of this type may be associated with the components of the matrix itself and therefore the extraction procedures would be inefficient.

141. In addition to being unable to give results as to specific nitrosamines, the test selected by GSK's One Year Study was further flawed because it risked registering ranitidine itself as a false positive. Conveniently, this "required" the testers to exclude all samples when nitrosamine and its metabolites—including NDMA—were in the gastric juice:

> N-nitroso compounds were assayed by measurement of nitrogen oxide evolved under special conditions. The assays were restricted to

[28] C.L. Walters et al., *Determination of a Non-volatile N-nitrosamine on a Food Matrix*, 103 Analyst 1127, 1127 (1978).

> ranitidine free samples because the *presence of ranitidine in gastric juice may result in falsely high concentrations of N-nitroso compounds being recorded.* Unlike cimetidine, the ranitidine molecule contains a C-terminal nitro group which was shown in preliminary studies to liberate nitrogen oxide under conditions of the assay, thus responding as if it were an N-nitroso compound.

142. This statement is remarkable—and consistent with Valisure's testing in 2019. Use of GC/MS testing on ranitidine could yield a falsely positive NDMA result, and this sentence, in 1986, *confirms* this.

143. The effects of the data restriction in GSK's One Year Study were severe, as approximately *two-thirds* of the data had to be excluded from the study (emphasis added):

> Because of the overriding need to be certain that ranitidine present in gastric juice would not be assayed as if it were a N-nitroso compound, aspirates of juice were only used for N-nitroso compound analysis at times when ranitidine was absent. Results for N-nitroso compounds are consequently **based on assay of approximately one third of the samples** that were analysed for pH, bacterial counts and nitrite concentration; conclusions must be correspondingly less certain, especially as no night-time samples were studied. N-nitroso compounds were not measured at all during study R2 but no increase in day time median values was found during (R3 and R4) or after (R5) maintenance treatment, an observation in agreement with other 24 hour studies.

144. GSK's earlier studies had shown that ranitidine and its metabolites are processed in the body mostly for the first eight hours after consumption. By excluding any data with ranitidine in it, GSK knew it was also excluding any data with ranitidine metabolites—including NDMA and its precursors. The following

chart from a 1981 study by GSK scientists[29] demonstrates GSK's prior knowledge:

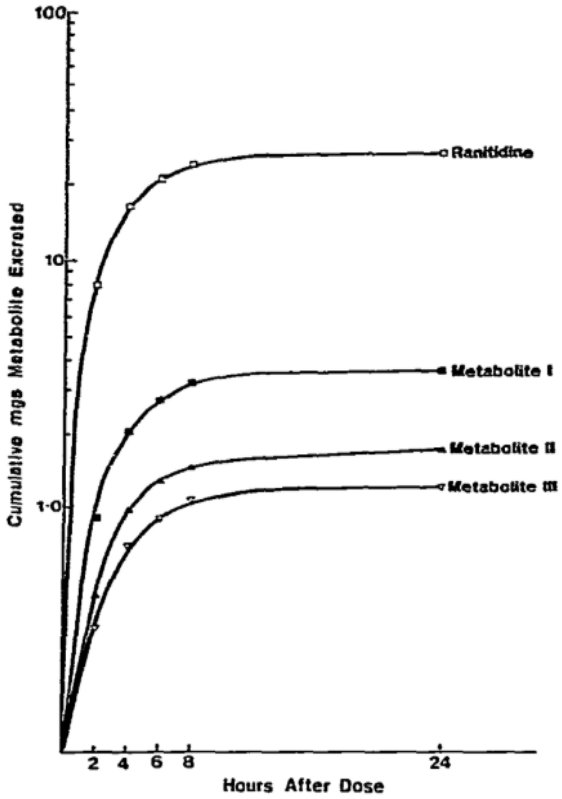

Fig. 4. Plot of mean cumulative excretion of ranitidine and its metabolites in urine from four volunteers given a single oral dose of 100 mg ranitidine.

145. There was no reason for GSK to use a bizarre assay methodology which "required" it to ignore all data where ranitidine was present. GC/MS techniques had been used to measure NDMA concentration in organic matter well before 1981. Moreover, a secondary detection method, like GSK's N-oxide assay, was a particularly poor choice when looking at a biological sample containing

[29] Patrick F. Carey et al., *Determination of Ranitidine and its Metabolites in Human Urine By Reversed-Phase Ion-Pair High-Performance Liquid Chromatography*, 225 J. OF CHROMATOGRAPHY 161, 165, fig. 4 (1981)

gastric juice, where there are thousands of unknown molecules.[30]

146. GSK knew of the NDMA issue, and specifically designed a test to avoid showing the issue.

11. GSK Made False and Misleading Statements in Zantac Product Labels and Other Submissions to the FDA

147. GSK's "Prescribing Information" on ranitidine's product label falsely represents that ranitidine's metabolism does not cause the formation of nitrosamines and conceals the existence of nitrosamines. By hiding this information from doctors and the FDA, GSK ensured that ranitidine products would be used by patients and reimbursed by the government.

148. In association with NDA 18-703, the original NDA application for ranitidine's first approval, GSK submitted proposed Zantac product label for prescribers that were approved by the FDA. Since Zantac's inception, GSK's product label has stated:

> Metabolism: In humans, the N-oxide is the principal metabolite in the urine; however, this amounts to <4% of the dose. Other metabolites are the S-oxide (1%) and the desmethyl ranitidine (1%). The remainder of the administered dose is found in the stool. Studies in patients with hepatic dysfunction (compensated cirrhosis) indicate that there are minor, but clinically insignificant, alterations in ranitidine half-life, distribution, clearance, and bioavailability.

149. GSK's inaccurate description of ranitidine's metabolism and the

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[30] Notably, GC/MS was used to measure NDMA concentration in tobacco. *See, e.g.*, Klaus D. Brunnemann et. al., *Assessment of Carcinogenic Volatile JV-Nitrosamines in Tobacco and in Mainstream and Sidestream Smoke from Cigarettes*, 37 CANCER RES. 3218, 3218–22 (1977).

metabolites has permeated millions of printed ranitidine labels.[31]

150. Although GSK submitted to the FDA almost twenty-five (25) different submissions and supplements related to Zantac product labeling from 1980 through the present, not one of them brought ranitidine's NDMA metabolic byproduct concerns to the FDA's attention.

151. On December 4, 1991, GSK submitted a supplemental new drug application requesting approval of additional packaging sizes for Zantac tablets (150 mg: 100 count, 60cc container and 1000 count, 500 cc container, and 300 mg: 500 count, 500 cc. container). In association with the new drug application, GSK was required to conduct a stability review and identify all impurities caused by decomposition. GSK never disclosed NDMA.

152. In its July 2, 1992 letter approving GSK's new packaging sizes, the FDA observed that GSK's stability study design was unscientific and inconsistent:

> Future stability studies should be conducted using the same methodology at all time points. Using an approved method and its "enhanced" version in the same stability study may lead to confusion and delay in Agency action. You are reminded of your commitment to provide a full description of the enhanced method for determining impurities in the next annual report.

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[31] Importantly, GSK scientists have published at least one article acknowledging that N-nitrosamine is a metabolite. *See* Claire Beaumont et al., *Human Absorption, Distribution, Metabolism and Excretion Properties of Drug Molecules: A Plethora Of Approaches*, 76 BRIT. J. CLINICAL PHARMACOL. 6, 1190 (2014) ("[Nuclear magnetic resonance] revealed the presence of a unique human circulating metabolite, an N-nitrosamine present at approximately 5% [drug-related material].")

Remarkably, GSK never identified the NDMA impurity, despite FDA specifically asking for GSK to do so.

153. GSK's recklessness was further highlighted on May 29, 1992, when GSK submitted Supplemental Application 47 to NDA 18-703, requesting approval for a 150 mg "b.i.d." (i.e., twice daily) treatment for long-term maintenance of patients with healed erosive esophagitis. In association with Supplemental Application 47, GSK submitted to the FDA its "Integrated Summary of Benefits and Risks," which stated in pertinent part:

> Zantac has been marketed continuously since approval in the United States (US) in 1983. The oral formulation has been used in more than 130 million patients worldwide and is among the most frequently prescribed medications for the treatment of gastrointestinal diseases. The well-acknowledged safety profile of Zantac is a factor underlying its widespread use.

154. The "Integrated Summary of Benefits and Risks," makes the following safety claims:

> 3. Evidence for Safety
>
> Long-term treatment with the currently-approved standard dosage of ranitidine does not appear to be associated with any unexpected or serious adverse events, or increased incidence of adverse events, including changes in clinical laboratory test results, according to the safety data integrated here.
>
> Six clinical studies of 815 GERD patients (41 % of whom had healed erosive esophagitis) treated with either placebo (369 patients) or ranitidine (446 patients) found no clinically remarkable differences between treatment groups in any of the safety assessments made. The assessments included treatment group comparisons of the incidence of adverse events, incidence of drug-related adverse events, types of adverse events, incidence of adverse events in elderly versus nonelderly patients and men versus women, frequencies of adverse events over time. incidence of shifts to abnormal clinical laboratory test results. and incidence of clinically significantly abnormal clinical laboratory test results.

> Fifty-eight (58) (7%) of 815 enrolled patients had some type of notable (serious or leading to withdrawal) adverse event. distributed between ranitidine and placebo groups as shown previously. Of the 58 patients. three (all of whom received ranitidine) had more than one notable event: one patient had two serious adverse events, neither of which led to withdrawal; one patient had one serious event and an unrelated adverse event leading to withdrawal; and one patient had two serious events, only one of which led to withdrawal.

155. GSK's Supplemental Application 47 also included a section titled "Integrated Summary of Safety," which purported to provide studies demonstrating that ranitidine was safe for long-term maintenance of patients with healed erosive esophagitis. However, these safety studies were all deceptive, because they failed to disclose the known nitrosation problem directly or indirectly, or the ability of ranitidine to form NDMA.

156. GSK's safety studies included in Supplemental Application 47 were materially deceptive because the studies were not designed to measure adverse events related to NDMA contamination. The longest of the studies lasted 12 months—too short of a time for observable cancer to manifest from NDMA. As such, Supplemental Application 47 was materially deceptive because none of the studies were capable of detecting carcinogenic harms caused by nitrosamines, including NDMA.

157. On March 10, 1994, GSK obtained FDA approval to update the label of 300 mg Zantac to include an indication to consume Zantac "after the evening

meal" for treatment of active duodenal ulcer.[32] Defendants requested the indication that Zantac be taken with food on the grounds of equivalence, even though they were on notice that mixing ranitidine with nitrites from food, and nitrites produced by the known increase in nitrate-reducing bacteria in the stomach, would increase the probability of nitrosation. Indeed, multiple peer-reviewed studies in the 1980s specifically warned about this issue and the risks of forming mutagenic nitrosamines when reacting with certain foods. GSK did not disclose this issue to the FDA and, instead, concealed the NDMA data from the FDA.

158. On December 16, 1996, GSK submitted Supplemental Application 56 to NDA 18-703, requesting permission to revise ranitidine labeling to include indications for "Pediatric Use" in patients from 1 month to 16 years of age. Supplemental Application 56 was materially false and misleading, because the safety studies underlying it were not designed to capture nitrosation dangers. The Adverse event reporting in the studies underlying Supplemental Application 56 was limited to one year. Supplemental Application 56 did not include any specific safety testing or protocol designed to capture adverse events related to ranitidine's known NDMA exposure risks.

159. In association with the FDA's review of Supplemental Application 56,

[32] This additional labeling was submitted by GSK as Supplemental Application 46 to NDA 18-703, as well as Supplemental Application 12 to NDA 19-675 (covering syrup-form ranitidine).

the FDA conducted a review of all efficacy and safety data submitted by GSK and discussed its findings in a report titled "Division of Gastrointestinal and Coagulation Drug Products Medical Officer's Review," dated May 21, 1997. The medical officer's review fails to evidence any knowledge of nitrosation or NDMA-formation concerns. The FDA's summary of the safety data submitted by GSK demonstrates that instead of studying or resolving nitrosation concerns in pediatric populations, GSK sought to conceal them entirely.

160. In addition to those above, GSK made the following submissions about Zantac to the FDA, in order to boost the drug's profitability, without identifying its nitrosamine link:

- On June 11, 2001, GSK notified the FDA of potential adverse reactions from ranitidine in the form of blood vessel inflammation.
- On October 27, 2004, GSK amended its ranitidine labels, but maintained as originally written essential portions including the "Metabolism" disclosure.
- On January 11, 2006, GSK notified the FDA of potential adverse reactions from ranitidine in the form of pneumonia.
- On April 2, 2008, GSK amended its ranitidine labels, but maintained as originally written essential portions including the "Metabolism" disclosure.
- On April 23, 2009, GSK requested that the FDA approve an amendment to its Zantac labels which denied any link between the drug and male hormonal problems such as impotence. Maintained as originally written were essential portions including the "Metabolism" disclosure.

161. It is common practice for pharmaceutical manufacturers of pharmaceuticals with potential nitrosation dangers to inform the government, doctors, researchers, and the public of these dangers in the manufacturer's product labeling warnings.

162. Antabuse (disulfiram) has been on the market since 1951.[33] Antabuse is chemically similar to ranitidine as it has terminal amines that are vulnerable to separation from the drug where the amine can directly generate a dangerous nitrosamine. Particularly, the disulfiram molecule includes two molecules of the group DEA (diethylamine), which may form into NDEA. NDEA and NDMA are chemically very similar and are both probable human carcinogens tightly regulated by the FDA. Both NDMA and NDEA have been the cause of recent FDA recalls of hypertension medication valsartan, losartan and irbesartan.

163. The FDA-approved warning label for Antabuse[34] states under "Drug Interactions":

> In rats, simultaneous ingestion of disulfiram and nitrite in the diet for 78 weeks has been reported to cause tumors, and it has been suggested that disulfiram may react with nitrites in the rat stomach to form a nitrosamine, which is tumorigenic. Disulfiram alone in the rat's diet did not lead to such tumors. The relevance of this finding to humans is not known at this time.

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[33] Antabuse is famous for helping alcoholics stop drinking by enhancing hangover effects.

[34] The original NDA for Antabuse is held by Teva Women's Health Inc.; the drug is now licensed for distribution by firms including Mylan Pharmaceuticals, Alvogen, and West-ward Pharmaceuticals.

164. Label warnings for sodium nitrite alert to the same potential interaction. For example, the warning label for the drug Nithiodote (sodium nitrite and sodium thiosulfate) advises, under the heading "Carcinogenesis" (emphasis added):

> *Sodium Nitrite*
>
> The potential benefit of an acute exposure to sodium nitrite as part of a cyanide antidote outweighs concerns raised by the equivocal findings in chronic rodent studies. Sodium nitrite (0, 750, 1500, or 3000 ppm equivalent to average daily doses of approximately 0, 35, 70, or 130 mg/kg for males and 0, 40, 80, or 150 mg/kg for females) was orally administered to rats (Fischer 344 strain) for 2 years via drinking water. There were no significant increases in the incidence of tumor in either male or female rats. Sodium nitrite (0, 750, 1500, or 3000 ppm equivalent to average daily doses of approximately 0, 60, 120, or 220 mg/kg for males and 0, 45, 90, or 165 mg/kg for females) was administered to B6C3F1 mice for 2 years via the drinking water. Equivocal results were obtained in female mice. Specifically, there was a positive trend toward an increase in the incidence of squamous cell papilloma or carcinoma in the forestomach of female mice. Although the incidence of hyperplasia of the glandular stomach epithelium was significantly greater in the high-dose male mice compared to controls, there were no significant increases in tumors in the male mice. *Numerous reports in the published literature indicate that sodium nitrite may react in vivo with secondary amines to form carcinogenic nitrosamines in the stomach.* Concurrent exposure to sodium nitrite and secondary amines in feed or drinking water resulted in an increase in the incidence of tumors in rodents.

165. Although it was known to GSK that ranitidine's DMA amine could also react with nitrite in the stomach, GSK failed to conduct any rat stomach tests with ranitidine and nitrite to address this concern. Indeed, GSK deliberately concealed the NDMA issue from the FDA and public.

166. Most damning for GSK is the warning label for competitor Takeda Pharmaceuticals America, Inc.'s Prevacid (lansoprazole), a PPI that has been on

the market since 1992. The Prevacid label states, under the heading "12.2 Pharmacodynamics":

> Other Gastric Effects in Humans
>
> Lansoprazole did not significantly affect mucosal blood flow in the fundus of the stomach. Due to the normal physiologic effect caused by the inhibition of gastric acid secretion, a decrease of about 17% in blood flow in the antrum, pylorus, and duodenal bulb was seen. Lansoprazole significantly slowed the gastric emptying of digestible solids. Lansoprazole increased serum pepsinogen levels and decreased pepsin activity under basal conditions and in response to meal stimulation or insulin injection. *As with other agents that elevate intragastric pH, increases in gastric pH were associated with increases in nitrate-reducing bacteria and elevation of nitrite concentration in gastric juice in patients with gastric ulcer.* No significant increase in nitrosamine concentrations was observed.

167. Warnings such as these appear on eighty-six (86) FDA-approved labels for 339 distinct product codes.

12. GSK Proceeds to Aggressively Market Ranitidine; Despite Numerous Studies Linking Ranitidine to NDMA Formation, GSK Never Tests Ranitidine Again for NDMA or Discloses Its Data to the FDA

168. Given that NDMA is a yellow oily liquid, when ranitidine degrades into NDMA, ranitidine becomes discolored. Indeed, in GSK's 2020 root-cause analysis, GSK observed that when ranitidine degrades into NDMA in the presence of moisture and heat, it changes color (turns yellow and then brown) and breaks down, and that this is directly related to NDMA content.

169. On February 13, 1984, shortly after the FDA's approval of ranitidine, GSK prepared a report titled, "Preliminary Results of an Investigation into the Thermal Degradation of Ranitidine Hydrochloride[.]" The report detailed that

ranitidine would rapidly degrade in the presence of moisture and heat, and that "[a]dditional, as yet unidentified, breakdown products are also produced within the liquid mass formed as a result[.]" The authors note that increased temperature and moisture "shows considerable darkening" and that existing method "HPLC assay procedure" was unable to properly identify these "break down products." GSK did not test these unidentified breakdown products for NDMA. Had GSK tested these impurities for NDMA they would have seen it—a fact confirmed by GSK's 2020 root cause analysis and the fact that NDMA has been discovered in nearly every ranitidine pill tested.

170. GSK has represented to the FDA that ranitidine is a stable molecule, not prone to oxidization. On October 21, 1986, GSK submitted a supplemental NDA requesting an extension of the shelf life for Zantac Tablets 300 mg from two years to three. This submission, and associated materials, were designed to create the false impression that ranitidine is a stable molecule, not prone to molecular breakdown. On April 4, 1987, GSK received approval from the FDA to elevate the Zantac shelf life, making the drug considerably less safe.

171. Over the course of the next several decades, as GSK did not change the ranitidine molecule, GSK continued to observe discoloration in Zantac pills, and instead of testing it to figure out what was causing it, they took actions to conceal it. For example, in the 1990s, when GSK was attempting to develop an

OTC product with Warner Lambert (Pfizer predecessor), they knew they had a discoloration problem. The white pills being sold in a plastic bottle and foil packets had "significant discolouration" at "the three month test point" when stored at elevated temperatures and humidity. Because they could not avoid discoloration, the "recommendations is that we should ASAP manufacture three full scale batches with a yellow coat… if we stay with the white coat we many not be able to offer" the product in plastic bottles. That recommendation was accepted: "Due to problems with discolouration of the while 75mg tablets on stability we have decided to change the colour to the same yellow as was used for the 25mg tablets[.]" Indeed, GSK admitted this was for the purposes of masking discoloration: "Replacement batches will be manufactured incorporating the yellow dye, previously used in the 25mg tablet, in the film coat to mask any potential discoloration."

172. In later years, when GSK was considering bulk packages (500 or 1000 pills) of Zantac, they indicated that such a product would need to be peach colored because "[i]t is believed that the peach coloured coating has superior ability to mask the yellow-brown discolouration of the tablet core relative to our white coating."

173. This issue concerning discoloration lasted decades and was even

reported in the literature.[35] In 2003, researchers published a paper "Stability of ranitidine in injectable solutions" reporting their own independent stability testing. They reported that ranitidine was unstable and at 2 months the "colour changed from light yellow to brown" and that the "amount of related substances has exceeded allowed limits even 1 month after the test." GSK researchers discussed this paper in 2008, when a GSK scientist noted concerns regarding injection forms of ranitidine turning from clear to yellow over time, remarking "we should ask how that happens. To know what we need to know the structure of the yellow metabolite/contaminant, and how it would be generated from the patent compound over time." In response, another GSK scientist stated, "I guess I am reluctant to add further information because of the limited amount of supporting information we have … I do stress the importance of noting that the colour can change over time, which is a valid point that prescribers must be aware of, since we have received many complaints, but we do not have a full analysis on this." He goes on to explain it "surely begs the question, 'if it changes with time, is it safe to use? … which we do not have sufficient supporting information on." It begs a question GSK did not want to answer. "[W]e [do] not have a full analysis of everything that is, or is not, known at this point in time."

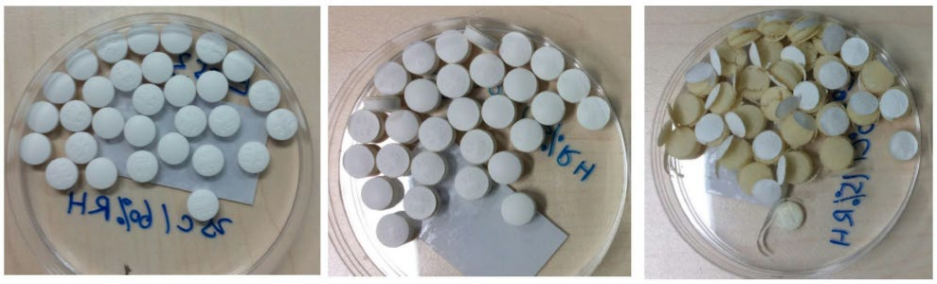
[35] Vehabovic, et al., *Stability of ranitidine in injectable solutions*, 256 INT. J. PHARMA. 109, 109–115 (2003).

174. In a 2011 study titled, "Investigation into Yellow Impurities in Ranitidine HCI Sterile Injection Formulation" conducted by Andrew Searle (the GSK researcher that would later oversee the 2020 RCA of ranitidine), it states "[t]here has been a long history of yellow discolouration of Ranitidine HCI … To date, the impurities responsible for the colour have not been identified." In the study, Dr. Searle concludes that "[t]he overriding conclusion from this initial study was that the yellow discolouration was a complex phenomenon, caused by a multitude of components." Dr. Searle was unable to actually identify the yellow degradants—and, of course, he never tested for NDMA. This lack of information continued for years. "There is no knowledge on the discolouration of Zantac IV … Analytical work conducted in the past …found that the level of impurity is likely to be in the ppm level which makes it extremely difficult to identify, characterize and control."

175. In 2014, GSK conducted a Zantac Discoloration Simulation Study on Zantac tablets. "During the period from 2005 to November 2013 a number of complaints were received" regarding "tablet disintegration and discoloration as well as 9 stability …tablet discoloration." GSK systematically tested Zantac tablets under different scenarios and concluded "color appearance and analytical results are impacted by effects of temperature and humidity. The tablet coat will come apart and fall off and tablet will disintegrate [and] also tablet ill discolor

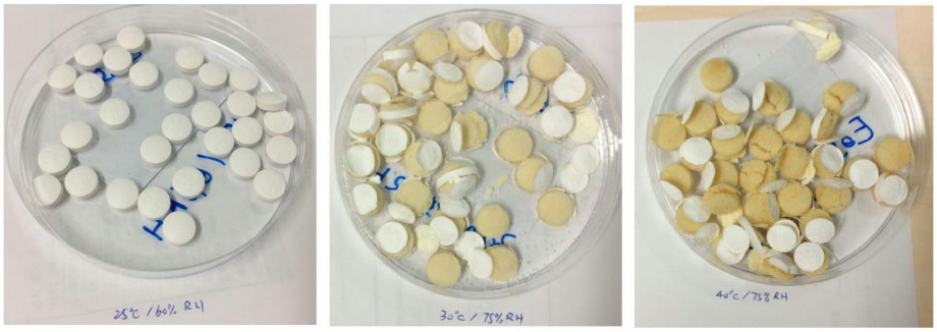
from yellow to dark yellow, brown and finally dark drown." In the accompanying presentation, GSK provides clear visual evidence of this issue:

Day 1

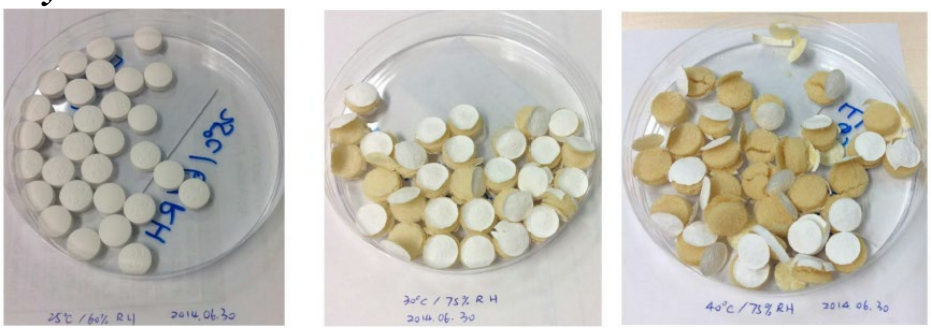


Day 2

Day 3

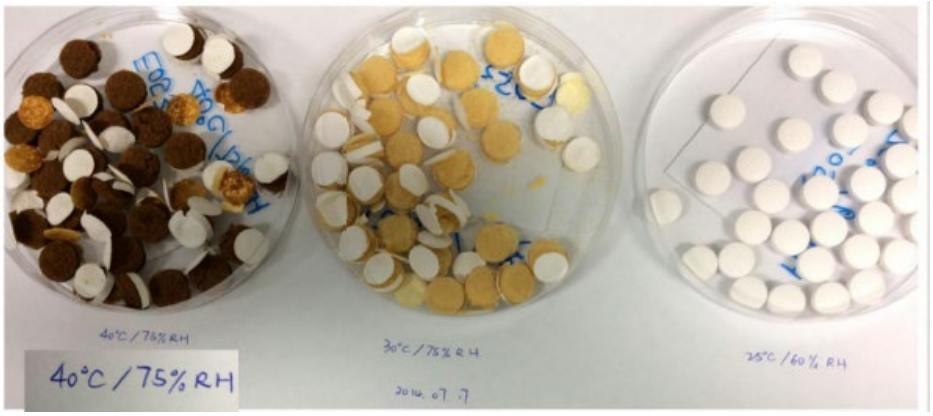


Day 4



2 Weeks

3 Weeks



176. While the pills at 25°C/60% RH stayed relatively intact, the 30°C/75% RH started discoloring on day 2. Peer-reviewed literature shows that temperatures routinely reach in excess of 30°C (upwards of 38°C) and relative humidity in excess of 75% (upwards of 100%) in a bathroom during a shower—the place where most people store their medications. Once again, as part of this discoloration simulation, GSK did not test for the yellow oily substances known as NDMA or identify the impurities.

177. In 2015, the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom, inspected a GSK manufacturing facility. The

MHRA identified "serious deficiencies in your operations[.]" Specifically, the MHRA cited GSK for failing to report or conduct safety assessments on batches of ranitidine that was becoming discolored. "One issue was raised today regarding the handling of discoloured Zantac tablets identified during stability testing and through customer complaints. Inspectors are questioning why this had not been reported[.]" The MHRA noted that these deficiencies were similar to another GSK facility cited in 2014. This led to GSK, at the request of the MHRA, to conduct "a toxicology assessment of impurities that form as a result of this tablet degradation." It was also performed by Dr. Searle. He identified "[t]he structures of all impurities that have been formally characterized" and were "toxicologically assessed." These included "many previously unidentified impurity structures." In the report, Dr. Searle represents that he ran the structures through the Derek Nexus database—a program the uses chemical structures to determine if they may be potentially genotoxic—and that they were not found to be a "cause for concern." However, internal GSK emails indicate that several of the unidentified impurities triggered alerts within the Derek system being "positive" and class "3" compounds, which were "aliphatic [oily] nitro compound." However, this was not disclosed in Dr. Searle's MHRA-ordered toxicology assessment. Instead, Dr. Searle concludes that there is no risk because "ingestion of a degraded tablets was considered unlikely to occur more than once in a lifetime."

178. GSK's failure to test discolored Zantac pills for NDMA over 37 years is difficult to justify, especially when GSK specifically identified the link to NDMA back in 1981. Indeed, during this period, there were numerous scientific publications linking ranitidine to NDMA—in addition to those discussed above (Maura, De Flora, and Brambilla) in 1983 noting the mutagenic effects of nitrosated ranitidine, with multiple studies comparing those effects specifically to NDMA.

179. For example, in 1990, scientists discovered that people taking ranitidine had elevated levels of NDMA in their stomach juices compared to people with the same medical condition that did not take ranitidine or any H2 blocker.[36]

180. That same year, researchers observed that rats treated with ranitidine for two years (lifetime) developed carcinoids in their stomach tissue, with 19 animals treated with ranitidine developing carcinoids and none in the control group.[37]

181. In 1994, GSK completed a long-term Zantac clinical trial, following

[36] Matsuda, et al., N-*Nitrosamines in gastric juice of patients with gastric ulcer before and during treatment with histamine Hz-receptor antagonists*, 25 GASTROENTEROLOGIA JAPONICA 2, 162–168 (1990).
[37] Havu, et al., *Enterochromaffin-Like Cell Carcinoids in the Rat Gastric Mucosa following Long-Term Administration of Ranitidine*, 45 DIGESTION 189, 189–195 (1990).

patients taking ranitidine for 11 years. At the end of the study, GSK observed that "bowel cancer was observed more frequently in the study population than would be expected (observed/expected ratio = 7/2.31 = 3.03)." It also noted that "[c]ases of prostate carcinoma arose more frequently than expected[.]" This long-term clinical trial provided a clear signal that people taking ranitidine were getting cancer a rate that was greater than expected, but GSK did not do *anything* about it. When reporting this to the FDA, GSK did not disclose whether the data was statistically significant.

182. In 2003, researchers tested whether ranitidine, in combination with levels of nitrite found in stomachs after a high-nitrite meal, was genotoxic.[38] They found that "ranitidine showed" genotoxic activity. Remarkably the authors could not identify the nitrosamine that was causing the genotoxicity, but noted that their "findings are in contrast to the reported that no mutagenic nitrosation product of ranitidine is to be formed in man under any conceivable physiological conditions" as reported by Brittain.

183. In 2002, researchers identified the ability of ranitidine to combine with nitirite in water treatment to form NDMA.[39] These concerns continued

[38] Ozhan, et al., *Genotoxic Activities of Drug-Nitrite Interaction Pro*ducts, 26 DRUG & CHEM. TOX. 4, 295–308 (2003).
[39] Mitch et al., *Formation of N-Nitrosodimethylamine (NDMA) from Dimethylamine during Chlorination*, 36 ENVIRON. SCI. & TECH. 4, 588–595 (2002).

throughout the 2000s, as researchers grew more and more concerned about NDMA forming in the water supply as part of water disinfecting.[40] Ranitidine reacts with chlorine to produce NDMA, noting that "Ranitidine, a pharmaceutical, showed extraordinary high conversion efficiency."

184. In 2011, researchers studied 20 common personal products, including ranitidine, to see how they reacted to chloramine to form NDMA: "Ranitidine shows the strongest potential to form NDMA[.]"[41] Indeed, the authors even explain how the chemical structure of ranitidine makes its susceptible to NDMA formation.

185. In 2015, another study examined how NDMA formed following ingestion in urine and feces, and there the authors reported that NDMA was endogenously formed from ranitidine consumption: "[T]hese results indicate that consumption of Zantac increased the loading of NDMA in urine as well as the amount of chloramine reactive NDMA precursors, which likely derived from ranitidine itself."[42] And that study was followed-up by a larger urinary study

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[40] Sacher, et al., *Strategies for Minimizing Nitrosamine Formation During Disinfection* (Winter 2007/2008).
[41] Shen, et al., *Demonstration of 20 pharmaceutical and personal care products as nitrosamine precursors during chloramine disinfection*, 45 WATER RES. 944, 944–952 (2011).
[42] Zeng, et al., *Contribution of N-Nitrosamines and Their Precursors to Domestic Sewage by Greywaters and Blackwaters*, 49 ENV. SCI. TECH. 22, 13158–13167 (2015).

involving NDMA formation after ranitidine ingestion, which showed hundreds of thousands of ngs of NDMA in urine following ranitidine consumption.[43] This study also replicated the Tanner experiments from 1982, whereby varying amounts of nitrite were shown to react with ranitidine to form NDMA in simulated gastric fluid. Despite these studies, GSK never tested ranitidine discoloration for NDMA nor disclosed any data concerning the link of ranitidine to NDMA.

186. There were also several studies specifically linking ranitidine to cancer, and still GSK did not do anything. Specifically, in 2000, scientists from Kaiser published an epidemiology study using data from Northern California.[44] They observed that people taking ranitidine were more likely to develop various cancers than people not taking ranitidine.

187. In 2004, researchers looked at data collected from health professionals around the U.S.[45] They reported "an increase in bladder cancer risk among men who reported taking either" ranitidine or cimetidine (a 58% increased risk) in 1986. And, that risk remained elevated even after adjusting for potential confounders.

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[43] Zeng, et al., *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37 CARCINOGENESIS 6, 625–634 (2016). This study was ultimately retracted in 2021, a year after the FDA pulled ranitidine from the market. However, it remained in the published literature for years and GSK did nothing to examine NDMA formation.

[44] Habel, L.A., et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 8 PHARMACOEPIDEMOLOGY & DRUG SAFETY 149, 149–155 (2000).

[45] Michaud, D.S., et al., *Gonorrhoea and male bladder cancer in a prospective study*, 96 BRIT. J OF CANCER 169, 169–171 (2007).

188. In 2008, a study was published showing that women taking ranitidine had a doubling of risk of developing breast cancer.[46]

189. Despite numerous studies linking ranitidine to NDMA and other studies linking ranitidine to cancer development, at no time did GSK test for NDMA or disclose to the FDA the truth about its experiments back in 1981.

13. Relator Tests Ranitidine Including the Same Tests GSK Concealed in 1981 But, Unlike GSK, Relator Shares that Data with the FDA

190. In January 2019, FDA established a protocol for testing for NDMA in pharmaceutical products. This emerged following the discovery of NDMA contamination in Valsartan products (which Valisure was instrumental in exposing) that led to mass recalls of contaminated medications.[47] This process utilized Gas Chromatography ("GC") Mass Spectrometry ("MS"). GC-MS has been regarded as a "gold standard" for forensic substance identification and can be used to identify small polar molecules like NDMA.

191. In early 2019, the infant daughter of a scientist at Valisure was prescribed ranitidine. Concerned with giving his infant daughter a prescription medication, Valisure scientists tested the drug for the presence of impurities,

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[46] Mathes, R.W., et al., *Relationship between Histamine^2-Receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 CANCER EPI. BIOMARKERS & PREVENTION 1, 67–72 (2008).

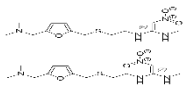
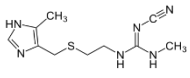
[47] U.S. Food & Drug Administration, *GC/MS Headspace Method for Detection of NDMA in Valsartan Drug Substance and Drug Products* (Jan. 25, 2019), *available at* https://www.fda.gov/media/115965/download.

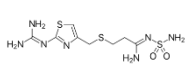
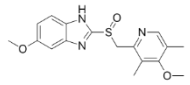
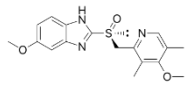
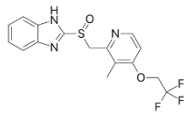
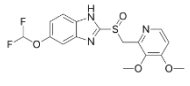
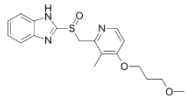
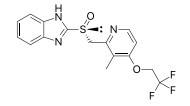
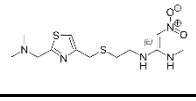
including NDMA. The initial testing occurred in the February – March 2019 timeframe, and Valisure continued its investigation for several months.

192. Valisure tested representative samples of Zantac using the FDA's January 2019 protocol. Valisure tested whole 150 mg ranitidine tablets issued by five different distributors. Ther results demonstrated exceedingly high levels of NDMA.

Sample	**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

193. Valisure also performed the FDA method on each of ranitidine's competitors in the H2 blocker and proton pump blockers classes as a control, and did not observe anything like they did with ranitidine:

Name	**Brand (lot#)**	**Structure**	**NDMA per tablet (ng)**
Ranitidine (1x 150 mg tablet)	Zantac (7702406A)		2,978,551
Cimetidine (1X 200 mg tablet)	Tagamet (9AE2576)		**0^+**

Famotidine (2x 40 mg tablets)	Pepcid (1805012732)		0[#]
Omeprazole (2x 40 mg capsule)	Prilosec (19182878)		0[#]
Esomeprazole (2x 40 mg capsule)	Nexium (C806922)		0[#]
Lansoprazole (3x 30 mg capsule)	Prevacid (C807365)		0[#]
Pantoprazole (2x 40 mg tablets)	Protonix (PAN18101)		0[#]
Rabeprazole (4x 20 mg capsules)	AcipHex (BY33E009)		0[#]
Dexlansoprazole (2x 60 mg capsule)	Dexilant (A27540)		0[#]
Nizatidine (1x 150 mg capsule)	Axid (1290625A)		41,490

[#] *No amounts detected* / [+] *Trace amounts detected near lower limit of detection*

194. Of ranitidine's competitors, only nizatidine exhibits measurable NDMA formation. That is not surprising. The nizatidine molecule is the only one of ranitidine's competitors that also contains an unstable dimethylamine group in addition to a nitro group. That said, a recent paper has found very high levels of NDMA in famotidine.[48]

[48] Safdari, A., et al., *Investigating the possibility of N-Nitrosodimethylamine (NDMA) in famotidine containing products*, 88 J. DRUG DELIVERY SCI. & TECH. 104908, 1–6 (2023).

195. These tests on ranitidine pills confirmed that ranitidine was fundamentally unstable and contained the constituent components to form NDMA at an alarming rate.

196. That said, Valisure recognized that the levels of NDMA observed in ranitidine were likely inflated due to the use of heat in the FDA's GC-MS method, which required heating the ranitidine samples at 130 °C (266 °F) for fifteen minutes. This elevated temperature, itself, was likely accelerating the degradation process of ranitidine and yielding artefactually higher levels of NDMA.

197. So, Valisure developed a GC-MS method that could operate at body temperatures, i.e., 37 °C (98.6 °F). Then using this method, which was less sensitive than a traditional GC-MS approach, Valisure conducted a NAP test on ranitidine, combining ranitidine with various amounts of sodium nitrite after incubating in simulated gastric fluid. In other words, Valisure conducted the same tests that GSK had done in 1981, but concealed from the FDA.

198. Valisure obtained results similar to GSK: ranitidine produces levels of NDMA at multiples of FDA daily limits in the gastric environment.

NAP Testing Results:

Tablet Studies Lot# 77024060A	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid	Not Detected	Not Detected

SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

199. Considering a human stomach can generate up to 3,000 ml of gastric fluid a day, this could result in millions of nanograms of NDMA exposure from a single dose of ranitidine.

200. In June 2019, Valisure submitted its ranitidine data to the FDA confidentially. FDA made inquiries regarding the data with GSK and others.

14. FDA Begins Disclosing Valisure Data to Other Agencies and the Ranitidine Manufacturers, and GSK Once Again Lies to the FDA

201. FDA shared Valisure's data with the European Medicines Agency, which on July 16, 2019, reached out to GSK and other ranitidine manufacturers for information about NDMA in ranitidine.

202. On August 6, 2019, the FDA disclosed the NDMA concerns confidentially to ranitidine manufacturers, including GSK, and requested information. Specifically, FDA sent a communication to GSK:

> Recently a private analytical pharmacy and advanced laboratory notified the FDA that Zantac (ranitidine) produces a very high quantity (thousands of times higher than the FDA limits) of a probable human carcinogen N-nitrosodimethylamine (NDMA) in a single tablet of 150 mg of Zantac, when analyzed using FDA's nitrosamine test methods. The same private laboratory also found that Zantac forms high quantity of NDMA in simulated human body gastric conditions. The preliminary reports seem to indicate that in certain conditions (e.g., high temperatures and presence of nitrites) ranitidine hydrochloride (API) and ranitidine tablets degrade to form high quantities of NDMA.

203. The FDA requested specific information from GSK:

1. Are you aware of the above information?

2. Is there any potential for NDMA to be present in the Zantac tablets or ranitidine hydrochloride API? Provide a detailed explanation for your response . Include in your explanation quality information for API, excipients, manufacturing process, etc.

3. Have you tested Zantac tablets or ranitidine hydrochloride for the presence of NDMA? If you have, what were the levels of NDMA found?

4. Have you tested Zantac tablets in simulated human body conditions (including gastric conditions)? If you have, have you detected NDMA? If you did, what were the levels observed?

204. In preparing a response, GSK scientists openly conceded (before any litigation had been filed against GSK): "N-nitrosamines such as NDMA [] are considered carcinogens and have been implicated in human cancers such as bladder, esophagus, stomach, and nasopharynx."

205. In response, on September 6, 2019, GSK stated that they had never tested ranitidine for NDMA. Regarding the fourth inquiry, GSK once again deflected to the Brittain study. GSK falsely stated: "There was no analysis for NDMA" because "NDMA would not have been predicted to form given the structures of the observed nitrosation products." This was a lie because not only had GSK specifically tested for NDMA in ranitidine nitrosation tests (Tanner Study), but it did so *after* predicting they would emerge based on the chemistry of the ranitidine molecule itself.

15. Valisure Files Citizen's Petition and this Lawsuit (under Seal) Prompting Statements from the FDA and Recalls by the Manufacturers

206. On Friday, September 13, 2019, Valisure submitted a Citizen's Petition to the FDA, disclosing the testing data.

207. The Citizen's Petition requested that the FDA take five actions:

1) request a recall and suspend sale of all lots of all products containing ranitidine. Given the drug's propensity to form the probable carcinogen NDMA, the drug is misbranded under Section 502 of the FDCA (21 U.S.C. § 352);

2) conduct examinations and investigation under Section 702 (a) of the FDCA (21 U.S.C. § 372(a)) regarding these products, their manufacturing processes, and the manufacturer submissions made for FDA approval under 704 (a) of the FDCA (21 U.S.C. § 374(a));

3) provide information to the public regarding these products under Section 705(b) of the FDCA (21 U.S.C. § 375(b));

4) in addition to the instructions for disposal and/or return in the recall notices, issue additional guidance to the public for the safe disposal of ranitidine, given the recognized potential that the drug may degrade to form the probable carcinogen NDMA in municipal wastewater treatment plants and impact the public water supply; and

5) promulgate regulations requiring robust independent chemical testing and verification of pharmaceuticals and, while these regulations are pending, issue guidance requesting such testing and verification.

208. Shortly thereafter, various personal injury and class action lawsuits were filed against GSK and other ranitidine manufacturers.

209. Within a few months, numerous voluntary recalls issued from various ranitidine manufacturers, including GSK.

210. On October 2, 2019, the FDA announced a new testing protocol for NDMA in ranitidine. Valisure's citizen's petition noted that the high levels of NDMA formation observed in its testing were caused, in part, by the elevated

temperatures used in GC-MS. So, the FDA developed and published a testing method using Liquid Chromatography ("LC"), which did not use elevated temperatures. This special protocol was limited to testing ranitidine—the January 2019 protocol for other drug substances remained the same.

211. On November 1, 2019, FDA announced preliminary testing results on ranitidine products.

Company	Product	Lots Tested	NDMA level ppm	NDMA level (micrograms-mcg/tablet or oral dose)
Sanofi Pharmaceutical	OTC Ranitidine 150mg	19E413M, 19D554, 19A432U, 19C540, 19D431I, 19D442N, 19D423M, 19D464M,	0.07-2.38	0.01-0.36
Sanofi Pharmaceutical	OTC Ranitidine 75mg	18L012U, 9A003U, 19B006M, 18M025M, 18N023U, 19B005N, 19A002U, 18N026U	0.10-0.55	0.01-0.04
Cardinal Health	OTC Ranitidine	9FE2953	1.02	0.15

Company	Product	Lots Tested	NDMA level ppm	NDMA level (micrograms-mcg/tablet or oral dose)
	150mg			
Watson	Rx Nizatidine 150mg	1350798M	0.05	0.01
Watson	Rx Nizatidine 300mg	1333973A	0.04	0.01
Strides Shasun Ltd	Rx Nizatidine 150mg	7704758A	0.11	0.02
Strides Shasun Ltd	Rx Nizatidine 300mg	7704022A	0.09	0.03
Novitium	Rx Ranitidine 300mg	S18038B	2.85	0.86
Dr Reddy's	Rx Ranitidine 300mg	C805265	0.68	0.20
Strides Shasun Ltd	Rx Ranitidine 300mg	7702255A	0.11	0.03
Sandoz	Rx Ranitidine 300mg	HU2207	0.82	0.25
Strides Shasun Ltd	Rx Ranitidine 300mg	7704537A	0.02	0.00
Aurobindo	Rx Ranitidine 300mg	RA3019001-A	1.86	0.56

Company	Product	Lots Tested	NDMA level ppm	NDMA level (micrograms-mcg/tablet or oral dose)
Ajanta Pharma USA Inc	Rx Ranitidine 300mg	PA1229B	0.23	0.07
Silarx Pharma	Ranitidine 150mg Syrup	3652081-02661	1.37	0.20
Pharma Associates	Ranitidine 150mg Syrup	BE00, BF75, BF77, BF78, BDFF, COAC	0.03-0.07	0.004-0.012
Amneal Pharmaceuticals	Ranitidine 300mg	AR181795A, AR190878A, AR190876A, AR191177A, HB05819, HB06119, HL08718	0.52-2.17	0.16-0.65
Sanofi Pharmaceutical	Ranitidine 150mg	19D570, 19D428U, 19E408M	0.08-2.17	0.01-0.33

212. On January 2, 2020, an independent laboratory, Emery Pharma, submitted a second Citizen's Petition, discussing the ability of ranitidine to degrade into NDMA during regular transport and storage.

16. With Mounting Pressure of Ranitidine Litigation Looming, GSK Finally Discloses the Truth to the FDA

213. GSK was cornered. Personal injury and class action litigation was swelling around the country, and GSK realized that, through discovery, it would no longer be able to conceal the Tanner study's existence. GSK finally disclosed the data to the FDA on December 11, 2019, but disclaimed that its prior statements to the FDA were false or misleading. This was the first time GSK disclosed its NDMA data after nearly forty years of concealment.

17. Further Investigations Lead to a Complete Market Withdrawal of All Ranitidine-Containing Drugs by the FDA

214. On January 2, 2020, Emery Pharma submitted a Citizen's Petition, disclosing experiments showing that ranitidine degrades into NDMA during regular transport and storage.

215. On April 1, 2020, the FDA issued a national withdrawal of ranitidine products. The FDA stated:

> The U.S. Food and Drug Administration today announced it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.
>
> …
>
> NDMA is a probable human carcinogen (a substance that could cause cancer). In the summer of 2019, the FDA became aware of independent

> laboratory testing that found NDMA in ranitidine. Low levels of NDMA are commonly ingested in the diet, for example NDMA is present in foods and in water. These low levels would not be expected to lead to an increase in the risk of cancer. However, sustained higher levels of exposure may increase the risk of cancer in humans. The FDA conducted thorough laboratory tests and found NDMA in ranitidine at low levels. At the time, the agency did not have enough scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines, and continued its investigation and warned the public in September 2019 of the potential risks and to consider alternative OTC and prescription treatments.
>
> New FDA testing and evaluation prompted by information from third-party laboratories confirmed that NDMA levels increase in ranitidine 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. The testing also showed that the older a ranitidine product is, or the longer the length of time since it was manufactured, the greater the level of NDMA. These conditions may raise the level of NDMA in the ranitidine product above the acceptable daily intake limit.

216. On that same date, the FDA issued a letter to Valisure, in formal response to the Valisue's Citizen's Petition, indicating that it was (1) granting its request for recall, (2) denying its request for a safe method of ranitidine disposal, and (3) denying its request that FDA issue regulatory guidance for independent testing of pharmaceutical quality and for impurities.

18.During Litigation, GSK Destroys Evidence

217. GSK's last batch of Zantac pills, Lot # 7ZP2359, was manufactured on April 3, 2017, in GSK's Zebulon, North Carolina facility. Lot 7ZP2359 consisted of 25,260 30-pill containers of 300 mg Zantac and used active pharmaceutical ingredient ("API") manufactured by Dr. Reddy's laboratories in India.

218. GSK testing has shown that products made with API from Dr.

Reddy's contain more NDMA than the same products using a different API supplier.

219. Whenever a lot is manufactured, the manufacturer is required to set aside, store, and maintain samples of that lot until 1 year after its expiration date. 21 C.F.R. § 211.170(a)(1). So, for Lot # 7ZP2359, GSK was required to maintain retained samples until at least April 30, 2020.

220. Following the 1 year after expiration, if there is "[a]ny evidence of reserve sample deterioration" the manufacturer is required to conduct a thorough investigation. 21 C.F.R. § 211.170(b); 21 C.F.R. § 211.192 (describing the type of investigation required and noting that "[a]ny unexplained discrepancy," like NDMA contamination, "shall be thoroughly investigated, whether or not the batch has already been distributed.").

221. GSK maintained samples of Lot # 7ZP2359 until April 30, 2020. However, in May 2020, GSK destroyed the samples and did not test the pills for NDMA. These were the *only* U.S. samples in GSK's possession and had been stored under ideal "labeled" conditions in GSK's own facilities. They would have provided powerful evidence of NDMA levels in GSK's U.S. product.

222. GSK's destruction of evidence was done despite (1) lawsuits being filed alleging NDMA contamination starting on September 13, 2019; (2) an order from a federal judge on November 19, 2019, ordering GSK to preserve "potentially

relevant … tangible things within the Parties' possession, custody and/or control[.]"; (3) an order from the MDL Court on February 6, 2020 directing GSK "to preserve evidence that may be relevant to this action" and "take reasonable steps to preserve all … tangible things[.]"; and (4) a request from the FDA on April 1, 2020, to remove all ranitidine from the market.

223. GSK violated multiple court orders and its obligations under federal and state law when it destroyed its last remaining U.S. retained samples of Zantac. And, even more vexing, GSK destroyed these pills without testing them for NDMA, in violation of federal regulations, even though it was well known at that point that ranitidine degraded into NDMA.

224. Remarkably, GSK's destruction of evidence was not limited to this last batch of pills, but it extended to the actual API used in GSK's pills. Specifically, between October 2019 and November 2020—a period of active litigation and multiple investigations into the presence of NDMA in ranitidine—GSK destroyed 9 batches of ranitidine API, which were all used in U.S. Zantac products. None of these batches of API were tested for NDMA.

225. As a Discovery Referee overseeing California state court litigation involving ranitidine explained it: "[T]he idea that a routine destruction policy could go on in the face of two federal court orders is enough to make me gag. . . . [I] think you're making me get a little more upset as you're defending something

that's indefensible[.]"

F. Since 1983, GSK's Fraud Caused the Distribution, Sale, Receipt, and Manufacture of Adulterated, Misbranded, Worthless, and/or False Brand Name and Generic Ranitidine Products Throughout the United States

226. The ability of ranitidine to degrade into NDMA is a chemical process. Ranitidine molecules in 1981 chemically react the same way ranitidine molecules in 2019 react. The scientific data is clear—the degradation process of ranitidine into NDMA involves an intermolecular reaction that is not affected by excipients, which occurs from the moment of manufacture until ingested, accelerated by heat and humidity.

227. It is a criminal offense to introduce or cause to be introduced into interstate commerce a drug that is adulterated or misbranded. 21 U.S.C. § 331(a). It is also a crime to cause the adulteration or misbranding of any drug in interstate commerce. 21 U.S.C. § 331(b). It is also a crime to cause receipt in interstate commerce of any drug that is adulterated or misbranded for pay or otherwise. 21 U.S.C. § 331(c). It is also a crime to manufacture a misbranded or adulterated drug in the United States. 21 U.S.C. § 331(g).

228. A drug is adulterated if "it consists in whole or in part of any filthy, putrid, or *decomposed substance*." 21 U.S.C. § 351(a) (emphasis added). NDMA is a decomposed substance of ranitidine. NDMA is a prohibited substance in medications that provides no therapeutic value. Indeed, NDMA is banned in all

drugs and is considered unsafe at levels in excess of 96 ngs / day. Thus, a ranitidine product containing NDMA is an adulterated drug, whose distribution within interstate commerce constitutes a criminal act. FDA has confirmed that ranitidine medications containing NDMA are adulterated and cannot be sold in the United States. This is why, when the FDA discovered the adulteration of ranitidine products, they were removed from the market and ordered to be immediately disposed.

229. This chemical degradation process occurs in prescription products and OTC ranitidine products. All prescription and OTC products were adulterated.

230. A drug is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a). It is also considered misbranded if the drug "is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed." 21 U.S.C. § 352(j).

231. Since first being approved, the ranitidine label for prescription ranitidine, which has been controlled at all times by GSK for both brand and generic versions, does not disclose that ranitidine can expose users to NDMA and is, therefore, false and misleading. Every prescription of ranitidine has been misbranded since 1983, and its sale, distribution, and manufacture within the United States constituted a criminal act. Similarly, the labeling for OTC ranitidine was false and misleading for the same reasons and rendered its sale a criminal act.

Importantly, GSK first developed and controlled the labeling of OTC ranitidine products and, thus, caused all OTC products thereafter to be misbranded, also in violation of 21 U.S.C. § 331(a). Moreover, the OTC products cited to and relied on GSK's prescription NDAs to obtain approval for all labeling.

232. As evidenced by the fact that the FDA removed ranitidine products due to its connection to NDMA in April 2020, had GSK been honest about its testing data prior to ranitidine's approval, the drug would not have been introduced into interstate commerce as an adulterated and/or misbranded drug. Importantly, by deceiving the FDA about the connection between ranitidine and NDMA, GSK defrauded the FDA into approving ranitidine and caused the widespread distribution, sale, receipt, and manufacture of adulterated and misbranded ranitidine within interstate commerce since 1983.

233. GSK's fraudulent conduct and false statements to the FDA caused the distribution, sale, receipt, and manufacture of adulterated and misbranded ranitidine for both brand and generic ranitidine products throughout the United States since 1983.

234. Ranitidine medication is a worthless product as evidenced by the FDA ordering the drug's removal from the market and the immediate disposal of all ranitidine products due to its inherent ability to form NDMA. Since being recalled, no ranitidine product has been permitted for sale within the United States.

235. All ranitidine products were not the products offered for sale, as in addition to containing the active ingredient ranitidine, those products also contained NDMA, which rendered ranitidine products not what they purported to be.

G. The Government Health Care Programs Covering Drug Costs

236. Various federal and state programs pay for prescription and OTC medications for patients, including, but not limited to, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, the Indian Health Service, Medicaid, and other state-funded programs.

237. For each program, as a precondition for payment or reimbursement, the drug must be approved by the FDA. None of these programs countenance payment for adulterated, misbranded, or worthless medications. None of these programs allow for the purchase of drugs that are unsafe for human consumption. None of these programs would have ever paid any money on ranitidine-containing products had GSK not lied to the FDA, federal government, and the medical community about the ability of ranitidine to decompose into NDMA.

1. Medicaid and Related State Medicaid Programs

238. Title XIX of the Social Security Act is a program which provides medical assistance for certain individuals and families with low incomes and

resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children.

239. The Medicaid Program (42 U.S.C. § 1395, *et seq.*) is administered through the Centers for Medicare and Medicaid Services ("CMS"), which is a division of the Department of Health and Human Services ("DHHS") of the federal government.

240. The U.S. Government partially funds state-sponsored medical-assistance programs for low-income individuals and families pursuant to the Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* ("Medicaid").

241. Each state—including each Plaintiff State—administers its own Medicaid program, but the states' programs are governed by federal statutes, regulations, and guidelines approved by DHHS through CMS. *See* 42 U.S.C. §§ 1396a(a)–(b). The individual state programs reimburse doctors, hospitals, pharmacies, and other providers for services and items—including outpatient drugs—provided to program participants, according to established rates. *See* 42 U.S.C. §§ 1903(a)(1), 1396b(a)(1). The states receive federal funds to pay for

Medicaid services and items. *See* 42 U.S.C. § 1396b(a)(1).

242. In order to qualify for federal funds for Medicaid expenditures, each Plaintiff State has been required to implement a plan containing certain specified minimum criteria for coverage and payment of claims. *See* 42 U.S.C. § 1396a(a)(30)(A). Benefits for drugs are optional, but all Plaintiff States have opted to provide Medicaid drug reimbursement coverage.

243. Medicaid's tailored program for drug reimbursement coverage has created significant and ongoing commercial, contractual, legal, and regulatory ties between pharmaceuticals manufacturers like GSK, and the federal and state governments.

244. As one recent expert analysis of Medicaid's pharmaceuticals program explained:

> Under federal law establishing the Medicaid Drug Rebate Program, in order for a drug to qualify for federal statutory Medicaid matching funds, manufacturers must sign an agreement with the Secretary of Health and Human Services stating that they will rebate a specified portion of the Medicaid payment for the drug to the states, who in turn share the rebates with the federal government. In return, Medicaid must cover almost all FDA-approved drugs that those manufacturers produce. Because most manufacturers participate in the Medicaid Drug Rebate Program, Medicaid essentially maintains an open formulary in which all drugs are covered. However, state Medicaid programs can and do implement drug utilization management techniques, such as preferred drug lists and prior authorizations, to manage utilization and spending.[49]

[49] Katherine Young, *Utilization & Spending Trends in Medicaid Outpatient Prescription Drugs*, Henry J. Kaiser Family Foundation (Issue Brief, Feb. 2019) (citing, *inter alia*, 42 USC § 1396r-8(a)(1)).

245. At times relevant here, CMS contracted with private contractors referred to as "fiscal intermediaries" and "carriers" to act as agents in receiving and paying Medicaid claims. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 431.100.

246. Drugs must be FDA-approved for safety and effectiveness to qualify for Federal and State payments under Medicaid and each state Medicaid program. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must be reasonable and necessary for the diagnosis or treatment of illness or injury. 42 U.S.C. § 1395y(a)(1)(A). Prescribed drugs are not reasonable and necessary if they have not received FDA approval.

247. The following chart estimates the money spent by Medicaid programs in each state for generic and brand name ranitidine products between 1991 and 2020. Public data regarding Medicaid expenditures prior to 1991 are not available. Relator estimates that two to three times as much was paid for branded and generic ranitidine between 1983 and 1991.

State	Brand	Generic	Total
AK	$4,205,969.50	$3,535,618.24	$7,741,587.74
AL	$48,286,434.50	$33,699,498.32	$81,985,932.82
AR	$27,578,850.16	$14,920,440.49	$42,499,290.65
AZ	$206,333.01	$15,762,298.91	$15,968,631.92
CA	$102,018,456.82	$75,297,312.27	$177,315,769.09
CO	$18,727,168.16	$19,878,979.32	$38,606,147.48
CT	$35,233,238.78	$18,688,722.61	$53,921,961.39
DC	$6,859,648.52	$3,522,824.86	$10,382,473.38
DE	$6,752,268.87	$2,805,669.51	$9,557,938.38
FL	$197,059,299.29	$83,371,179.49	$280,430,478.78

GA	$58,414,774.58	$56,733,032.62	$115,147,807.20
HI	$5,643,889.27	$3,784,522.51	$9,428,411.78
IA	$20,974,303.14	$15,225,497.64	$36,199,800.78
ID	$7,787,334.84	$5,667,230.76	$13,454,565.60
IL	$109,920,559.27	$80,686,213.72	$190,606,772.99
IN	$51,319,501.33	$27,789,562.50	$79,109,063.83
KS	$14,044,507.11	$5,023,293.55	$19,067,800.66
KY	$76,604,681.43	$78,192,656.88	$154,797,338.31
LA	$94,681,479.52	$30,583,900.11	$125,265,379.63
MA	$81,727,409.42	$39,218,704.44	$120,946,113.86
MD	$39,863,276.28	$11,202,594.42	$51,065,870.70
ME	$22,063,936.19	$9,618,026.86	$31,681,963.05
MI	$88,508,853.03	$36,998,516.98	$125,507,370.01
MN	$40,738,533.49	$17,043,474.37	$57,782,007.86
MO	$60,127,339.21	$79,716,703.18	$139,844,042.39
MS	$32,686,371.98	$27,576,411.83	$60,262,783.81
MT	$9,718,742.55	$3,437,340.69	$13,156,083.24
NC	$48,854,061.15	$47,918,901.32	$96,772,962.47
ND	$5,455,205.73	$1,463,198.13	$6,918,403.86
NE	$16,361,601.88	$5,328,778.31	$21,690,380.19
NH	$17,922,644.07	$6,478,254.95	$24,400,899.02
NJ	$100,695,431.56	$27,912,380.50	$128,607,812.06
NM	$8,540,446.69	$6,175,943.44	$14,716,390.13
NV	$37,241,251.10	$6,110,827.27	$43,352,078.37
NY	$201,490,982.64	$114,954,157.17	$316,445,139.81
OH	$128,922,744.63	$41,383,528.02	$170,306,272.65
OK	$25,490,432.26	$16,953,047.51	$42,443,479.77
OR	$15,317,939.86	$8,371,737.27	$23,689,677.13
PA	$147,773,136.10	$45,305,450.46	$193,078,586.56
RI	$16,516,007.77	$6,575,709.46	$23,091,717.23
SC	$54,248,615.76	$33,831,091.03	$88,079,706.79
SD	$16,497,846.77	$87,320,400.37	$103,818,247.14
TN	$103,034,258.04	$665,781,122.96	$768,815,381.00
TX	$128,038,104.83	$43,119,196.19	$171,157,301.02
UT	$10,399,185.18	$5,517,329.70	$15,916,514.88
VA	$80,049,568.07	$36,141,829.72	$116,191,397.79
VT	$9,279,127.18	$1,614,896.52	$10,894,023.70
WA	$56,296,070.12	$583,558,441.73	$639,854,511.85
WI	$50,864,170.47	$16,609,758.64	$67,473,929.11

WV	$44,073,810.12	$31,179,235.50	$75,253,045.62
WY	$4,305,645.83	$1,060,227.78	$5,365,873.61
Total	**$2,589,421,448.06**	**$2,640,645,671.03**	**$5,230,067,119.09**

2. Medicare

248. Congress created the program known as "Medicare" in 1965 when it enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. Entitlement to Medicare is based primarily on advanced age or disability. 42 U.S.C. §§ 426, 426A. Medicare uses federal government funds to reimburse hospitals and medical providers for certain healthcare costs for program participants.

249. At all times relevant here, CMS contracted with private contractors referred to as "fiscal intermediaries" and "carriers" to act as agents in receiving and paying Medicare claims. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 431.100.

250. Drugs must be FDA-approved for safety and effectiveness to qualify for Federal and State payments under Medicare. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

251. Medicare is organized into several coverage initiatives known as "Parts."

252. Medicare Part B has long covered outpatient prescription drugs provided to a patient "incident to" physician services. 42 U.S.C. § 1395x(s)(2)(a).

Like all drugs paid for through Medicare, for a drug to be reimbursable, it must be FDA approved and legally permitted in commerce.

253. Public data concerning Medicare Part B reaches back to 2000. Between 2000 and 2020, Medicare reimbursed 5.7 million ranitidine products, paying an estimated $5,489,635.

254. Since January 1, 2006, Medicare Part D has provided comprehensive outpatient prescription drug coverage for brand name and generic drugs according to national and local coverage determinations. *See* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173.[50] Coverage of drugs under Medicare Part D is subject to the same regulations as coverage under Medicaid as described above.

255. The Medicare Part D prescription drug benefit is offered by private prescription drug plans ("PDPs") and Medicare Advantage prescription drug plans ("MA-PDs"). Medicare beneficiaries have a choice among many different plans in each state. Medicare reimburses the private plans for its coverage of Medicare beneficiaries.

256. The various versions of brand and generic ranitidine as identified in

[50] For "dual eligibles"—individuals who received drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005—enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

this complaint are covered drugs under Medicare Part D, and the federal and state governments—including the Government Plaintiffs—are thus among the largest, if not the largest, end-purchasers of these products.

257. Drugs must be FDA-approved for safety and effectiveness to qualify for Federal and State payments under Medicaid and each state Medicaid program. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

258. Data since 2006 for Medicare Part D is not all available. However, as shown in the chart below, the following payments were made under Part D for ranitidine products between 2012 and 2019.

Medicare Part D Ranitidine Expenditures	
2012	$76,256,189.80
2013	$92,572,018.39
2024	$97,708,749.38
2015	$94,275,651.50
2016	$106,696,509.45
2017	$108,931,496.03
2018	$125,853,897.48
2019	$92,409,996.73
Total	**$794,704,508.76**

3. The Railroad Retirement Medicare Program

259. The Railroad Retirement Medicare program is authorized by the Railroad Retirement Act of 1974, at 45 U.S.C. §231 *et seq.* It is administered

through the United States Railroad Retirement Board, "RRB," and furnishes Medicare coverage to retired railroad employees.

260. Drugs must be FDA-approved for safety and effectiveness to qualify for Federal and State payments under the RRB Medicare program. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

261. Payments for ranitidine containing products were issued in the RRB program.

4. Tri-Care

262. The Tri-Care program, formerly CHAMPUS, is administered by the United States Department of Defense ("DoD") through its component in agency, CHAMPUS, under the authority of 10 U.S.C. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents.

263. Drugs must be FDA-approved for safety and effectiveness to qualify for payments under Tri-Care. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

264. Payments for ranitidine containing products were issued in the Tri-

Care program.

5. The Veterans Administration

265. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares program is administered by Health Administration Center and its offices are located in Denver, Colorado. In general, the CHAMPVA program covers most health care services and supplies that are medically necessary.

266. Due to the similarity between CHAMPVA and the DoD Tri-Care program, the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases, a veteran may appear to be eligible for both/either program on paper. However, military retirees, or the spouse of a veteran who was killed in action, are and will always be Tri-Care beneficiaries.

267. Pursuant to 38 U.S.C. §8126, and the regulations based thereon, and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

268. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of

military veterans, their spouses (or widowed spouses) and other beneficiaries.

269. Drugs must be FDA-approved for safety and effectiveness to qualify for payments by the Veterans Administration. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

270. Payments for ranitidine containing products were issued by the Veterans Administration. A recent report by federal auditors found that ranitidine ranked twelfth in a survey of the drugs most commonly utilized by providers who reimburse through the DOD or VA. *See Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices*, at 19, U.S. Gov't Accountability Office (Apr. 2013).[51]

6. Indian Health Service

271. The Indian Health Service ("HIS"") is responsible for providing

[51] The DOD and VA spend approximately $12 billion a year to purchase drugs on behalf of roughly 18.5 million active-duty and retired military personnel, their dependents, and eligible veterans, according to the most recent data from the federal government. *See* Joanna Shepherd, *The Prescription for Rising Drug Prices: Competition or Price Controls?*, 27 Health Matrix 315, 334–35 (2017). These agencies face substantial complexity and obscurity concerning the prices paid for pharmaceuticals. *See Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices*, at 1, U.S. Gov't Accountability Office (Apr. 2013) ("DOD and VA face continued challenges in controlling drug costs. While the prescription drug market is complex and there are many factors affecting the prices DOD and VA are able to obtain for directly purchased drugs, differences in prices paid for specific drugs may provide insights into opportunities for each agency to obtain additional savings on at least some of the drugs they purchase.").

comprehensive health services to more than 2,100,000 Americans. It is administered by the department of health and human services pursuant to 42 U.S.C.A. 2002 *et seq*. IHS provides health care to American Indians and Alaska Natives who live on or near Indian reservations or in Alaska Native villages. HIS provides services free of charge to all eligible beneficiaries.

272. Drugs must be FDA-approved for safety and effectiveness to qualify for payments by the IHS. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

273. Payments for ranitidine containing products were issued by the HIS.

7. The Federal Employees Health Benefits Program

274. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5 U.S.C. § 8901 *et seq.*, and provides health care coverage to federal employees, retirees and their dependents and survivors.

275. Drugs must be FDA-approved for safety and effectiveness to qualify for payments under the FEHBP. Specifically, as a precondition for payment or reimbursement of ranitidine containing products, the drug must first be approved by the FDA and eligible for sale within the United States.

276. Payments for ranitidine containing products were issued by the

FEHBP.

H. The Regulatory System Governing Pharmaceuticals Eligible for Taxpayer-Funded Reimbursement

277. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of, among other things, drugs administered to human patients. The FDA is also responsible for administration of the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.*[52]

278. Through the FDA, the federal government endeavors to assure the safety and efficacy of drug products consumed daily by millions of Americans through a combination of approvals, inspections, enforcement, and self-regulation by manufacturers like GSK. As one FDA attorney has noted, these manufacturers "occupy a virtual fiduciary relationship to the public. . . . FDA shares this trustee relationship to the consumer with industry leaders, but the initial and ultimate responsibility remains with those leaders. This is true not only because the law makes it so, but also for the practical reason that the FDA cannot . . . monitor every decision that is made every day that affects the quality of our . . . drugs."[53]

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[52] The FDCA has been amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, 21 U.S.C. § 355(j), 35 U.S.C. § 271(e) (2005).

[53] Eric M. Blumberg, "Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug, and Cosmetics Act," 55 Food & Drug L.J., 145, 147. (emphasis added).

279. The brand drug maker bears responsibility for the accuracy and content of the drug label at all times, and is charged with updating it upon discovery of information that would bear upon the safety or efficacy of the medication.

280. Under the FDCA, new pharmaceutical drugs cannot be marketed or sold in interstate commerce in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), -(d).

281. The FDCA requires that pre-market approval for a new drug must be sought by filing an NDA with the FDA. 21 U.S.C. § 355(b). As a condition for FDA approval, the manufacturer must present substantial evidence of its safety and effectiveness for its intended use through adequate and well-controlled studies. 21 C.F.R. § 314.50(d).

282. FDA regulations specify the characteristics of what constitutes an adequate and well-controlled study. Noting that these characteristics "have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation[,]" the regulations detail the following requirements, among others: a clear statement of the objective of the investigation and a summary of the methods of analysis actually used; a study design "that permits a valid comparison with a control"

group; and adequate measures to minimize bias on the part of the subjects, observers and analysts of the data. 21 C.F.R. § 314.126(a)–(b).

283. The FDA does not approve a drug for treatment of a disease in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested. The specific approved uses are called the "indications" for which the drug may be prescribed. For each approved indication, the FDA will specify particular dosages and dosage frequency determined to be safe and effective. In approving a drug for a given indication, the FDA also approves the language of the product's label (the package insert or prescribing information).

284. The FDCA defines labeling very broadly, such that it includes "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). Promotional materials for a specific drug are considered labeling, and they must conform with the substance and information contained in the FDA-approved label.

285. The FDCA prohibits drug companies from promoting approved drugs by making misleading claims as to any drug's safety. *See* 21 U.S.C. §§ 331, 352, 355(d). Specifically, an advertisement for a drug (as defined above) is "false, lacking in fair balance, or otherwise misleading" if, among other representations, it:

> Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience;
>
> * * *
>
> Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; [or]
>
> * * *
>
> Uses literature, quotations, or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim[.]

21 C.F.R. § 202.1(i)–(ii), -(x).

286. Generic drugs are drugs that the FDA has found to be equivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the same side effects and safety profile as its corresponding brand-name drug.

287. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

288. Generic drug manufacturers are not allowed to devise their own safety information for the consumer. The Hatch-Waxman Act specifically requires the generic drugs' labels be "the same as the labeling approved for the brand-name

drug" in order to gain approval by the FDA. *See* 1984 Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585. Additionally, as a generic medication is considered the bioequivalent to the brand, it cannot contain any substances within it that would render it adulterated or misbranded, such as NDMA.

289. Brand manufacturers who submit NDAs to the FDA for approval are on notice that subsequent generic manufacturers, and the government, will entirely rely on the brand manufacturer's safety and health representations. Brand manufacturers also know that if they conceal safety information from the FDA and from doctors, purchasers of the related generics will rely on the brand manufacturer's misrepresentations. Indeed, GSK actually manufactured ranitidine drug substances and pills for various generic companies.[54]

290. The FDA imposes upon pharmaceuticals companies an ongoing duty to report promptly to the FDA any "adverse drug experience," defined as "[a]ny adverse event[55] associated with the use of a drug in humans, whether or not considered drug related, including . . . any failure of expected pharmacological action." 21 C.F.R. § 314.80(a), (c); *see Wyeth v. Levine*, 555 U.S. 555, 608 (2009)

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[54] For example, from March 2007 to March 2009, GSK and Par Pharmaceutical operated a joint supply-and-distribution agreement, pursuant to which GSK manufactured a generic equivalent to its Zantac syrup, and Par marketed and supplied the product (with GSK earning a percentage of net sales).

[55] The FDA defines "adverse event" as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 312.32.

(Once the FDA approves a drug, "the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug.").

291. This responsibility extends not only to the original NDA applicant, but also "to any person other than the applicant whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor (nonapplicant)." 21 C.F.R. § 314.80(c)(1)(iii).

292. The scope of this ongoing requirement is broad. Applicants and nonapplicants for a given drug must create and follow "written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA[,]" a process that must involve "promptly review[ing] all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b).

293. The requirement to conduct postmarketing surveillance of adverse events concerning a drug is a condition to its continued FDA approval. This requirement is a material one, because the FDA would not continue to approve a

drug where the applicant or nonapplicant ignores or suppresses adverse information—for example, that the drug causes cancer. Drugs whose applicants and nonapplicants fail to meet this requirement are due for prohibition by the FDA. *See* § 314.80(k). The FDA specifically told Defendants, on numerous occasions, of their obligation to meet this requirement with respect to ranitidine.

294. A manufacturer must advise healthcare providers and the medical community of any known facts regarding the safety and/or efficacy of its products, including by updating the product label information, if necessary.

295. When manufacturers learn that their products create a risk to health or safety, they must revise their labels and issue corresponding warnings to providers and the public. The prohibition against misbranded drugs is material, because the FDA does not allow misbranded drugs to be marketed in the United States, which includes sales covered or reimbursed by the government-funded programs.

V. EQUITIBLE TOLLING

296. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

297. GSK designed its fraud to be self-concealing because it knew that once it concealed ranitidine's NDMA potential no medical tester would know to look for it. Further, GSK engaged in substantial conduct to conceal the NDMA-formation dangers.

298. GSK concealed its fraud by concealing its NDMA data in 1981 from the FDA and the medical community.

299. GSK also concealed its fraud by designing its safety studies and NDA application such as to conceal the NDMA dangers of ranitidine. While N-nitrosamine and NDMA formation were known dangers to GSK, it did not draw these dangers to the FDA's attention, nor did it engage in fair and balanced scientific testing to assuage FDA's express concerns. Instead, GSK lied to the FDA.

300. GSK, while on notice of the dangers of NDMA formation in the body as a result of taking ranitidine, conducted junk science with the intention of dissuading investigation into ranitidine's NDMA-formation dangers.

301. GSK designed its product monograph to conceal ranitidine's likelihood of degradation when exposed to acid.

302. GSK submitted materially false and misleading product label inserts to the FDA.

303. GSK issued studies touting Zantac's safety profile by conducting bad science and misrepresenting the science of others.

304. GSK, in contravention of its duties to update under the law, concealed from the FDA—and from CMS and other agencies involved in running Government Health Care Programs—studies that would have demonstrated

ranitidine's NDMA risk.

305. GSK engaged in a massive, nationwide marketing campaign to convince doctors—and patients, for the first time ever—to use ranitidine because of its purportedly superior safety profile, all the while knowing that it was concealing important health safety data.

VI. CAUSES OF ACTION

1. COUNT I: Violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

306. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

307. This Count is brought by Relator in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for GSK's violation of 31 U.S.C. § 3729 *et seq*., as amended.

308. By virtue of the above-described acts, GSK knowingly caused to be presented false or fraudulent claims for ranitidine containing products for payment or approval to the United States, between 1983 and April 1, 2020.

309. Plaintiff United States, unaware of the false or fraudulent nature of the claims caused to be made by GSK and in reliance on the accuracy thereof, paid for ranitidine containing products that would otherwise not have been allowed or permitted but for GSK's fraud as alleged herein.

310. These claims were false because claims for mislabeled, misbranded,

adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for drugs that were worthless; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by government-funded programs.

311. Further, throughout the relevant time period, GSK, through the acts and omissions described herein, have caused false records or statements material to false or fraudulent claims to government-funded programs. GSK knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine, including that it has the safety profile warranted by GSK to the FDA, which it does not. Each claim for reimbursement for such prescriptions and/or OTC ranitidine product, both brand and generic, submitted to a government-funded health insurance program represents a false or fraudulent claim for payment in reliance on GSK's fraudulent statements concerning ranitidine's safety profile, its ability to decompose into NDMA, and whether the drug was adulterated, misbranded, false, or worthless.

312. Each claim and/or payment for ranitidine was factually false because GSK's fraudulent conduct caused the United States to pay for ranitidine products that were not actually ranitidine, rather, they were ranitidine with NDMA. Each claim was factually false because ranitidine products with NDMA are not what

they purport to be and/or are worthless drugs, as evidenced by the FDA ordering all ranitidine products disposed of following the revelation that ranitidine products decompose into NDMA from the point of manufacturer, due to a chemical reaction, during regular transport and storage, prior to being ingested by a taxpayer. Because of GSK's fraudulent statements to the FDA, federal government, and medical community, ranitidine was approved for sale despite the drug being unsafe, unstable, and incapable of not turning into an adulterated, misbranded, and/or worthless drug.

313. Each claim and/or payment for ranitidine was legally false because GSK expressly misrepresented the safety of ranitidine and its ability to decompose into NDMA to the FDA, federal government, and medical community. These express misrepresentations, outlined in detail throughout this complaint, caused each claim for ranitidine to be false and, thus, each payment for a false ranitidine product constituted a false claim under the FCA. Furthermore, GSK expressly certified that ranitidine products were unadulterated, not misbranded, had worth, and were safe for human consumption as a precondition to being able to receive payments from government-funded programs for ranitidine products. Indeed, these express false certifications to the FDA and government-funded programs were the but-for cause for the submission and payment of all ranitidine containing products since 1983 until April 1, 2020.

314. Each claim and/or payment for ranitidine was legally false because GSK impliedly certified that the drugs were unadulterated, not misbranded, had worth, and where safe for human consumption—all preconditions for payment. These implied misrepresentations, outlined in detail throughout this complaint, caused each claim for ranitidine to be false and, thus, each payment for a false ranitidine product constituted a false claim under the FCA. Indeed, these implied false certifications to the FDA and government-funded programs were the but-for cause for the submission and payment of all ranitidine containing products since 1983 until April 1, 2020.

315. Relator cannot at this time identify all the false claims for payment that were caused by GSK's conduct. The false claims were presented by thousands of separate entities, and over decades, until the truth finally came out and the FDA pulled all ranitidine products off the market on April 1, 2020.

316. By reason of GSK's wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the FCA, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim caused to be submitted by GSK.

2. COUNT II: Violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

317. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

318. This Count is brought by Relator in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for GSK's violation of 31 U.S.C. § 3729(a)(1)(B).

319. By virtue of the above-described acts, GSK knowingly caused false records or statements material to false or fraudulent claims for ranitidine to be paid or approved by the United States.

320. Plaintiff United States, unaware of the false or fraudulent nature of the records and/or statements caused to be made and used by GSK, and in reliance on the accuracy thereof, has paid and approved claims for ranitidine that were ineligible for reimbursement and would not have been paid or approved if the truth were known.

321. These claims were false because claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for drugs that were worthless; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by government-funded programs. Relator alleges factual and legal falsity, as outline throughout this complaint.

322. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by

thousands of separate entities, and over many years.

323. By reason of GSK's wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the FCA, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false statement caused to be made or used by GSK.

3. COUNT III: Violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(C)

324. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

325. Defendants entered into conspiracies with third parties for the purpose of defrauding the Plaintiff United States.

326. By the foregoing acts and omissions, Defendants took actions in furtherance of its conspiracies, including but not limited to its joint marketing venture with Par Pharmaceutical, Pfizer, and BI, thereby exponentially increasing the number of ranitidine prescriptions submitted to the United States for payment.

327. By the foregoing acts and omissions, GSK entered into these unlawful conspiracies to defraud the United States by causing false and fraudulent claims to be paid and approved in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

328. At all times relevant to the complaint, GSK acted with the requisite

knowledge.

329. As a direct and proximate consequence of GSK's conspiratorial conduct, the United States has suffered significant, material financial damages in an amount to be proved at trial.

330. GSK are liable for multiple damages under the FCA, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each ineligible ranitidine claim submitted to the United States for payment.

4. COUNT IV: Violations of the California False Claims Act, Cal. Gov't Code § 12651(a)

331. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

332. This is a claim for treble damages and penalties under the California False Claims Act.

333. Cal. Gov't Code § 12651(a) provides liability for the costs of a civil action, a civil penalty of up to $11,000 and treble damages for all damages sustained by the state for any person who—

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the

state or any political subdivision;

(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision; [or]

(8) is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

334. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. These claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by California. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to California in violation of Section 12651(a) of the California False Claims Act.

335. Further, throughout the relevant time period, Defendants, through the acts and omissions described herein, have knowingly made or used, or caused to be

made or used, false records or statements material to false or fraudulent claims to California, in violation of Section 12651(a). Defendants knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

336. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

337. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

338. The California State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

339. By reason of Defendants' acts and omissions, the California State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

340. The State of California is entitled to the maximum penalty of

$11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

341. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

342. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of California in the operation of its Medicaid program.

343. As a result of Defendant's knowing violations of the California False Claims Act, the United States has sustained actual damages.

5. COUNT V: Violations of the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-305(1)

344. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

345. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

346. The Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-305(1)(a)–(b), provides for liability for anyone who—

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (b) Knowingly makes, uses, or causes to be made or used a false

record or statement material to a false or fraudulent claim . . . .

347. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for reimbursement by Colorado. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1) of the Colorado Medicaid False Claims Act.

348. Further, throughout the relevant time period, Defendants, through the acts and omissions described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Colorado, in violation of Section 25.5-4-305(1) of the Colorado Medicaid False Claims Act. Defendants knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Colorado

in violation of Section 25.5-4-305(1).

349. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

350. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

351. The Colorado State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

352. By reason of Defendants' acts and omissions, the Colorado State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

353. The State of Colorado is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

354. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

355. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

356. As a result of Defendants' knowing violations of the Colorado Medicaid False Claims Act, the United States has sustained actual damages.

6. COUNT VI: Violations of the Connecticut False Claims Act, Conn. Gen. Stat. Ann. § 4-275(a)

357. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

358. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

359. The Connecticut False Claims Act, Conn. Gen. Stat. Ann. § 4-275(a), provides for liability for individuals and entities who—

> (1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;
>
> (2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program; [or]
>
> (3) Conspire to commit a violation of [the act] . . . .

360. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for reimbursement by Connecticut. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 4-275(a) of the Connecticut False Claims Act.

361. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Connecticut, in violation of Section 4-275(a). Defendants knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

362. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement.

Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

363. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

364. The Connecticut State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

365. By reason of Defendants' acts and omissions, the Connecticut State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

366. The State of Connecticut is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

367. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

368. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Connecticut in

the operation of its Medicaid program.

369. As a result of Defendants' knowing violations of the Connecticut False Claims Act, the United States has sustained actual damages.

7. COUNT VII: Violations of the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)

370. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

371. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

372. The Delaware False Claims and Reporting Act, Del Code Ann. tit. 6, § 1201(a)(1), provides that any person who:

> knowingly presents or causes to be presented, directly or indirectly, a false or fraudulent claim for payment or approval . . . shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

373. The Delaware False Claims and Reporting Act, Del Code Ann. tit. 6, § 1201(a)(2), provides that any person who:

> knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent

> claim paid or approved . . . shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

374. The Delaware False Claims and Reporting Act, Del Code Ann. tit. 6, § 1201(a)(3), provides that any person who:

> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid . . . shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

375. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by

provide the product the government contracted to purchase are not eligible for reimbursement by Delaware. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 1201(a) of the Delaware False Claims and Reporting Act.

376. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Connecticut, in violation of Section 1201(a). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

377. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

378. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

379. The Delaware State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid

and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

380. By reason of Defendants' acts and omissions, the Delaware State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

381. The State of Delaware is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

382. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

383. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

384. As a result of Defendants' knowing violations of the Delaware False Claims and Reporting Act, the United States has sustained actual damages.

8. COUNT VIII: Violations of the Florida False Claims Act, Fla. Stat. § 68.082(2)

385. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

386. This is a claim for treble damages and penalties under the Florida

False Claims Act.

387. Fla. Stat § 68.082(2)(a)-(c) provides that any person who—

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a fraudulent claim . . . is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.
>
> (c) Conspires to commit a violation of [the Florida False Claims Act] . . . is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

388. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs

whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for reimbursement by Florida. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082 of the Florida False Claims Act.

389. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Florida, in violation of Section 68.082(2). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

390. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

391. Relator cannot at this time identify all the false claims for payment

that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

392. The Florida State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

393. By reason of Defendants' acts and omissions, the Florida State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

394. The State of Florida is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

395. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

396. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

397. As a result of Defendants' knowing violations of the Florida False Claims Act, the United States has sustained actual damages.

9. COUNT IX: Violations of the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)

398. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

399. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

400. The Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1)–(3), provides for liability for anyone who—

> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program; [or]
>
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid . . . .

401. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs

unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for reimbursement by Georgia. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Florida in violation of Section 49-4-168.1 of the Georgia False Medicaid Claims Act.

402. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Georgia, in violation of Section 49-4-168.1. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

403. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

404. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

405. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

406. By reason of Defendants' acts and omissions, the Georgia State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

407. The State of Georgia is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

408. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

409. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

410. As a result of Defendants' knowing violations of the Georgia False Medicaid Claims Act, the United States has sustained actual damages.

10. COUNT X: Violations of the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)

411. Relator restates and incorporates each and every allegation above as if

the same were fully set forth herein.

412. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

413. The Hawaii False Claims Act, Haw. Rev. Stat § 661-21(a) specifically provides that any person who—

> (1) Knowingly presents, or causes to be presented, a false or-fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (8) Conspires to commit any of the conduct described in this subsection, shall be liable to the State for a civil penalty of not less than $ 5,500 and not more than $ 11,000, plus three times the amount of damages that the State sustains due to the act of that person.

414. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product

the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for reimbursement by Hawaii. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section § 661-21 of the Hawaii False Claims Act.

415. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Hawaii, in violation of Section § 661-21. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

416. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

417. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

418. The Hawaii State Government, unaware of the falsity of the records,

statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

419. By reason of Defendants' acts and omissions, the Hawaii State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

420. The State of Hawaii is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

421. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

422. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

423. As a result of Defendants' knowing violations of the Hawaii False Claims Act, the United States has sustained actual damages.

11. COUNT XI: Violations of the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/3(a)

424. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

425. This is a claim for treble damages and penalties under the Illinois False Claims Act.

426. The Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/3(a)(1), specifically provides that any person who—

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of [the Act] . . .
>
> is liable to the State for a civil penalty of not less than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

427. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for worthless drugs unfit for human consumption; claims for drugs that are not "reasonable and necessary" for treatment of patients; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for

reimbursement by Illinois. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Illinois in violation of Section § 175/3 of the Illinois False Claims Act.

428. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Illinois, in violation of Section § 175/3. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

429. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

430. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

431. The Illinois State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and

omissions.

432. By reason of Defendants' acts and omissions, the Illinois State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

433. The State of Illinois is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

434. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

435. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

436. As a result of Defendants' knowing violations of the Illinois False Claims Act, the United States has sustained actual damages.

12. COUNT XII: Violations of the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-2(b)

437. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

438. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

439. The Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-2(b), specifically provides that by engaging in certain acts a person commits an unlawful act and shall be liable to the state for civil penalties of at least $5,000 and for up to three times the amount of damages that the state sustains because of the act of that person, including knowingly or intentionally:

> (1) present[ing] a false claim to the state for payment or approval;
>
> (2) mak[ing] or us[ing] a false record or statement to obtain payment or approval of a false claim from the state; . . .
>
> (8) conspiring with another person to perform an act described in subdivisions (1) through (6); [or]
>
> (9) caus[ing] or induc[ing] another person to perform an act described in subdivision (1) through (6).

440. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for worthless drugs unfit for human consumption; claims for drugs that are not "reasonable and necessary" for treatment of patients; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide

the product the government contracted to purchase are not eligible for reimbursement by Indiana. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Indiana in violation of Section § 5-11-5.5-2(b) of the Indiana False Claims and Whistleblower Protection Act.

441. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Indiana, in violation of Section § 5-11-5.5-2(b). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

442. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

443. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

444. The Indiana State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and

continues to pay the claims that would not be paid but for Defendants' acts and omissions.

445. By reason of Defendants' acts and omissions, the Indiana State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

446. The State of Indiana is entitled to the maximum penalty of at least $5,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

447. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

448. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

449. As a result of Defendants' knowing violations of the Indiana False Claims and Whistleblower Protection Act, the United States has sustained actual damages.

13. COUNT XIII: Violations of the Iowa False Claims Act, Iowa Code § 685.2(1)

450. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

451. This is a claim for treble damages and penalties under the Iowa False Claims Act.

452. The Iowa False Claims Act, Iowa Code § 685.1(1), provides for liability for anyone who—

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (c) Conspires to commit a violation of [the act] . . . .

453. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by provide the product the government contracted to purchase are not eligible for reimbursement by Iowa. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Iowa in violation of Section § 685.2(1) of the Iowa False Claims Act.

454. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Iowa, in violation of Section § 685.2(1). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

455. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

456. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

457. The Iowa State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

458. By reason of Defendants' acts and omissions, the Iowa State Government has been damaged, and continues to be damaged, in substantial

amounts to be determined at trial.

459. The State of Iowa is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

460. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

461. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Iowa in the operation of its Medicaid program.

462. As a result of Defendants' knowing violations of the Iowa False Claims Act, the United States has sustained actual damages.

14. COUNT XIV: Violations of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:438.3

463. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

464. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

465. The Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:438.3, provides that:

> A. No person shall knowingly present or cause to be presented

a false or fraudulent claim.

B. No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.

C. No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

D. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

466. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for worthless drugs unfit for human consumption; and claims for drugs that are not "reasonable and necessary" for treatment of patients; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by

Louisiana. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3 of the Louisiana Medical Assistance Programs Integrity Law.

467. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Louisiana, in violation of Section 46:438.3. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

468. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

469. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

470. The Louisiana State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and

omissions.

471. By reason of Defendants' acts and omissions, the Louisiana State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

472. The State of Louisiana is entitled to the maximum penalty of $10,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

473. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

474. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

475. As a result of Defendants' knowing violations of the Louisiana Medical Assistance Programs Integrity Law, the United States has sustained actual damages.

15. COUNT XVI: Violations of the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, § 5B

476. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

477. This is a claim for treble damages and penalties under the

Massachusetts False Claims Law.

478. The Massachusetts False Claims Law, Mass. Gen. Laws, ch. 12, § 5B(a), provides that any person who—

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim; [or]
>
> (3) conspires to commit a violation of this subsection . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $ 5,500 and not more than $ 11,000 per violation . . . , plus 3 times the amount of damages, including consequential damages, that the commonwealth or a political subdivision thereof sustains because of such violation.

479. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by

Massachusetts. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B of the Massachusetts False Claims Law.

480. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Massachusetts, in violation of Section 5B. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

481. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a Massachusetts-funded health insurance program represents a false or fraudulent claim for payment.

482. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

483. The Commonwealth of Massachusetts Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by

Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

484. By reason of Defendants' acts and omissions, the Commonwealth of Massachusetts Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

485. The Commonwealth of Massachusetts is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

486. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

487. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

488. As a result of Defendants' knowing violations of the Massachusetts False Claims Law, the United States has sustained actual damages.

16. COUNT XVII: Violations of the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.607, as amended by 2008 PA 421

489. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

490. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

491. The Michigan Medicaid False Claims Act imposes liability upon, among others, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Mich. Comp. Laws § 400.607(1).

492. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Michigan. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607 of the Michigan Medicaid False Claims Act.

493. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or

fraudulent claims to Michigan, in violation of Section 400.607. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

494. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

495. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

496. The Michigan State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

497. By reason of Defendants' acts and omissions, the Michigan State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

498. The State of Michigan is entitled to the maximum penalty under the law for each and every false or fraudulent claim, record, or statement made, used,

presented, or caused to be made, used, or presented by Defendants.

499. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

500. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

501. As a result of Defendants' knowing violations of the Michigan Medicaid False Claims Act, the United States has sustained actual damages.

17. COUNT XVIII: Violations of the Michigan Public Acts, 1977 PA 72, As amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421

502. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

503. Relator states a claim for treble damages and penalties under the Michigan Medicaid False Claims Act, brought by Relator on behalf of itself and, among others, the State of Michigan.

504. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for worthless drugs unfit for

human consumption; claims for drugs that are not "reasonable and necessary" for treatment of patients; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Michigan. Through this conduct, Defendants knowingly violated the Michigan Medicaid False Claims Act.

505. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Michigan, in violation of the Michigan Medicaid False Claims Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

506. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

507. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

508. The Michigan State Government, unaware of the falsity of the

records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

509. By reason of Defendants' acts and omissions, the Michigan State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

510. The State of Michigan is entitled to the maximum penalty under the law for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

511. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

512. Relator's principals are private persons with direct and independent knowledge of the allegations in this Complaint, and they have caused Relator to bring this action pursuant to Michigan's False Medicaid Claims Act on behalf of both Relator and the State of Michigan.

513. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

514. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

18. COUNT XIX: Violations of the Minnesota False Claims Act, Minn. Stat. § 15C.02(a)

515. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

516. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

517. The Minnesota False Claims Act, Minn. Stat. § 15C.02(a), provides for liability for anyone who—

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (3) knowingly conspires to commit a violation of [the act] . . . .

518. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not

"reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Minnesota. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a) of the Minnesota False Claims Act.

519. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Minnesota, in violation of Section 15C.02(a). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

520. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

521. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

522. The Minnesota State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

523. By reason of Defendants' acts and omissions, the Minnesota State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

524. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

525. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

526. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

527. As a result of Defendants' knowing violations of the Minnesota False Claims Act, the United States has sustained actual damages.

19. COUNT XX: Violations of the Montana False Claims Act, Mont. Code Ann. § 17-8-403(1)

528. Relator restates and incorporates each and every allegation above as if

the same were fully set forth herein.

529. This is a claim for treble damages and penalties under the Montana False Claims Act.

530. The Montana False Claims Act, Mont. Code Ann., § 17-8-403(1) provides for liability for any person who engages in any or all the following conduct:

> (a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (c) conspires to commit a violation of this subsection (1); [or]
>
> (h) as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim.

531. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs

whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Montana. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403 of the Montana False Claims Act.

532. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Montana, in violation of Section 17-8-403. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

533. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

534. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by

thousands of separate entities, and over many years.

535. The Montana State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

536. By reason of Defendants' acts and omissions, the Montana State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

537. The State of Montana is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

538. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

539. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

540. As a result of Defendants' knowing violations of the Montana False Claims Act, the United States has sustained actual damages.

20. COUNT XXI: Violations of the Nevada False Claims Act, Nev. Rev. Stat. § 357.040

541. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

542. This is a claim for treble damages and penalties under the Nevada False Claims Act.

543. The Nevada False Claims Act, Nev. Rev. Stat., § 357.040(1) provides for liability for any person who—

> (a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; [or]
>
> (b) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim . . . .

544. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Nevada. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040 of the Nevada False

Claims Act.

545. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Nevada, in violation of Section 357.040. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

546. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

547. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

548. The Nevada State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

549. By reason of Defendants' acts and omissions, the Nevada State

Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

550. The State of Nevada is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

551. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

552. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

553. As a result of Defendants' knowing violations of the Nevada False Claims Act, the United States has sustained actual damages.

21. COUNT XXII: Violations of the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b

554. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

555. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

556. The New Hampshire False Claims Act, N.H. Rev. Stat. Ann., § 167:61-b, provides for liability for any person who—

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval[; or]
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.

557. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by New Hampshire. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Hampshire in violation of Section 167:61-b of the New Hampshire False Claims Act.

558. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to New Hampshire, in violation of Section 167:61-b. Defendants

have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

559. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

560. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

561. The New Hampshire State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

562. By reason of Defendants' acts and omissions, the New Hampshire State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

563. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

564. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

565. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

566. As a result of Defendants' knowing violations of the New Hampshire False Claims Act, the United States has sustained actual damages.

22. COUNT XXIII: Violations of the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-3

567. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

568. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

569. The New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-3, provides for liability for any person who—

> (a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used a false

> record or statement to get a false or fraudulent claim paid or approved by the State; [or]
>
> (c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State . . . .

570. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by New Jersey. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3 of the New Jersey False Claims Act.

571. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to New Jersey, in violation of Section 2A:32C-3. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as

warranted by Defendants to the FDA.

572. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

573. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

574. The New Jersey State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

575. By reason of Defendants' acts and omissions, the New Jersey State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

576. The State of New Jersey is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

577. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

578. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

579. As a result of Defendants' knowing violations of the New Jersey False Claims Act, the United States has sustained actual damages.

23. COUNT XXIV: Violations of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-4

580. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

581. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

582. The New Mexico Meidcaid False Claims Act, N.M. Stat. Ann. § 27-14-4, provides for liability for any person who—

> (a) presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent; . . .
>
> (c) makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false; [or]

> (d) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent . . . .

583. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by New Mexico. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4 of the New Mexico Medicaid False Claims Act.

584. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to New Mexico, in violation of Section 27-14-4. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

585. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

586. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

587. The New Mexico State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

588. By reason of Defendants' acts and omissions, the New Mexico State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

589. The State of New Mexico is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

590. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

591. As a result of Defendants' knowing violations of the New Mexico

Medicaid False Claims Act, the United States has sustained actual damages.

592. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

593. As a result of Defendants' knowing violations of the New Mexico Medicaid False Claims Act, the United States has sustained actual damages.

24. COUNT XXV: Violations of the New York False Claims Act, N.Y. State Fin. Law § 189(1)

594. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

595. This is a claim for treble damages and penalties under the New York False Claims Act.

596. The New York False Claims Act, N.Y. State Fin. Law § 189(1), provides for liability for any person who—

> (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (c) conspires to commit a violation of [the act] . . . .

597. Throughout the relevant time period, Defendants caused the

submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by New York. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1) of the New York False Claims Act.

598. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to New York, in violation of Section 189(1). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

599. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

600. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

601. The New York State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

602. By reason of Defendants' acts and omissions, the New York State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

603. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

604. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

605. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

606. As a result of Defendants' knowing violations of the New York False

Claims Act, the United States has sustained actual damages.

25. COUNT XXVI: Violations of the North Carolina False Claims Act, N.C. Gen. Stat. § 1-607(A)

607. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

608. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

609. The North Carolina False Claims Act, N.C. Gen. Stat. § 1-607(A), provides for liability for any person who—

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (3) Conspires to commit a violation of [the act] . . . .

610. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by North

Carolina. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(A) of the North Carolina False Claims Act.

611. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to North Carolina, in violation of Section 1-607(A). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

612. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

613. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

614. The North Carolina State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and

omissions.

615. By reason of Defendants' acts and omissions, the North Carolina State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

616. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

617. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

618. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

619. As a result of Defendants' knowing violations of the North Carolina False Claims Act, the United States has sustained actual damages.

26. COUNT XXVII: Violations of the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B)

620. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

621. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

622. The Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B), provides for liability for any person who—

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; [or]
>
> (3) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid . . . .

623. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Oklahoma. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Oklahoma in violation of Section 5053.1(B) of the Oklahoma Medicaid False Claims Act.

624. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Oklahoma, in violation of Section 5053.1(B). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

625. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

626. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

627. The Oklahoma State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

628. By reason of Defendants' acts and omissions, the Oklahoma State Government has been damaged, and continues to be damaged, in substantial

amounts to be determined at trial.

629. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

630. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

631. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

632. As a result of Defendants' knowing violations of the Oklahoma Medicaid False Claims Act, the United States has sustained actual damages.

27. COUNT XXVIII: Violations of the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a)

633. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

634. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

635. The Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a), provides for liability for any person who—

(1) Knowingly presents, or causes to be presented, a false or

fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]

(3) Conspires to commit a violation of [the act] . . . .

636. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Rhode Island. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a) of the Rhode Island False Claims Act.

637. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Rhode Island, in violation of Section 9-1.1-3(a). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as

warranted by Defendants to the FDA.

638. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

639. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

640. The Rhode Island State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

641. By reason of Defendants' acts and omissions, the Rhode Island State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

642. The State of Rhode Island is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

643. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

644. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

645. As a result of Defendants' knowing violations of the Rhode Island False Claims Act, the United States has sustained actual damages.

28. COUNT XXIX: Violations of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)

646. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

647. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

648. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1), provides for liability for any person who—

> (A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program;
>
> (B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program; [or]
>
> (C) Conspires to commit a violation of [the act] . . . .

649. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Tennessee. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(a) of the Tennessee Medicaid False Claims Act.

650. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Tennessee, in violation of Section 71-5-182(a). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

651. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded

health insurance program represents a false or fraudulent claim for payment.

652. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

653. The Tennessee State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

654. By reason of Defendants' acts and omissions, the Tennessee State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

655. The State of Tennessee is entitled to the maximum penalty of $25,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

656. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

657. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

658. As a result of Defendants' knowing violations of the Tennessee Medicaid False Claims Act, the United States has sustained actual damages.

29. COUNT XXX: Violations of the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.002

659. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

660. This is a claim for maximum damages and penalties under the Texas Medicaid Fraud Prevention Act.

661. The Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.002, provides for liability for any person who—

> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized; [or]
>
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized . . . .

662. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for

mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Texas. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002 of the Texas Medicaid Fraud Prevention Act.

663. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Texas, in violation of Section 36.002. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

664. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

665. Relator cannot at this time identify all the false claims for payment

that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

666. The Texas State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

667. By reason of Defendants' acts and omissions, the Texas State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

668. The State of Texas is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

669. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

670. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

671. As a result of Defendants' knowing violations of the Texas Medicaid Fraud Prevention Act, the United States has sustained actual damages.

30. COUNT XXXI: Violations of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)

672. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

673. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

674. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A), provides for liability for any person who—

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (3) Conspires to commit a violation of [the act] . . . .

675. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Virginia. Through this conduct, Defendants knowingly caused false or fraudulent

claims for payment to Virginia in violation of Section 8.01-216.3(A) of the Virginia Fraud Against Taxpayers Act.

676. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to Virginia, in violation of Section 8.01-216.3(A). Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

677. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a Virginia-funded health insurance program represents a false or fraudulent claim for payment.

678. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

679. The Commonwealth of Virginia Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants'

acts and omissions.

680. By reason of Defendants' acts and omissions, the Commonwealth of Virginia Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

681. The Commonwealth of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

682. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

683. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

684. As a result of Defendants' knowing violations of the Virginia Fraud Against Taxpayers Act, the United States has sustained actual damages.

31. COUNT XXXII: Violations of the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.020(1)

685. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

686. This is a claim for treble damages and penalties under the Washington State Medicaid Fraud False Claims Act.

687. The Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.020(1), provides for liability for any person who—

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (c) Conspires to commit one or more violations [of the act] . . . .

688. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by Washington. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Washington in violation of Section 74.66.020 of the Washington State Medicaid Fraud False Claim Act.

689. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or

fraudulent claims to Washington, in violation of Section 74.66.020. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

690. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

691. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

692. The Washington State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

693. By reason of Defendants' acts and omissions, the Washington State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

694. The State of Washington is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made,

used, presented, or caused to be made, used, or presented by Defendants.

695. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

696. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claims, and merely asserts separate damage to the State of Washington in the operation of its Medicaid program.

697. As a result of Defendants' knowing violations of the Washington State Medicaid Fraud False Claims Act, the United States has sustained actual damages.

32. COUNT XXXIII: Violations of the District of Columbia False Claims Act, D.C. Code § 2-381.02

698. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

699. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

700. The District of Columbia False Claims Act, D.C. Code § 2-381.02, provides for liability for any person who—

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (2) Knowingly makes, uses, or causes to be made or used, a false

record or statement material to a false or fraudulent claim . . . .

701. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for ranitidine. Claims for mislabeled, misbranded, adulterated, or falsely certified drugs; claims for drugs whose FDA approval is subject to withdrawal; claims for drugs that are not "reasonable and necessary" for treatment of patients; claims for worthless drugs unfit for human consumption; and claims for drugs that did not provide the product the government contracted to purchase are not eligible for reimbursement by the District of Columbia. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-381.02 of the District of Columbia False Claims Act.

702. Further, throughout the relevant time period, Defendants, through their acts and omissions as described herein, have knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to the District of Columbia, in violation of Section 2-381.02. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding ranitidine's safety profile, including that it is safe for use as warranted by Defendants to the FDA.

703. Each prescription that was written as a result of Defendants' illegal practices as described above represents a false or fraudulent record or statement.

Each claim for reimbursement for such prescriptions submitted to a District of Columbia-funded health care program represents a false or fraudulent claim for payment.

704. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

705. The District of Columbia Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' acts and omissions.

706. By reason of Defendants' acts and omissions, the District of Columbia Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

707. The District of Columbia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

708. Relator believes and avers that it is an "original source" of the facts and information on which this action is based.

709. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the

federal claims, and merely asserts separate damage to the District of Columbia in the operation of its health care services.

710. As a result of Defendants' knowing violations of the District of Columbia False Claims Act, the United States has sustained actual damages.

VII. PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the Government Plaintiffs, respectfully requests that this Court enter judgment against Defendants as follows:

A. That Defendants be enjoined from violating the provisions of 31 U.S.C. § 3729 *et seq.* and the equivalent State False Claims Acts claims for relief;

B. That this Court enter monetary judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained as a result of Defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 31 U.S.C. § 3729 *et seq.*;

C. That, with respect to the State False Claims Acts claims as set forth above, this Court enter monetary judgment against Defendants for the maximum damages permitted by those statutes (including without limitation trebling or imposition of any other multiplier provided for therein), the maximum fine or penalty permitted by those statutes, and any other recoveries or relief provided for under those statutes.

D. That Relator be awarded the maximum amount allowable pursuant to 31 U.S.C. § 3730(d) of the FCA, and the equivalent provisions of the State False Claims Acts, of the proceeds of this action or settlement of this action collected by the United States and/or any Plaintiff State, with such award being based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action;

E. That Relator be awarded all costs of this action, including reasonable attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and the equivalent provisions of the State False Claims Acts; and

F. That Relator and the Government Plaintiffs be granted such other and further relief as the Court deems just and proper.

VIII. JURY DEMAND

A jury trial is demanded in this case, pursuant to Federal Rule of Civil Procedure 38 and all other applicable law.

Dated: May 20, 2024

Respectfully submitted,

KLINE & SPECTER, P.C.

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Counsel for Relator

CERTIFICATE OF SERVICE

On May 20, 2024, I electronically submitted the foregoing document with the Clerk of the Court for the U.S. District Court, Eastern District of Pennsylvania, using the electronic case filing system of the court. I hereby certify that I served all counsel and/or pro se parties of record via electronic filing.

KLINE & SPECTER, P.C.

May 20, 2024

BY: /s/ Conor Lamb

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