UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

DAVID S. SEBAG,

Plaintiff,

vs.

SANOFI US SERVICES INC., SANOFI- AVENTIS U.S. LLC, SANOFI S.A., CHATTEM, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. GLAXOSMITH KLINE, LLC AND

PFIZER, INC.

Defendants.
_____/

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

COMPLAINT [& JURY DEMAND]

CIVIL ACTION NO. _____

THIS DOCUMENT RELATES TO: *DAVID S. SEBAG v. SANOFI S.A., et. al.*

Plaintiff David S. Sebag sues Defendants SANOFI US SERVICES, INC., SANOFI-AVENTIS U.S. LLC., SANOFI S.A., CHATTEM, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; GLAXOSMITHKLINE, LLC and PFIZER, INC., and upon information and belief, states as follows:

Jurisdiction and Venue

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332

because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Plaintiff is a citizen of a state different from any defendant.

2. Venue is proper because Plaintiff resides in Broward County, Florida and it was the county where he was injured. Venue is also proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business in this District and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market and/or distribute Zantac within Florida and this District and a substantial part of the events giving rise to this action occurred within this District.

Introduction

3. Zantac is the brand name for Ranitidine. Zantac and Ranitidine are used to treat certain stomach and throat problems such as erosive esophagitis, gastroesophageal reflux disease- "GERD", and Zollinger-Ellison syndrome. Zantac is also used to treat ulcers of the stomach and intestines and prevent them from coming back after they have healed.

4. Zantac works by decreasing the amount of acid created by the stomach. Zantac relieves symptoms such as persistent coughs, stomach pain, heartburn, and difficulty swallowing. Zantac and Ranitidine belong to a class of drugs known as H2 receptor blockers.

5. Defendants, Sanofi US Services Inc., Sanofi-Aventis U.S. LLC., Sanofi S.A., Chattem, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., GlaxoSmithKline, LLC and Pfizer, Inc. (hereinafter collectively referred to as "Defendants") designed, developed, researched, manufactured, packaged, tested, advertised, promoted, marketed, distributed, and/or sold Ranitidine products, including Zantac.

6. Plaintiff maintains that Zantac and Ranitidine are defective, dangerous to

human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper warnings and directions as to the dangers associated with their use.

7. Plaintiff seeks compensatory damages as a result of his use of Zantac, which has caused Plaintiff to suffer and continue to suffer from bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of additional health consequences.

8. When warning of safety and risks of Ranitidine, including Zantac, become known, Defendants negligently represented to the medical and healthcare community, the FDA, Plaintiff's treating physicians, and the public in general, that Ranitidine products, including Zantac, had been tested and were found to be safe and/or effective for their indicated use.

9. Defendants concealed their knowledge of Zantac's defects, specifically the fact that it causes cancer and other injuries, from Plaintiff's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

10. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff, Plaintiff's physicians, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Zantac or Ranitidine for the treatment of certain stomach and throat conditions which include GERD, erosive esophagitis, and Zollinger-Ellison syndrome, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of Plaintiff.

11. As a result of the foregoing acts and omissions, Plaintiff was and still is caused to

suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional health consequences.

12. Consequently, Plaintiff seeks compensatory damages as a result of his use of Zantac, which has caused Plaintiff to suffer from bladder cancer as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTIES

13. Plaintiff, David S. Sebag, resides in Ft. Lauderdale, Broward County, Florida, and is *sui juris.*

14. Since the mid-1990s, Plaintiff had endured gastrointestinal conditions such as acid indigestion, heartburn, and stomach pain. Over that period, to relieve these symptoms I was advised to use Zantac. Following that advice, I purchased and used Zantac for several weeks as directed and my gastrointestinal conditions and pain went away. Thereafter, when Plaintiff had acid indigestion and stomach pain, he used Zantac to alleviate the pain, sometimes taking up to 3 pills a day for several weeks to get symptom relief.

15. As result of Plaintiffs ingestion of Defendants' Zantac, in 2005 Plaintiff was diagnosed with noninvasive stage 1 bladder cancer. As a result thereof, Plaintiff was required to undergo numerous bladder surgeries between 2005 and 2017, followed by courses of chemotherapy treatments, as well as any and all of their sequelae and attendant pain, suffering,

and emotional distress.

16. The injuries and damages sustained by Plaintiff were caused by Defendants' Ranitidine products, including Zantac, and their unlawful conduct with respect to Zantac's design, manufacture, marketing and sale.

17. At all times material hereto, Defendant, Sanofi US Services Inc. ("Sanofi") was and is a Delaware corporation with its principal place of business located at 55 Corporate Drive Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of Sanofi, S.A. Sanofi US Services Inc. is duly licensed to transact business in the State of Florida, and lists its registered agent as Corporation Service Company, with the address 1201 Hays Street, Tallahassee, FL 32301-2525. Sanofi controlled the U.S. rights to Zantac from about January 2017 to the present, and manufactured and distributed the drug in the United States during that period.

18. Upon information and belief Sanofi US Services Inc., is or was a manufacturer and distributor of Zantac®, Zantac 75®, Maximum Strength Zantac 150®, and Maximum Strength Zantac 150® Cool Mint Tablets.

19. At all times relevant hereto, Defendant Sanofi US Services Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Ranitidine products, including Zantac.

20. Upon information and belief, at all relevant times, Defendant Sanofi US Services Inc. was present and doing business in the State of Florida.

21. Upon information and belief, at all relevant times, Defendant Sanofi US Services Inc. transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business.

22. Upon information and belief, at all times relevant hereto, Defendant Sanofi US Services Inc. expected or should have expected that its acts would have consequences within the United States of America, and the State of Florida

23. At all times material hereto, Defendant, Sanofi-Aventis U.S. LLC, was and is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a wholly owned subsidiary of Sanofi S.A. Sanofi-Aventis U.S. LLC is duly licensed to transact business in the State of Florida, and lists its registered agent as Corporation Service Company, with the address 1201 Hays Street, Tallahassee, FL 32301-2525. Upon information and belief Sanofi-Aventis U.S. LLC, is or was a manufacturer and distributor of Zantac®, Zantac 75®, Maximum Strength Zantac 150®, and Maximum Strength Zantac 150® Cool Mint Tablets.

24. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Ranitidine products, including Zantac. Upon information and belief, at all relevant times, Defendant Sanofi-Aventis U.S. LLC was present and doing business in the State of Florida.

25. Upon information and belief, at all relevant times, Defendant Sanofi-Aventis U.S. LLC transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business.

26. Upon information and belief, at all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC expected or should have expected that its acts would have consequences within the United States of America, and the State of Florida

27. At all times material hereto, Defendant, Sanofi Consumer Healthcare also

known as Sanofi S.A. is a French multinational pharmaceutical company headquartered in Paris, France, with its principal place of business located 54, Rue La Boetie in the 8th arrondissement. As of2013, Sanofi S.A. was the world's fifth-largest by prescription sales generally.

28. The Defendant company Sanofi S.A. was formed as Sanofi-Aventis in 2004 by the merger of Aventis and Sanofi-Synthelabo, which were each the product of several previous mergers. The Defendant company Sanofi S.A. changed its name to Sanofi in May 2011. Upon information and belief Sanofi S.A., is or was a manufacturer and distributor of Zantac®, Zantac 75®, Maximum Strength Zantac 150®, and Maximum Strength Zantac 150® Cool Mint Tablets.

29. At all times relevant hereto, Defendant Sanofi Consumer Healthcare also known as Sanofi S.A. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Ranitidine products, including Zantac.

30. Upon information and belief, at all relevant times, Defendant Sanofi Consumer Healthcare also known as Sanofi S.A. was present and doing business in the State of Florida. Upon information and belief, at all relevant times, Defendant Sanofi Consumer Healthcare also known as Sanofi S.A. transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business.

31. Upon information and belief, at all times relevant hereto, Defendant Sanofi Consumer Healthcare also known as Sanofi S.A. expected or should have expected that its acts would have consequences within the United States of America, and the State of Florida.

32. Defendants Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and Sanofi

Consumer Healthcare also known as Sanofi S.A. are collectively referred to as the "Sanofi Defendants."

10. Upon information and belief, the Sanofi Defendants are or were the manufacturers and distributors of Zantac products. Sanofi controlled the New Drug Application ("NDA") for over-the-counter ("OTC") Zantac starting in January 2017 through present. At all times relevant hereto, the Sanofi Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac.

33. Defendant Chattem, Inc. is a Tennessee corporation with its principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A., through its subsidiary Chattem, Inc., exercised substantial control over the design, testing, manufacture, packaging and/or labeling of Zantac that caused the harm to Plaintiff for which recovery is sought.

34. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer Ingelheim Pharmaceuticals, Inc. is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to OTC Zantac between 2006 and January of 2017, and, manufactured and distributed the drug in the United States during that period. Boehringer Ingelheim Pharmaceuticals, Inc. is duly licensed to transact business in the State of Florida and lists its registered agent as C T Corporation System, with the address 1200 South Pine Island Road Plantation, FL 33324.

35. Defendant GlaxoSmithKline, LLC ("GSK") is a Delaware corporation with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania 19112 and

Five Moore Drive, Research Triangle, North Carolina 27709. GSK is duly licensed to transact business in the State of Florida. GSK was the original innovator of the Zantac drug and controlled the NDA for prescription Zantac between 1983 and 2009. By controlling the Zantac NDA, it also directly controlled the labeling for all Zantac products through 2009. And, GSK's negligence and misconduct related to Zantac as an innovator directly led to the failure to warn for other OTC versions of Zantac.

36. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer was the original NDA holder for OTC Zantac and controlled the NDA between August 2004 and December 2006. Pfizer is duly licensed to transact business in the State of Florida, and lists its registered agent as CT Corporation Service System, with the address of 1200 South Pine Island Road, Plantation, Florida 33324.

FACTUALBACKGROUND

37. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering bladder cancer and other injuries caused by Plaintiff's ingestion of Zantac.

38. Ranitidine was discovered in 1976 and came into commercial use in 1981. In 2019 it was the 50th most prescribed medication in the United States with more than 15 million prescriptions.

39. Ranitidine was first approved by the FDA on June 9, 1983.

40. Plaintiff began taking Defendants Zantac in or around 1997 and continued to use Zantac through at least 2017.

41. At all relevant times, Defendants heavily marketed Ranitidine products,

including Zantac, to treat peptic disorders, including but not limited to GERD, peptic ulcer disease, and Zollinger-Ellison syndrome.

42. Defendants' marketing of Ranitidine products, including Zantac, included advertisements, press releases, web site publications, sales representative pitches and other communications.

43. Materials including advertisements, press releases, webs site publications and other communications regarding Ranitidine products, including Zantac, are part of the labeling of the drug and could be altered by Defendants without prior FDA approval.

44. Defendants' Ranitidine products, including Zantac, are some of the most commonly prescribed medications in the United States, and are available over the counter in addition to prescription.

45. Ranitidine was the world's biggest-selling prescription drug by 1987.

Ranitidine, Zantac and NDMA

46. Valisure, LLC is an online pharmacy currently licensed in 38 states and an analytical laboratory that is **ISO** 17025 accredited by the International Organization for Standardization **("ISO").** Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV743l137, Laboratory: RV0484814) and the FDA (FEI #: 3012063246). Valisure's mission is to help ensure the safety, quality and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

47. Valisure discovered the link between ranitidine and NDMA formation during its routine analysis of drug products in its pharmacy.

48. Valisure found incredibly high levels if NDMA in every lot of Ranitidine it tested. For example, Valisure found 2,511,469 ng ofNDMA in Zantac, Brand OTC, and 3,267,968 ng of NDMA in Zantac (mint), CVS.

49. Again, the FDA daily limit is 96 ng.

50. During the period in which Ranitidine products, including Zantac, have been soldin the United States, hundreds of reports of injuries, including but not limited to various cancers have been submitted to the FDA in association with ingestion of Ranitidine and Zantac.

51. NDMA is a member of a family of extremely potent carcinogens, the N-nitrosamines

52. NDMA is a volatile, combustible, yellow, oily liquid nitrosamine with a faint characteristic odor that decomposes when exposed to light and emits toxic fumes of nitrogen oxides when heated to decomposition. NDMA is primarily used in laboratory research to induce tumors in experimental animals. This substance may be formed during the cooking of foods, especially cured meats and fish, that contain sodium nitrite as a preservative, but is also found in several vegetables, cheeses, alcoholic beverages and fruits, and as a contaminant in rubber products. Exposure to NDMA irritates the skin and eyes and damages the liver. This substance is reasonably anticipated to be a human carcinogen. https://pubchem.ncbi.nl.m.nih.gov/compound/N-Nitrosodimethvlarnine (accessed September 13, 2019).

53. NDMA is also used to create cancer in rats for cancer research.

https://cancerres.aacrjoumals.org/contenlicames/51/23 Part 2/6452.full.pdf (accessed September 13, 2019).

54. There has been a significant increase in rates of bladder cancer.

55. Sanofi is involved in multiple cases as a result of the damage their drugs cause including an action in the Philippians where multiple children have died. In fact, in March of 2019, The Philippine Department of Justice said it had found probable cause to indict officials from French drug maker Sanofi. https://www.reuters.com/article/us-sanofi-fr-philippines/philippines-to-charge-officials-of-sanofi-govermnent -over- dengue-vaccine-id USKCNl QI4 lL.

56. Defendants have had notice of serious adverse health outcomes regarding cancer and other injuries associated with their Ranitidine products, including Zantac through case reports, clinical studies and post-market surveillance.

57. As such, these numerous reports of cancer, put Defendants on notice as to the excessive risks of injuries related to the use of Ranitidine products, including Zantac and yet, those products remain easily accessible to consumers like Plaintiff to their detriment, even over the counter.

58. In fact, almost half of the drugs the Sanofi Defendants currently have in development are used to treat cancers including ovarian, breast, and childhood cancers, the ones frequently caused by Zantac. https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi- COl'v1iHome/common/docs/science-and-innovation/RD-Portfolio-07 l9-47-48- 50.pdf?la=en&hash= l58488E2DDCB75l C7BO1524E858AC7A6288C338B.

59. Several observational studies have linked NDMA use, including use of Ranitidine

products, including Zantac, to serious adverse health outcomes.

60. Defendants knew or should have known of the risk of cancer based on the data available to them or that could have been generated by them, including but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

61. Despite their knowledge of the risks of cancer associated with Ranitidine and Zantac, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Ranitidine products, including Zantac, did not pose any risks of cancer or other serious health conditions. Defendants promoted and marketed Ranitidine products, including Zantac, as safe and effective for persons such as Plaintiff throughout the United States, including Florida.

62. Defendants knew of the significant risk of cancer that could result from the use of Ranitidine products, including Zantac, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff, Plaintiff's physician or the medical community in a timely manner.

63. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with Ranitidine products, including Zantac, including, but not necessarily limited to, long-term usage and the cumulative effects of long-term usage.

64. In omitting, concealing, and inadequately providing critical safety information regarding the use of Ranitidine products, including Zantac, in order to induce their purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff. This conduct is fraudulent, unfair, and unlawful.

65. Despite clear knowledge that Ranitidine products, including Zantac, cause a significantly increased risks of cancer and other severe health problems, Defendants continued to market and sell Ranitidine products, including Zantac, without warning consumers or healthcare providers of these significant risks.

66. Even if used as directed, persons who ingested Ranitidine products, including Zantac, such as the Plaintiff, were exposed to significant risks stemming from unindicated and/or long-term usage.

67. Consumers, including Plaintiff, and Plaintiff's physicians relied on the Defendants' false representations and were misled as to Zantac's safety.

68. Had the Plaintiff known of the risks of cancer and other injuries associated with Zantac, Plaintiff would not have used Defendants' Zantac.

69. Plaintiff purchased at least some of the Zantac he ingested at a Publix Supermarket located in Miami-Dade County, Florida.

70. As a result of Defendants' action and inactions as outlined herein, Plaintiff was injured due to Plaintiff's ingestion of Zantac, which caused Plaintiff to suffer from bladder cancer and any and all sequelae.

FIRST CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (NEGLIGENCE)

71. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

72. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of

Ranitidine products, including Zantac, into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

73. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Ranitidine products, including Zantac, into interstate commerce in that Defendants knew or should have known that using Ranitidine products, including Zantac, could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Ranitidine products, including Zantac. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

(a) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Ranitidine products, including Zantac;

(b) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Ranitidine products, including Zantac, in unsafe doses;

(c) Failure to use reasonable care in testing and inspecting Ranitidine products, including Zantac, so as to ascertain whether or not they were safe for the purpose for which they were designed, manufactured and sold;

(d) Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Zantac;

(e) Failure to use reasonable care in the process of manufacturing Ranitidine products, including Zantac, in a reasonably safe condition for the use for which it was intended;

(f) Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Ranitidine products, including Zantac, in unsafe doses; and

(g) Such further acts and/or omissions that may be proven at trial.

74. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

75. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Ranitidine products, including Zantac, without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Ranitidine products, including Zantac, without adequately testing it;

(c) Not conducting sufficient testing programs to determine

whether or not Ranitidine products, including Zantac, were safe for use; in that Defendants herein knew or should have known that Ranitidine products, including Zantac, were unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Ranitidine products, including Zantac, without making proper and sufficient tests to determine the dangers to their users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Ranitidine products, including Zantac;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Zantac;

(g) Failing to test Ranitidine products, including Zantac, and/or failing to adequately, sufficiently, and properly test Ranitidine products, including Zantac.

(h) Negligently advertising and recommending the use of Ranitidine products, including Zantac, without sufficient knowledge as to their dangerous propensities;

(i) Negligently representing that Ranitidine products, including Zantac, were safe for use for its intended purpose, when, in

fact, they were unsafe;

G) Negligently designing Ranitidine products, including Zantac, in a manner which was dangerous to their users;

(k) Negligently manufacturing Ranitidine products, including Zantac, in a manner which was dangerous to their users;

(1) Negligently producing Ranitidine products, including Zantac, in a manner which was dangerous to their users;

(m) Negligently assembling Ranitidine products, including Zantac, in a manner which was dangerous to their users;

(n) Concealing information from the Plaintiff in knowing that Ranitidine products, including Zantac, were unsafe, dangerous, and/or non- conforming with FDA regulations.

76. Defendants under-reported, underestimated and downplayed the serious dangers of Ranitidine products, including Zantac.

77. Defendants negligently compared the safety risk and/or dangers of Ranitidine products, including Zantac, with other forms of treatment of peptic disorders, which include erosive esophagitis, gastroesophageal reflux disease-"GERD", and Zollinger-Ellison syndrome.

78. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Ranitidine products, including Zantac, in that they:

(a) Failed to use due care in designing and manufacturing Ranitidine products, including Zantac, so as to avoid the

aforementioned risks to individuals when Ranitidine products, including Zantac, were used for treatment of peptic disorders which include erosive esophagitis, gastroesophageal reflux disease-"GERD", and Zollinger-Ellison syndrome;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the uses of Ranitidine products, including Zantac;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Ranitidine products, including Zantac;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Ranitidine products, including Zantac;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Ranitidine products, including Zantac;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of Ranitidine products, including Zantac; either directly or indirectly, orally or in writing, about the need for more

comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

79. Despite the fact that Defendants knew or should have known that Ranitidine products, including Zantac, caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Ranitidine products, including Zantac, to consumers, including the Plaintiff.

80. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

81. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered and/or will continue to suffer.

82. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

83. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

84. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount to be proven at trial.

SECOND CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (STRICT PRODUCTS LIABILITY)

85. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

86. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Ranitidine products, including Zantac, as hereinabove described that was used by the Plaintiff.

87. That Ranitidine products, including Zantac, were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

88. At those times, Ranitidine products, including Zantac, were in unsafe, defective, and inherently dangerous conditions, which was dangerous to users, and in particular, the Plaintiff herein.

89. The Ranitidine products, including Zantac, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the Ranitidine products, including Zantac.

90. The Ranitidine products, including Zantac, designed, researched,

manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants manufacturers and/or suppliers, they were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

91. At all times herein mentioned, Ranitidine products, including Zantac, were in defective conditions and unsafe, and Defendants knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by the Defendants.

92. Defendants knew or should have known that at all times herein mentioned its Ranitidine products, including Zantac, were in defective conditions and were and are inherently dangerous and unsafe.

93. At the time of the Plaintiffs uses of Zantac, the Zantac were being used for the purposes and in a manner normally intended for the treatment of peptic disorders, which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

94. Defendants with this knowledge voluntarily designed Ranitidine products, including Zantac, in a dangerous condition for use by the public, and in particular the Plaintiff.

95. Defendants had a duty to create products that were not unreasonably dangerous for its normal, intended use.

96. Defendants created products unreasonably dangerous for their normal, intended use.

97. The Ranitidine products, including Zantac, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by

Defendants were manufactured defectively in that Ranitidine products, including Zantac, left the hands of Defendants in a defective condition and were unreasonably dangerous to their intended users.

98. The Ranitidine products, including Zantac, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Ranitidine products, including Zantac, were manufactured.

99. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

100. The Plaintiff could not, by the exercise of reasonable care, have discovered Zantac's defects herein mentioned and perceived its danger.

101. The Ranitidine products, including Zantac, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including cancer as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

102. Ranitidine products, including Zantac, were designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

103. Ranitidine products, including Zantac, designed, researched, manufactured,

tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including cancer as well as other severe and permanent health consequences from Ranitidine products, including Zantac product use. Defendants failed to provide adequate warnings to users or consumers of their products, and continued to improperly advertise, market and/or promote their Ranitidine products, including Zantac.

104. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of defective products-the Ranitidine products, including.

105. Defendants' defective design, manufacturing defect, and inadequate warnings of Ranitidine products, including Zantac, were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

106. That said defects in Defendants' drug Ranitidine products, including Zantac, were a substantial factor in causing Plaintiff's injuries.

107. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

108. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future

be required to obtain further medical and/or hospital care, attention, and services.

109. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount to be proven at trial.

THIRD CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (BREACH OF EXPRESS WARRANTY)

110. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

111. Defendants expressly warranted that Ranitidine products, including Zantac, were safe and well accepted by users.

112. Ranitidine products, including Zantac, do not conform to these express representations because Ranitidine products, including Zantac, are not safe and have numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

113. Plaintiff did rely on the express warranties of the Defendants herein.

114. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Ranitidine products, including Zantac, in recommending, prescribing, and/or dispensing Ranitidine products, including Zantac.

115. The Defendants herein breached the aforesaid express warranties, as their drug Ranitidine products, including Zantac, were defective.

116. Defendants expressly represented to Plaintiff's physicians, healthcare

providers, and/or the FDA that Ranitidine products, including Zantac, were safe and fit for use for the purposes intended, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

117. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Ranitidine products, including Zantac, were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

118. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer and renal injuries including but not limited to acute kidney injuries, renal insufficiency and/or renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

119. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Ranitidine products, including Zantac.

120. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

121. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount to be proven at trial.

FOURTH CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

122. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

123. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Ranitidine products, including Zantac, and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Ranitidine products, including Zantac, for the treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

124. At the time Defendants marketed, sold, and distributed Ranitidine products, including Zantac, for use by Plaintiff, Defendants knew of the uses for which Ranitidine products, including Zantac, was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

125. The Defendants impliedly represented and warranted to the users of Ranitidine products, including Zantac, and their physicians, healthcare providers, and/or the FDA that Ranitidine products, including Zantac, were safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

126. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Ranitidine products, including Zantac, were unsafe, unreasonably

dangerous, improper, not of merchantable quality, and defective.

127. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

128. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Ranitidine products, including Zantac, were of merchantable quality and safe and fit for their intended use.

129. Ranitidine products, including Zantac, were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

130. The Defendants herein breached the aforesaid implied warranties, as their Ranitidine products, including Zantac, were not fit for its intended purposes and uses.

131. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

132. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

133. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount to be proven at trial.

FIFTH CAUSE OF ACTION AS AGAINST THE SANOFI DEFENDANTS (FRAUDULENT MISREPRESENTATION)

134. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

135. The Sanofi Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said products, Ranitidine products, including Zantac, had been tested and were found to be safe and/or effective for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger- Ellison syndrome.

136. Those representations made by the Sanofi Defendants were, in fact, false.

137. When said representations were made by the Sanofi Defendants, they knew those representations to be false or they willfully, wantonly and recklessly disregarded whether the representations were true.

138. Those representations were made by the Sanofi Defendants with the intent of defrauding and deceiving the Plaintiff, Plaintiff's physician, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Zantac, for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare

of the Plaintiff herein.

139. At the time the aforesaid representations were made by the Sanofi Defendants and, at the time the Plaintiff used Zantac, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

140. In reliance upon said representations, the Plaintiff was induced to and did use Ranitidine products, including Zantac, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

141. The Sanofi Defendants knew and were aware or should have been aware that Ranitidine products, including Zantac, had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

142. The Sanofi Defendants knew or should have known that Ranitidine products, including Zantac, had a potential to, could, and would cause severe and grievous injury to the users of said products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

143. The Sanofi Defendants brought Ranitidine products, including Zantac, to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

144. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer and renal injuries including but not limited to acute kidney injuries, renal insufficiency and/or renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

145. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

146. By reason of the foregoing, Plaintiff has been damaged as against the Sanofi Defendants in an amount to be proven at trial.

SIXTH CAUSE OF ACTION AS AGAINST THE SANOFI DEFENDANTS (FRAUDULENT CONCEALMENT)

147. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

148. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, the Sanofi Defendants misrepresented the safety of Ranitidine products, including Zantac, for their intended use.

149. The Sanofi Defendants knew or were reckless in not knowing that their representations were false.

150. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, the Sanofi Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Ranitidine products, including Zantac, were not as safe as other forms of treatment for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger- Ellison syndrome;

(b) that the risks of adverse events with Ranitidine products, including Zantac, were higher than those with other forms of treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome;

(c) that the risks of adverse events with Ranitidine products, including Zantac, were not adequately tested and/or known by the Sanofi Defendants;

(d) that the Sanofi Defendants were aware of dangers in Ranitidine products, including Zantac, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome;

(e) that Ranitidine products, including Zantac, were defective, and that they caused dangerous side effects, including but not limited to bladder cancer, stomach cancer and renal injuries including but not limited to renal insufficiency and/or renal failure;

(f) that patients needed to be monitored more regularly than normal while using Ranitidine products, including Zantac;

(g) that Ranitidine products, including Zantac, were manufactured negligently;

(h) that Ranitidine products, including Zantac, were

manufactured defectively;

(i) that Ranitidine products, including Zantac, were manufactured improperly;

(j) that Ranitidine products, including Zantac, were designed negligently;

(k) that Ranitidine products, including Zantac, were designed defectively; and

(1) that Ranitidine products, including Zantac, were designed improperly.

151. The Sanofi Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Zantac, including but not limited to the heightened risks of stomach cancer and renal injuries.

152. The Sanofi Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Ranitidine products, including Zantac, including the Plaintiff, in particular.

153. The Sanofi Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of Ranitidine products, including Zantac, were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Zantac, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Ranitidine products, including Zantac, and/or use the products.

154. The Sanofi Defendants knew that Plaintiff, and Plaintiff's physicians,

hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind the Sanofi Defendants' concealment and omissions, and that these included material omissions of facts surrounding Ranitidine products, including Zantac, as set forth herein.

155. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Sanofi Defendants.

156. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer and renal injuries including but not limited to acute kidney injuries, renal insufficiency and/or renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

157. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

158. By reason of the foregoing, Plaintiff has been damaged as against the Sanofi Defendants in an amount to be proven attrial.

SEVENTH CAUSE OF ACTION AS AGAINST THE SANOFI DEFENDANTS (NEGLIGENT MISREPRESENTATION)

159. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

160. The Sanofi Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said products, Zantac, had been tested and found to be safe and effective for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

161. The representations made by the Sanofi Defendants were, in fact, false.

162. The Sanofi Defendants failed to exercise ordinary care in the representation of Ranitidine products, including Zantac, while involved in their manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Zantac's high risks of unreasonable, dangerous side effects.

163. The Sanofi Defendants breached their duty in representing Zantac's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

164. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer and acute kidney injuries, renal injuries including but not limited to renal insufficiency and/or renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

165. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

166. By reason of the foregoing, Plaintiff has been damaged as against the Sanofi Defendants in an amount to be proven attrial.

EIGHTH CAUSE OF ACTION AS AGAINST THE SANOFI DEFENDANTS (FRAUD AND DECEIT)

167. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

168. The Sanofi Defendants conducted research and used Ranitidine products, including Zantac, as part of theirresearch.

169. As a result of the Sanofi Defendants' research and testing, or lack thereof, the Sanofi Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Ranitidine products, including Zantac, were safe and effective for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

170. As a result of the Sanofi Defendants' research and testing, or lack thereof, the Sanofi Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

171. The Sanofi Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA

172. The information distributed to the public, the FDA, and the Plaintiff by the Sanofi Defendants, including but not limited to reports, press releases, advertising

campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

173. The information distributed to the public, the FDA, and the Plaintiff by the Sanofi Defendants intentionally included representations that the Sanofi Defendants' Ranitidine products, including Zantac were safe and effective for use for treatment of peptic disorders, which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

174. The information distributed to the public, the FDA, and the Plaintiff, by the Sanofi Defendants intentionally included representations that the Sanofi Defendants' drugs Zantac, carried the same risks, hazards, and/or dangers as other forms of treatment for treatment of peptic disorders, which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

175. The information distributed to the public, the FDA, and the Plaintiff, by the Sanofi Defendants intentionally included false representations that Ranitidine products, including Zantac, were not injurious to the health and/or safety of its intended users.

176. The information distributed to the public, the FDA, and the Plaintiffs, by the Sanofi Defendants intentionally included false representations that Ranitidine products, including Zantac, were as potentially injurious to the health and/or safety of its intended as other forms of treatment for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

177. These representations were all false and misleading.

178. Upon information and belief, the Sanofi Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Ranitidine products, including Zantac, were not safe as a means of

treatment for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

179. The Sanofi Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs, regarding the safety of Ranitidine products, including Zantac, specifically but not limited to Zantac, not having dangerous and serious health and/or safety concerns.

180. The Sanofi Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiffs, regarding the safety of Ranitidine products, including Zantac, being safe means for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

181. That it was the purpose of the Sanofi Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Ranitidine products, including Zantac, induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Zantac.

182. The Sanofi Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Ranitidine products, including Zantac, were fit and safe for use for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

183. The Sanofi Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA,

and/or the Plaintiff that Ranitidine products, including Zantac, were fit and safe for use for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

184. That the Sanofi Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Ranitidine products, including Zantac, did not present serious health and/or safety risks.

185. That the Sanofi Defendants made claims and representations m its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Ranitidine products, including Zantac, did not present health and/or safety risks greater than other oral forms for treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

186. That these representations and others made by the Sanofi Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

187. That these representations and others, made by the Sanofi Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Ranitidine products, including Zantac.

188. That the Sanofi Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Ranitidine products, including Zantac, to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing

of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

189. That the Sanofi Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Ranitidine products, including Zantac, by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Ranitidine products, including Zantac.

190. That the Sanofi Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Ranitidine products, including Zantac, and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

191. The Sanofi Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

192. The Sanofi Defendants utilized direct to consumer adverting to market, promote, and/or advertise Ranitidine products, including Zantac.

193. That the Plaintiff and/or Plaintiffs respective healthcare professionals did in fact rely on and believe the Sanofi Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment of peptic disorders which include erosive esophagitis, GERD, and Zollinger-Ellison syndrome.

194. That at the time the representations were made, the Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Ranitidine products, including Zantac.

195. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of the Sanofi Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

196. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Ranitidine products, including Zantac, Plaintiff would not have purchased, used and/or relied on the Sanofi Defendants' drug Ranitidine products, including Zantac.

197. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

198. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer and renal injuries including but not limited to acute kidney injuries, renal insufficiency and/or renal failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

199. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

200. By reason of the foregoing, Plaintiff has been damaged as against the Sanofi

Defendants in an amount to be proven attrial.

NINTH CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (STRICT LIABILITY - FAILURE TO WARN)

201. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

202. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Zantac, and through that conduct have knowingly and intentionally placed Zantac into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff.

203. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Zantac to Plaintiff and to Plaintiff's prescribing physicians. Additionally, Defendants expected the Zantac that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Zantac did in fact reach – prescribing physicians and consumers, including Plaintiff and Plaintiff's prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

204. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and used by Plaintiff. The defective condition of Zantac was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing cancer as a result of its use.

205. This defect caused serious injury to Plaintiff, who used Zantac in its intended and foreseeable manner.

206. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

207. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Zantac, namely its potential to cause cancer.

208. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Zantac caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing cancer from Zantac use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

209. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

210. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

211. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

212. Had Defendants properly disclosed the risks associated with Zantac, including cancer, Plaintiff would not have used Zantac.

213. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

TENTH CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (PUNITIVE DAMAGES)

214. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 – 70 inclusive, with the same force and effect as if more fully set forth herein.

215. At all times material, Defendants had actual knowledge of the wrongfulness of their conduct and the high probability that users of Zantac products containing NDMA, like Plaintiff would sustain injury or damage, and despite that knowledge, willfully, wantonly, and recklessly pursued their course of conduct.

216. The Defendants, conduct was so gross and flagrant as to show a reckless disregard or a conscious wanton, reckless indifference to consequences or a grossly careless disregard for the life, safety, or rights of the Plaintiff, and the Defendants actively and knowingly participated in such conduct, and/or their officers, directors, or managers knowingly condoned, ratified or consented to such conduct.

217. Defendants, willful, wanton, malicious, and/or reckless conduct includes but is not limited to Defendants' failure to take all reasonable measures to ensure Zantac products containing NOMA as the active ingredient, which they knew to be carcinogenic, were not ingested by Plaintiff, warranting the imposition of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the

above- referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Awarding Plaintiffs reasonable attorneys' fees;

3. Awarding Plaintiff the costs of these proceedings; and

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: April 06, 2020

Respectfully Submitted,

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