UNITED STATES DISTRIC COURT
SOUTHERN DISTRICT OF OHIO

ANTOINE DODSON, TABATHA LAFFERTY, RONNIE LAWRENCE, CARRIE LUPIEN, DARLENE MAPHIS, ANTHONY MILINER, THELMA MYLES, CHRIS TROYAN, CONNIE MCCARTNEY, SAMMY BRYSON, JOHNNY DUYN, RONALD RAGAN, JOLETTA JORDAN, Plaintiffs, v. SANOFI S.A., SANOFI-AVENTIS US LLC, SANOFI US SERVICES INC, CHATTEM, INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and GLAXOSMITHKLINE, LLC, Defendants.	)	Case No. 20-356 **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs, Antoine Dodson, Tabatha Lafferty, Ronnie Lawrence, Carrie Lupien, Darlene Maphis, Anthony Miliner, Thelma Myles, Chris Troyan, Connie McCartney, Sammy Bryson, Johnny Duyn, Ronald Ragan, Joletta Jordan (hereinafter referred to collectively as "Plaintiffs"), individually and on behalf of all others similarly situated, alleges on personal knowledge, investigation of their counsel, and on information and belief as follows:

NATURE OF ACTION

1. Plaintiffs bring this action for damages and other legal and equitable remedies resulting from the actions of Defendants Sanofi S.A., Sanofi-Aventis U.S. LLC, Sanofi

US Services Inc., Chattem Inc. (hereinafter collectively referred to as "Sanofi" or "Sanofi Defendants"), Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter referred to as "Boehringer"), and GlaxoSmithKline, LLC ("GSK") in the design, development, manufacturing, packaging, marketing, advertising, promoting, labeling, distribution and/or sale of the drug Zantac. Plaintiffs represent individuals who have yet to be diagnosed with cancer as a result of taking Zantac, and seek medical monitoring and other related remedies in order to manage the consequences of their exposure.

JURISDICTION AND VENUE

2. This matter in controversy exceeds $5,000,000, as each member of the proposed Class of hundreds of thousands has suffered future harm in the form of greatly increased risk of life-threatening diseases including cancer. Accordingly, this Court has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). Further, Plaintiffs allege a national class, which will result in at least one Class member belonging to a different state. Therefore, both elements of diversity jurisdiction under the Class Action Fairness Act of 2005 ("CAFA") are present, and this Court has jurisdiction.

3. This Court has personal jurisdiction over the Defendants because, all Defendants are authorized to do business in Ohio and the conduct at issue occurred in or was directed toward individuals in the state of Ohio. As a result, all Defendants have established minimum contacts showing it has purposefully availed itself of the resources and protection of the State of Ohio.

4. Venue is proper in the United States District Court for the Southern District of Ohio pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1441(a) because the Defendants are deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced and the Defendants' contacts with this District are sufficient to subject it to personal jurisdiction. Defendants sell, market and/or distribute Zantac within this district.

PARTIES

5. Plaintiff Antoine Dodson is and at all times mentioned herein was, an individual citizen of the State of Maryland.

6. Plaintiff Tabatha Lafferty is and at all times mentioned herein was, an individual citizen of the State of Ohio.

7. Plaintiff Ronnie Lawrence is and at all times mentioned herein was, an individual citizen of the State of New Jersey.

8. Plaintiff Carrie Lupien is and at all times mentioned herein was, an individual citizen of the State of Maryland.

9. Plaintiff Darlene Maphis is an at all times mentioned herein was, an individual citizen of the State of Arizona.

10. Plaintiff Anthony Miliner is and at all times mentioned herein was, an individual citizen of the State of Ohio.

11. Plaintiff Thelma Myles is and at all times mentioned herein was, an individual citizen of the State of New Jersey.

12. Plaintiff Chris Troyan is an at all times mentioned herein was, an individual citizen of the State of Ohio.

13. Plaintiff Sammy Bryson is an at all times mentioned herein was, an individual citizen of the State of Indiana.

14. Plaintiff Sammy Bryon is an at all times mentioned herein was, an individual citizen of the State of Indiana.

15. Plaintiff Connie McCartney is an at all times mentioned herein was, an individual citizen of the State of West Virginia.

16. Plaintiff Ronald Ragan is an at all times mentioned herein was, an individual citizen of the State of Colorado.

17. Plaintiff Joletta Jordan is an at all times mentioned herein was, an individual citizen of the State of Illinois.

18. Defendant Sanofi S.A. is a French multinational pharmaceutical company headquartered in Paris, France, with its principal place of business located at 54, Rue La Boetie, in the 8th arrondissement. Defendant Sanofi S.A. changed its name to Sanofi in May 2011.

19. Defendant Sanofi-Aventis US LLC was and is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis US LLC is a wholly owned subsidiary of Sanofi S.A. Sanofi Aventis US LLC is duly licensed to transact business in the State of Ohio, and lists its registered agent as Corporation Service Company, with the address 50 West Broad Street, Suite 1330, Columbus, Ohio 43215.

20. Defendant Sanofi US Services Inc. 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 a duly licensed to transact business in the State of Ohio, and lists its registered agent as Corporation Service Company, with the address 50 West Broad Street, Suite 1330, Columbus, Ohio 43215.

21. 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 need for the medical monitoring class for Plaintiffs.

22. 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 2017, and manufactured and distributed the drug in the United States during that period.

23. 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. GS was the original inventor 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.

NDMA

24. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[1] According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[2] NDMA can be unintentionally produced in, and released from, industrial sources through chemical reactions involving other chemicals called alkylamines.

25. NDMA is unequivocally a harmful carcinogen. It has been known to be a byproduct of making rocket fuel in the early 1900s. Today it is used to induce tumors in animals for scientific testing purposes.

26. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[3] The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[4] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[5]

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[1] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[2] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[3] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[4] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[5] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

27. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable carcinogen. The World Health Organization ("WHO") has stated that scientific testing indicates that NDMA consumption is positively associated with either gastric or colorectal cancer and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

28. Exposure to high levels of NDMA has been linked to liver damage in humans.[6] According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[7]

29. Other studies showed an increase in other types of cancers, including but not limited to, stomach, colorectal, intestinal, and other digestive tract cancers.

30. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[8]

ZANTAC AND RANITIDINE

31. Zantac was developed by Glaxo – now known as GlaxoSmithKline, post-merger – and approved for prescription use by the FDA in 1983. The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

32. Zantac was the world's best-selling drug in 1988 and in the fiscal year that ended in June 1989, Zantac accounted for over half of Glaxo's sales of $3.98 billion. Even as late

[6] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[7] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.

[8] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

as 2016, Zantac was the 50th most prescribed drug in the United States with over 15 million prescriptions..

33. Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year. Beginning in late 2012, the manufacturer Defendants, by and through their subsidiaries, manufactured Zantac as a generic drug. Zantac has been marketed as a safe and effective treatment for infants, children, and adults

34. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[9]

35. On September 13, 2019, in response to a citizen's petition filed by Valisure, Inc., U.S. and European regulators stated that they are reviewing the safety of ranitidine.

36. On September 18, 2019, Novartis AG's Sandoz Unit, which makes generic drugs, stated that it was halting the distribution of its versions of Zantac in all markets, while Canada requested drug makers selling ranitidine to stop distribution.

37. On September 28, 2019, CVS Health Corp. announced that it would stop selling Zantac and its own generic ranitidine products out of concern that it might contain a carcinogen. Walmart, Inc., Walgreens, and Rite Aid Corp have announced removed Zantac and ranitidine products from their shelves.

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

39. On October 18, 2019, Sanofi recalled all of its Zantac OTC in the United States, which included Zantac 150, Zantac 150 Cool Mint, and Zantac 75.

40. This is not a contamination case—the levels of NDMA that researchers are seeing in Zantac is not the product of some manufacturing error. The high levels of NDMA

[9] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

produced by Zantac are not caused by a manufacturing defect but are inherent to the molecular structure of ranitidine, the active ingredient in Zantac. The ranitidine molecule contains both a nitrite and a dimethylamine ('DMA') group which are well known to combine to form NDMA. Thus, ranitidine produces NDMA by "react[ing] with itself", which means that every dosage and form of ranitidine, including Zantac, exposes users to NDMA.

41. As a result, anyone who has taken Zantac is a potential class participant because of the metabolic breakdown in the body, which creates NDMA.

42. The FDA has announced a permissible intake limit of 96 ng of NDMA per day. Valisure's testing, detected 2,511,469 ng of NDMA per 150 mg tablet of Zantac, i.e., more than 26,000 times the amount that can be safely ingested daily.

43. The typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for 4 to 8 weeks, and maintenance doses of 150 mg once daily. Moreover, chronic use of the drug is common for therapy of heartburn and indigestion.

44. Thus, a typical consumer who is taking Zantac over the course of eight weeks to treat peptic ulcer disease is exposed to more than 280,000,000 ng (or 0.28 grams) of NDMA. And a consumer who takes a 150 mg maintenance dose of Zantac once daily is 3 exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year, in comparison to the FDA's permissible intake limit of NDMA is 96 ng per day, which translates to just 0.000034 grams per year.

45. In addition to the FDA-recommended testing described above, when Zantac was tested in conditions simulating the human stomach, the quantity of NDMA detected was as high as 304,500 ng per tablet—3,171 times more than the amount that can be safely ingested daily.

46. Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 mg Zantac, ranging between

245 and 3,100 times above the FDA-allowable limit. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 ng level (over 7,000 for the 50 µg level).

47. During the time that Defendants manufactured and sold over-the-counter Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. Neither Sanofi nor Boehringer disclosed this risk to consumers on the drug's label—or through any other means—nor did Defendants report these risks to the FDA, despite being on notice of the risk.

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

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

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

50. "The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product." 21 C.F.R. § 314.81(b)(2)(v).

51. Defendants ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Zantac.

FACTS RELATING TO THE NAMED PLAINTIFFS

Plaintiff Dodson

52. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

53. Beginning in 2017, Plaintiff Dodson took Zantac consistently as an anti-acid.

54. As of the present time, Plaintiff Dodson has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Dodson has undertaken additional efforts to monitor his medical condition.

Plaintiff Lafferty

55. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

56. Beginning in 2007, Plaintiff Lafferty took Zantac consistently as an anti-acid.

57. As of the present time, Plaintiff Lafferty has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Lafferty has undertaken additional efforts to monitor her medical condition.

Plaintiff Lawrence

58. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

59. Beginning in 2017, Plaintiff Lawrence took Zantac consistently as an anti-acid.

60. As of the present time, Plaintiff Lawrence has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Lawrence has undertaken additional efforts to monitor his medical condition.

Plaintiff Lupien

61. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

62. Beginning in 2016, Plaintiff Lupien took Zantac consistently as an anti-acid.

63. As of the present time, Plaintiff Lupien has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Lupien has undertaken additional efforts to monitor her medical condition.

Plaintiff Maphis

64. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

65. Beginning in 2005, Plaintiff Maphis took Zantac consistently as an anti-acid.

66. As of the present time, Plaintiff Maphis has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of

prolonged exposure to Zantac, Plaintiff Maphis has undertaken additional efforts to monitor her medical condition.

Plaintiff Miliner

67. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

68. Beginning in 2005, Plaintiff Miliner took Zantac consistently as an anti-acid.

69. As of the present time, Plaintiff Miliner has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Miliner has undertaken additional efforts to monitor his medical condition.

Plaintiff Myles

70. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

71. Beginning in 2016, Plaintiff Myles took Zantac consistently as an anti-acid..

72. As of the present time, Plaintiff Myles has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Myles has undertaken additional efforts to monitor her medical condition.

Plaintiff Troyan

73. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

74. Beginning in 2009, Plaintiff Troyan took Zantac consistently as an anti-acid.

75. As of the present time, Plaintiff Tryoyan has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Myles has undertaken additional efforts to monitor his medical condition.

Plaintiff McCartney

76. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

77. Beginning in 2009, Plaintiff McCartney took Zantac consistently as an anti-acid. As of the present time, Plaintiff McCartney has not been diagnosed with cancer. However, in light of her significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff McCartney has undertaken additional efforts to monitor his medical condition.

Plaintiff Bryson

78. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

79. Beginning in 2002, Plaintiff Bryson took Zantac consistently as an anti-acid.

80. As of the present time, Plaintiff Bryson has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of

prolonged exposure to Zantac, Plaintiff Bryson has undertaken additional efforts to monitor his medical condition.

Plaintiff Duyn

81. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

82. Beginning in 2009, Plaintiff Duyn took Zantac consistently as an anti-acid.

83. As of the present time, Plaintiff Duyn has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Duyn has undertaken additional efforts to monitor his medical condition.

Plaintiff Ragan

84. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

85. Beginning in 2014, Plaintiff Ragan took Zantac consistently as an anti-acid.

86. As of the present time, Plaintiff Ragan has not been diagnosed with cancer. However, in light of his significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Ragan has undertaken additional efforts to monitor his medical condition.

Plaintiff Jordan

87. Plaintiff is, and at all times mentioned herein was, a "person" as defined by 47 U.S.C. § 153(39).

88. Beginning in 2012, Plaintiff Jordan took Zantac consistently as an anti-acid.

89. As of the present time, Plaintiff Jordan has not been diagnosed with cancer. However, in light of her significantly increased risk of contracting cancer as a result of prolonged exposure to Zantac, Plaintiff Jordan has undertaken additional efforts to monitor his medical condition.

CLASS ACTION ALLEGATIONS

90. Plaintiffs bring this action on behalf of themselves and all other persons similarly situated (hereinafter referred to as "the Class").

91. Plaintiffs propose the following Class definition, subject to amendment as appropriate:

> All persons within the United States who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Class members." Plaintiffs Dodson, Lafferty, Lawrence, Lupien, Maphis, Milinier, Myles, and Troyan represent, and are members of, the Class. Excluded from the Class are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

92. Plaintiffs Ragan also proposes the following Subclass definition, hereafter known as the "Colorado Subclass," subject to amendment as appropriate:

> All residents of the State of Colorado who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Colorado Subclass members." Plaintiff Ragan represents, and is a member of, the Colorado Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

93. Plaintiff Lupien and Dodson also propose the following Subclass definition, hereafter known as the "Maryland Subclass," subject to amendment as appropriate:

> All residents of the State of Maryland who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Maryland Subclass members." Plaintiffs Dodson and Lupien represent, and are members of, the Maryland Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

94. Plaintiff Maphis also proposes the following Subclass definition, hereafter known as the "Arizona Subclass," subject to amendment as appropriate:

> All residents of the State of Arizona who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Arizona Subclass members." Plaintiff Maphis represents, and is a member of, the Arizona Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

95. Plaintiffs Johnny Duyn and Sammy Bryson also propose the following Subclass definition, hereafter known as the "Indiana Subclass," subject to amendment as appropriate:

> All residents of the State of Indiana who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Indiana Subclass members." Plaintiffs Duyn and Bryson represent, and are a member of, the Indiana Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

96. Plaintiffs Lafferty, Milnier, and Troyan also proposes the following Subclass definition, hereafter known as the "Ohio Subclass," subject to amendment as appropriate:

> All residents of the State of Ohio who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Ohio Subclass members." Plaintiffs Lafferty, Milnier, and Troyan represent, and are members of, the Ohio Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

97. Plaintiff Jordan also proposes the following Subclass definition, hereafter known as the "Illinois Subclass," subject to amendment as appropriate:

> All residents of the State of Maryland who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "Illinois Subclass members." Plaintiff Jordan represents, and is a member of, the Illinois Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

98. Plaintiffs Lawrence and Myles also propose the following Subclass definition, hereafter known as the "New Jersey Subclass," subject to amendment as appropriate:

> All residents of the State of New Jersey who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "New Jersey Subclass members." Plaintiffs Lawrence and Myles represent, and are members of, the New Jersey Subclass. Excluded from the Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

99. Plaintiff Connie McCartney also proposes the following Subclass definition, hereafter known as the "West Virginia Subclass," subject to amendment as appropriate:

> All residents of the State of Maryland who took the drug Zantac and who do not have a diagnosis of cancer that has been attributed to Zantac as of the filing of this complaint.

Collectively, these persons will be referred to as "West Virginia Subclass members." Plaintiff McCartney represents, and is a member of, the West Virginia Subclass. Excluded from the West Virginia Subclass are all Defendants, any entities in which a Defendant has a controlling interest, any agents and employees of any Defendant, any Judge to whom this action is assigned and any member of such Judge's staff and immediate family, and claims for economic loss.

100. Plaintiffs do not know the exact number of members in the Class and Subclasses, but Plaintiffs reasonably believes that Class members number at minimum in the thousands.

101. Plaintiffs and all members of the Class have been harmed by the acts of the Defendants, because they are subject to significantly increased risk of cancer and other life-threatening diseases as a result of exposure to the contaminated medications produced and distributed by Defendants.

102. This Class Action Complaint seeks injunctive relief and money damages.

103. The joinder of all Class members is impracticable due to the size of the Class and Subclasses and relatively modest value of each individual claim. The disposition of the claims in a class action will provide substantial benefit to the parties and the Court in avoiding a multiplicity of identical suits. The Class can be identified through records maintained by Defendants or third-parties such as pharmacies.

104. There are well defined, nearly identical, questions of law and fact affecting all parties. The questions of law and fact involving the class claims predominate over questions which may affect individual Class members. Those common questions of law and fact include, but are not limited to, the following:

a. Whether Zantac was safe for its intended use;

b. Whether Zantac was adequately and properly tested before and after placing it on the market;

c. Whether the Defendants failed to properly warn Plaintiffs and Plaintiffs' healthcare providers that the use of Zantac carried a risk of developing cancer;

d. Whether the Defendants failed to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of cancer associated with the use of Zantac;

e. Whether the Defendants' conduct was knowing and/or willful; and

f. Whether the Defendants should be required to provide medical monitoring relief on a going-forward basis.

105. As persons who took Zantac and who are at increased risk of developing life-threatening diseases as a result of taking Zantac, Plaintiffs assert claims that are typical of each Class member. Plaintiffs will fairly and adequately represent and protect the interests of the Class and Subclasses, and has no interests which are antagonistic to any member of the Class or Subclasses.

106. Plaintiffs have retained counsel experienced in handling class action claims on behalf of a wide variety of types of consumers all over the country.

107. A class action is the superior method for the fair and efficient adjudication of this controversy. Classwide relief is essential to ensure that all individuals who have taken Zantac have access to appropriate and necessary medical care. The interest of Class members in individually controlling the prosecution of separate claims against the Defendants is small.

108. The Defendants have acted on grounds generally applicable to the Class, thereby making final injunctive relief and corresponding declaratory relief with respect to the Class and Subclasses as a whole appropriate.

CAUSES OF ACTION

FIRST COUNT

DEFECTIVE PRODUCT
(On Behalf of the Class Against All Defendants)

109. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully stated herein.

110. The Defendants, collectively, manufactured, marketed, sold and distributed Zantac in an unreasonably dangerous and defective condition and/or placed this dangerous and defective product into the stream of commerce knowing it would be taken by patients, including Plaintiffs and members of the proposed Class.

111. Zantac that was distributed by the Defendants was defective in that, when placed in the stream of commerce, (1) the foreseeable risks exceeding the benefits associated

with consumption; (2) Zantac was more dangerous than the ordinary consumer, including Plaintiffs and the Class they seek to represent, would expect, and more dangerous than other alternatives (such as other anti-acids without ranitidine); (3) there were no warnings provided about the dangerous nature of the product; and (4) the drugs were not properly tested, if tested at all for the creation of NDMA.

112. As a result of the dangerous nature of the product, and the lack of warning provided by the Defendants as to its dangerous nature, the Defendants are strictly liable to Plaintiffs and the Class.

SECOND COUNT

NEGLIGENCE
(On Behalf of the Colorado Subclass Against All Defendants)

113. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

114. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

115. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

116. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

117. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

118. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

119. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

120. To safeguard their health against life-threatening diseases that Plaintiff Ronald Ragan and the Colorado Subclass members are now at greater risk of contracting, Plaintiffs Ragan and the Colorado Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

121. As such, Plaintiff Ragan and members of the Colorado Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Ragan and members of the Colorado Subclass.

THIRD COUNT

NEGLIGENCE
(On Behalf of the Maryland Subclass Against All Defendants)

122. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

123. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

124. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

125. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

126. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

127. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

128. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

129. To safeguard their health against life-threatening diseases that Plaintiffs Lupien and Dodson, and the Maryland Subclass members are now at greater risk of contracting, Plaintiffs Lupien and Dodson, and the Maryland Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

130. As such, Plaintiffs Lupien and Dodson, and members of the Maryland Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Lupien and Dodson and members of the Maryland Subclass.

FOURTH COUNT

NEGLIGENCE
(On Behalf of the Arizona Subclass Against All Defendants)

131. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

132. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

133. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

134. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

135. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

136. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

137. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

138. To safeguard their health against life-threatening diseases that Plaintiff Maphis and the Arizona Subclass members are now at greater risk of contracting, Plaintiff Maphis and the Arizona Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

139. As such, Plaintiff Maphis, and members of the Arizona Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Maphis and members of the Arizona Subclass.

FIFTH COUNT

NEGLIGENCE
(On Behalf of the Indiana Subclass Against All Defendants)

140. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

141. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

142. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

143. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

144. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

145. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

146. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

147. To safeguard their health against life-threatening diseases that Plaintiffs Bryson, Duyn and the Indiana Subclass members are now at greater risk of contracting, Plaintiffs Bryson, Duyn, and the Indiana Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

148. As such, Plaintiffs Bryson, Duyn, and members of the Indiana Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Bryson, Duyn and members of the Indiana Subclass.

SIXTH COUNT

NEGLIGENCE
(On Behalf of the Ohio Subclass Against All Defendants)

149. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

150. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

151. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

152. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

153. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

154. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

155. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

156. To safeguard their health against life-threatening diseases that Plaintiffs Lafferty, Miliner, Troyan, and the Ohio Subclass members are now at greater risk of contracting, Plaintiffs Lafferty, Miliner, and Troyan, and the Ohio Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

157. As such, Plaintiffs Lafferty, Troyan and Miliner, and members of the Ohio Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Lafferty, Miliner, and Troyan and members of the Ohio Subclass.

SEVENTH COUNT

NEGLIGENCE
(On Behalf of the Illinois Subclass Against All Defendants)

158. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

159. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

160. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

161. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

162. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

163. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

164. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

165. To safeguard their health against life-threatening diseases that Plaintiff Jordan and the Illinois Subclass members are now at greater risk of contracting, Plaintiff Jordan and the Illinois Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

166. As such, Plaintiffs Jordan and members of the Illinois Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Jordan and members of the Illinois Subclass.

EIGHTH COUNT

NEGLIGENCE
(On Behalf of the New Jersey Subclass Against All Defendants)

167. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

168. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

169. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

170. NDMA is a hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

171. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

172. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

173. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

174. To safeguard their health against life-threatening diseases that Plaintiffs Lawrence, Myles and the New Jersey Subclass members are now at greater risk of contracting, Plaintiffs Lawrence, Myles, and the New Jersey Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

175. As such, Plaintiffs Lawrence, Myles and members of the New Jersey Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff Lawrence, Myles, and members of the New Jersey Subclass.

NINTH COUNT

MEDICAL MONITORING
(On Behalf of the West Virginia Subclass Against All Defendants)

176. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

177. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to dangerous and carcinogenic compounds in the form of NDMA.

178. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

179. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

180. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

181. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

182. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

183. To safeguard their health against life-threatening diseases that Plaintiff McCartney and the West Virginia Subclass members are now at greater risk of contracting, Plaintiff McCartney and the West Virginia Subclass will suffer annoyance, fear, humiliation, embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

184. As such, Plaintiff McCartney and members of the West Virginia Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff McCartney and members of the West Virginia Subclass.

TENTH COUNT

NEGLIGENCE *PER SE*
(On Behalf of the West Virginia Subclass Against All Defendants)

185. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

186. Each person who has taken Zantac, as a result of the tortious conduct of the Defendants, has been exposed to metabolic reaction that create dangerous and carcinogenic compounds in the form of NDMA.

187. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

188. NDMA is a proven hazardous substance that has been shown to have a probable link to human disease, including stomach, colon, liver and other digestive cancers.

189. Each person who has been exposed to Zantac has a significantly increased risk of contracting one or more serious latent diseases relative to what would be the case in the absence of such exposure.

190. The increases risk of serious latent disease described above makes it reasonably necessary to each person so exposed to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of such exposure.

191. Monitoring procedures exist that make possible the early detection of the diseases that have been linked to NDMA exposure.

192. To safeguard their health against life-threatening diseases that Plaintiff McCartney and the West Virginia Subclass members are now at greater risk of contracting, Plaintiffs McCartney and the West Virginia Subclass will suffer annoyance, fear, humiliation,

embarrassment, and the cost in time and effort of monitoring their health status. These damages are a proximate result of the acts and omissions of the Defendants.

193. As such, Plaintiff McCartney and members of the West Virginia Subclass seek the formation of a medical monitoring fund to pay for the costs and expenses of medical monitoring for Plaintiff McCartney and members of the West Virginia Subclass.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant Plaintiffs and all Class members the following relief against Defendants:

A. An order certifying this action to be a proper class action pursuant to Federal Rule of Civil Procedure 23, establishing an appropriate Class and any Subclasses the Court deems appropriate, finding that Plaintiffs are proper representatives of the Class and Subclasses, and appointing the lawyers and law firms representing Plaintiffs as counsel for the Class and Subclasses;

B. The establishment of a medical monitoring program, funded by the Defendants, for all members of the Class and Subclasses;

C. The establishment of a science board, funded by the Defendants, to conduct additional research on the future impact of Zantac on members of the Class and Subclasses, in order to improve the effectiveness of the medical monitoring program;

D. An award of attorneys' fees and costs to counsel for Plaintiffs and the Class;

E. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts so triable.

Dated: January 22nd, 2020 [redacted]