IN THE SUPREME COURT OF THE STATE OF NEVADA

Supreme Court Case No. ___

GLAXOSMITHKLINE LLC,
Petitioner,

v.

THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, in and for the County of Clark, and **THE HONORABLE JOE HARDY JR.**
Respondents

SARA ELABBASSY, as Special Administrator of the **ESTATE OF DECEDENT HUSROM**, deceased; **JAMIL HUSROM**, individually and as a legal guardian for **KHULOD HUSROM**, a minor, **SALIH HUSROM**, a minor, **FATIMA HUSROM**, a minor, and **MOHAMMED HUSROM**, a minor
Real Parties in Interest

District Court Case No. A-21-835385-C

PETITIONER'S APPENDIX TO PETITION FOR WRIT OF PROHIBITION

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GLAXOSMITHKLINE LLC, v. THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, et al.

Index of Exhibits

PETITION FOR WRIT OF PROHIBITION

Exhibit	Document
A	Plaintiff Husrom Second Amended Complaint [PA-001 – PA-068]
B	Defendant GlaxoSmithKline Motion to Dismiss [PA-069 – PA-081]
C	Plaintiff Husrom Opposition to Motion to Dismiss [PA-082 – PA-099]
D	Defendant GlaxoSmithKline Reply in Support of Motion to Dismiss [PA-100 – PA-110]
E	Hearing Transcript of April 20, 2022 [PA-111 – PA-175]
F	Plaintiff Husrom Notice of Entry of Order Denying Defendant GlaxoSmithKline Motion to Dismiss [PA-176 – PA-194]

Exhibit A

Plaintiff Husrom Second Amended Complaint

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DISTRICT COURT
CLARK COUNTY, NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as the legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor;

Plaintiffs,

vs.

LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC.; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES I through X; and ROE CORPORATIONS XI through XX, inclusive,

Defendants.

Case No.: A-21-835385-C
Dept. No.: 15

SECOND AMENDED COMPLAINT FOR COMPENSATORY AND PUNITIVE DAMAGES & DEMAND FOR JURY TRIAL

Exempt from Arbitration
(Medical Malpractice-NAR 3(A))

Plaintiffs, SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM ("ELABBASSY") and JAMIL HUSROM ("JAMIL") individually and as the legal guardian for KHULOD HUSROM ("KHULOD"), a minor, SALIH HUSROM ("SALIH"), a minor, FATIMA HUSROM ("FATIMA"), a minor, and MOHAMMED HUSROM ("MOHAMMED"), a minor, by and through their attorneys of record, MICHAEL C. KANE, ESQ., and BRADLEY J. MYERS, ESQ., of THE702FIRM, and for their Complaint against Defendants, states, asserts and alleges as follows:

JURISDICTIONAL STATEMENT

1. The Eighth Judicial District Court has jurisdiction of this civil tort action pursuant to NRCP 8(a)(4), NRS 13.040, and NRS 41.130, as the occurrence giving rise to this matter took place in Clark County, Nevada, and the amount in controversy exceeds $15,000.00.

PARTIES

2. At all times relevant hereto, ELABBASSY, as Special Administrator of the Estate of DECEDENT HUSROM, deceased ("DECEDENT") was a resident of the County of Clark, State of Nevada.

3. At all times relevant hereto, JAMIL was a resident of the County of Clark, State of Nevada.

4. At all times relevant hereto, KHULOD was a resident of the County of Clark, State of Nevada.

5. At all times relevant hereto, SALIH was a resident of the County of Clark, State of Nevada.

6. At all times relevant hereto, FATIMA was a resident of the County of Clark, State of Nevada.

7. At all times relevant hereto, MOHAMMED was a resident of the County of Clark, State of Nevada.

8. At all times relevant hereto, Decedent HUSROM ("Decedent") was a resident of Clark County Nevada.

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9. Based on information and belief, at all times relevant hereto, at all times relevant hereto, Defendant Las Vegas Medical Group, LLC ("LVMG") was and is a Nevada limited liability company doing business as a medical provider in the County of Clark, State of Nevada.

10. Based on information and belief, at all times relevant hereto, Defendant Nauman Jahangir, M.D. ("Dr. Jahangir") was a duly licensed physician practicing medicine in the State of Nevada and an employee/agent of LVMG.

11. Based on information and belief, at all times relevant hereto, Defendant GlaxoSmithKline, LLC ("GSK") is a Delaware limited liability corporation. At all times relevant hereto, GSK manufactured and distributed in the United States Zantac, a drug used to treat gastroesophageal reflux disease.

12. Since 1983, Defendants GSK LLC and GSK PLC (collectively "GSK"), and its predecessors, have controlled the prescription Zantac new drug applications ("NDA").

13. Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Inc.") is a Delaware corporation. Boehringer Inc. is a subsidiary of the German company Boehringer Ingelheim Corporation ("Boehringer Corporation"). Boehringer Inc. owned and controlled the NDAs for over-the-counter ("OTC") Zantac between December 2006 and January 2017, and manufactured and distributed the drug in the United States during that period. At all relevant times, Boehringer Inc. has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Nevada and Clark County.

14. Defendant, Boehringer Ingelheim USA Corporation ("Boehringer USA") is a Delaware corporation. At all relevant times, Boehringer USA has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Nevada and Clark County.

15. Defendant Boehringer Corporation is a German multinational pharmaceutical corporation. Boehringer Corporation is the parent company of Defendants Boehringer Inc. and Boehringer USA. At all relevant times, Boehringer Corporation has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and

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marketing of Zantac within the State of Nevada and Clark County.

16. Until January 2017, Boehringer Inc., Boehringer USA, and Boehringer Corporation (collectively "Boehringer) controlled the NDAs for OTC Zantac in the United States.

17. Defendant, Sanofi US Services, Inc. ("Sanofi US") is a Delaware corporation and is a wholly owned subsidiary of Sanofi S.A. Sanofi US controlled the NDA for OTC Zantac starting in January 2017 through the present and manufactured and distributed the drug in the United States during that period. Sanofi US voluntarily recalled all brand name OTC Zantac on October 18, 2019. At all relevant times, Sanofi US has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Nevada and Clark County.

18. Defendant Sanofi S.A. ("Sanofi S.A.") is a French multinational pharmaceutical company. Sanofi S.A. changed its name to Sanofi in May 2011. As of 2013, Sanofi S.A. was the world's fifth largest pharmaceutical company by prescription sales. At all relevant times, Sanofi S.A. has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Nevada and Clark County.

19. Defendant Sanofi-Aventis U.S. LLC ("Sanofi-Aventis") was and is a Delaware limited liability company. Sanofi-Aventis is a wholly owned subsidiary of Sanofi S.A. At all relevant times, Sanofi-Aventis conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Nevada and Clark County.

20. 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.

21. Collectively, Defendants Sanofi US, Inc., Sanofi S.A., Sanofi-Aventis and Chattem, Inc. shall be referred to as "Sanofi."

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22. At all relevant times, Defendants Boehringer, GSK, and Sanofi (collectively the "Zantac Manufacturer Defendants") designed, manufactured, sold, marketed, advertised, promoted, tested, labeled, packaged, handled, distributed, stored ranitidine-containing drugs including the brand name, Zantac, and its various generic forms ("Ranitidine-Containing Drugs").

23. Defendant Smith's Food & Drug Centers, Inc. ("Smith's) was and is a foreign corporation. Smith's has conducted business and derived substantial revenue from its advertising, selling, and marketing of Ranitidine-Containing Drugs within the State of Nevada and Clark County. Specifically, Smith's supplied Decedent with the Ranitidine-Containing Drugs which caused Decedent's injuries.

24. Defendant Walmart, Inc. ("Walmart") was and is a foreign corporation. Walmart has conducted business and derived substantial revenue from its advertising, selling, and marketing of Ranitidine-Containing Drugs within the State of Nevada and Clark County. Specifically, Walmart supplied Decedent with the Ranitidine-Containing Drugs which caused Decedent's injuries.

25. Defendant CVS Pharmacy, Inc. ("CVS") was and is a foreign corporation. CVS has conducted business and derived substantial revenue from its advertising, selling, and marketing of Ranitidine-Containing Drugs within the State of Nevada and Clark County. Specifically, CVS supplied Decedent with the Ranitidine-Containing Drugs which caused Decedent's injuries.

26. Defendant Walgreen Co. d/b/a Walgreens ("Walgreens") was and is a foreign corporation. Walgreens has conducted business and derived substantial revenue from its advertising, selling, and marketing of Ranitidine-Containing Drugs within the State of Nevada and Clark County. Specifically, Walgreens supplied Decedent with the Ranitidine-Containing Drugs which caused Decedent's injuries.

27. Defendants Smith's, Walmart, CVS, and Walgreens shall be referred to collectively as the "Zantac Retailer Defendants." The Zantac Manufacturer Defendants and the Zantac Retailer Defendants shall be referred to collectively as the "ZANTAC Defendants."

28. The true names and capacities, whether individual, corporate, associate or otherwise of Defendants DOES I through X and ROE CORPORATIONS XI through XX,

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inclusive, are unknown to Plaintiffs, who therefore sue such Defendants by fictitious names. Plaintiffs are informed and believe and thereon allege that each of these fictitiously named Defendants are responsible in some manner for the occurrences alleged in this Amended Complaint, and that Plaintiffs' injuries described in this Complaint were proximately caused by their tortious conduct. Plaintiffs therefore sue these fictitiously named Defendants by their fictitious names and will amend this Complaint to show their true names and identities when ascertained.

29. Plaintiffs are informed and believe that, at all relevant times, LVMG and Dr. Jahangir (collectively, the "Medical Defendants"), and all of the other medical facilities, doctors, nurses, assistants, attendants, employees and the like, whose names cannot be read from the medical records presently in Plaintiffs' possession, and are therefore presently unknown and unascertained and who are included among DOES I-X, inclusive, and other Defendants fictitiously named herein, were all hospitals, physicians or surgeons, licensed by the State of Nevada to provide medical services in the State of Nevada, and/or are nurses, assistants, attendants, employees and the like.

30. Plaintiffs are informed and believe that at all times herein mentioned Medical Defendants, and ROE CORPORATIONS XI-XX, inclusive, whether they are corporate, a partnership, privately owned or other business enterprise, were and are authorized and licensed to conduct and did conduct a hospital or clinic or laboratory, business or businesses in the State of Nevada, to which hospital or clinic the members of the public were invited, including Decedent herein, on the representation that adequate and careful health care was offered, that such facility was properly equipped, fully accredited and licensed, and competently staffed by qualified, able, and competent personnel, operating in compliance with the standard of care maintained in other properly equipped and efficiently operate and administered accredited hospitals in their communities offering full, competent and efficient hospital and medical, surgical, laboratory, diagnostic, and paramedical services to the general public and to Decedent; and that these Defendants administered, governed, controlled, managed, and directed all the necessary functions, activities and operation in these medical facilities, including care by physician assistants, nurses,

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physicians and surgeons, medical staff, and including, but not limited to, personnel and staff in specialized departments, where such specialized departments were organized and represented to the public as a specialized hospital or such facility, in a careful, competent and lawful manner and in a manner which was not below the standard of care to which such facilities are governed and to which similar facilities in the community manage their conduct, care, and affairs.

31. Plaintiffs are informed and believe and thereon allege that at all times herein mentioned, Dr. Jahangir was the agent and/or employee of Defendants LVMG and/or Roe Defendants XI-XX, inclusive, and was acting within the course and scope of such agency and/or employment, in furtherance of the profit-making business of Defendants LVMG and/or Roe Defendants XI-XX, inclusive.

32. Plaintiffs are informed and believe and allege that at all times mentioned herein, Zantac Manufacturer Defendants and Zantac Retail Defendants, DOES I through X and ROE CORPORATIONS XI through XX, inclusive, and each of them, were also known as, formerly known as and/or were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were members in an entity or entities engaged in the funding, researching, studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging and advertising of Ranitidine-Containing Drugs. Zantac Manufacturer Defendants and Zantac Retail Defendants, DOES I through X and ROE CORPORATIONS XI through XX, inclusive, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Zantac Manufacturer Defendants and Zantac Retail Defendants, DOES I through X and ROE CORPORATIONS XI through XX, inclusive, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product

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line (or portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendants has the ability to assume the risk spreading role of each such alternate entity.

33. Upon information and belief, at relevant times, Zantac Manufacturer Defendants and Zantac Retail Defendants, DOES I through X and ROE CORPORATIONS XI through XX, inclusive, were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of Nevada, including in Clark County, either directly or indirectly, through third parties or related entities, Ranitidine-Containing Drugs.

34. At relevant times, Zantac Manufacturer Defendants and Zantac Retail Defendants, DOES I through X and ROE CORPORATIONS XI through XX, inclusive, and each of them, conducted regular and sustained business and engaged in substantial commerce and business activity in the State of Nevada, which included but was not limited to selling, marketing and distributing Ranitidine-Containing Drugs in the State of Nevada and Clark County.

35. At all relevant times, Zantac Manufacturer Defendants and Zantac Retail Defendants, DOES I through X and ROE CORPORATIONS XI through XX, inclusive, and each of them, expected or should have expected that their acts would have consequences within the United States of America including the State of Nevada and including Clark County, said Defendants derived and derive substantial revenue therefrom.

AUTHORITY OF PARTNERSHIP DEFENDANTS, AGENTS, SERVANTS, EMPLOYEES, AND REPRESENTATIVES

36. Whenever it is alleged in this Complaint that a Defendant did any such act or thing, it is meant that such Defendant's officers, agents, servants, employees, or representatives did such act or thing and at the time such act or thing was done, it was done with full authorization or ratification of such Defendant or was done in the normal and routine course and scope of business, or with the actual, apparent and/or implied authority of such Defendant's officers, agents, servants, employees, or representatives. Specifically, Defendants are liable for the actions of their officers,

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agents, servants, employees, and representatives.

JOINT AND SEVERAL LIABILITY

37. All of the Defendants as named herein are jointly and severally liable to Plaintiffs for their damages. Plaintiffs are informed and believe and thereupon allege that Defendants, and each of them, jointly and in concert undertook to perform the acts as alleged herein, that Defendants and each of them had full knowledge of the acts of each Co-Defendant as alleged herein, and that each Defendant authorized or subsequently ratified the acts of each Co-Defendant as alleged herein, making each Co-Defendant an agent of the other Defendants and making each Defendant jointly responsible and liable for the acts and omissions of each Co-Defendant as alleged herein.

38. Plaintiffs are informed and believe, and thereon allege that, at all times re1evant, Defendants were the agents, servants, employees, employers, co-partners, joint venturers and affiliates of each of the other Defendants, and in doing the acts alleged herein were acting within the course and scope of such capacity, and that each and every Defendant herein when acting as principal was negligent in the selection, luring, association, and partnership of each and every other Defendant herein.

FACTUAL ALLEGATIONS (MEDICAL DEFENDANTS)

39. Plaintiffs repeat and reallege the allegations above, as though fully set forth herein.

40. On March 11, 2019, Decedent (age 32) presented to Vishvinder Sharma, MD, a Gastroenterologist with Digestive Associates, LLP, with "worsening dysphagia to both liquids and solids."

41. On March 19, 2019, Dr. Sharma performed an esophagogastroduodenoscopy (EGD) and a biopsy of Decedent's proximal esophagus.

42. The biopsy report revealed "Esophageal Intraepithelial Neoplasia with High Grade Dysplasia" and "fragment of inflamed necrotic on the epithelium consistent with ulcer base."

43. On April 27, 2019, Decedent presented to Dr. Sharma who noted, among other things, that "CT scan of the neck performed showed effacement of the left vallecula, cervical esophagus showed thickening and she also has an aberrant right subclavian artery which courses

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posterior to the upper thoracic esophagus." Dr. Sharma further noted that "Histology Biopsies revealed esophageal Intraepithelial new plays [sic] a with high-grade dysplasia; in addition there was fragmented inflamed necrotic epithelium consistent with ulcer."

44. On June 13, 2019, Decedent presented to Dr. Jahangir, a Cardiovascular Thoracic Surgeon who was an employee/agent of LVMG, to address the esophageal high grade dysplasia diagnosis. During the visit, Dr. Jahangir, while in the course and scope of his employment with LVMG, noted that "Her most recent endoscopy was in March of this year by Dr. Sharma who also took biopsies and this revealed high grade dysplasia of the esophagus." At that time, Dr. Jahangir was concerned about the dysplasia and determined that "She would most likely require some sort of surgical resection."

45. On July 18, 2019, Decedent returned to Dr. Jahangir. During that visit, Dr. Jahangir, while in the course and scope of his employment with LVMG, scheduled Decedent for an endoscopy, and he planned to perform a biopsy if a stricture is noted.

46. On July 29, 2019, Dr. Jahangir (while in the course and scope of his employment with LVMG) performed the endoscopy on Decedent. According to Dr. Jahangir "The mid and distal esophagus appeared to be normal without obvious lesions nor strictures" and that "A systematic examination of the esophagus was then performed from the GE junction to the pharynx. There is no area of stricture nor is there any mass lesions seen though in the proximal esophagus/hypopharynx, there is some raw area possibly related to prior interventions but definitely no area of stenosis."

47. On July 29, 2019, Dr. Jahangir (while in the course and scope of his employment with LVMG) failed to perform a biopsy of Decedent's esophagus (including the "raw area" in the proximal esophagus/hypopharynx noted in his report), which was found to have "Esophageal Intraepithelial Neoplasia with High Grade Dysplasia" in a March 19, 2019 biopsy performed by Dr. Sharma.

48. On August 1, 2019, Decedent returned to Dr. Jahangir. During that visit, Dr. Jahangir (while in the course and scope of his employment with LVMG) explained to Decedent that "there is nothing inherently wrong with her esophagus however there is external compression

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of the esophagus from an aberrant blood vessel, the right subclavian artery and that is the source of her symptoms which needs to be addressed."

49. Consequently, Dr. Jahangir, (while in the course and scope of his employment with LVMG) decided not to perform surgical resection of Decedent's dysplastic area in the proximal esophagus as he had previously planned, and he did not order any treatment to address Decedent's high grade dysplasia that was diagnosed by a biopsy performed by Dr. Sharma on March 19, 2019.

50. However, Dr. Jahangir (while in the course and scope of his employment with LVMG) recommended that Decedent undergo reimplantation of the aberrant right subclavian artery via sternotomy with cardiopulmonary bypass at Spring Valley Hospital, which Decedent did not undergo because it was not an urgent surgery.

51. Decedent trusted Dr. Jahangir's professional opinion and assurances (which were made while in the course and scope of his employment with LVMG) that "there is nothing inherently wrong with her esophagus," that she did not have precancer/cancer in her esophagus, and that she did not need any treatment to address the high grade dysplasia diagnosis from the biopsy performed by Dr. Sharma on March 19, 2019.

52. As a result, Decedent did not seek any medical care and treatment relating to the high-grade dysplasia diagnosis from the biopsy performed by Dr. Sharma on March 19, 2019.

53. On March 12, 2020, Decedent returned to Dr. Jahangir with continued difficulty swallowing. At that time, Dr. Jahangir (while in the course and scope of his employment with LVMG) reiterated his prior diagnosis of esophageal compression due to aberrant right subclavian artery and the need for Decedent to undergo surgical repair.

54. On May 28, 2020, Dr. Jahangir (while in the course and scope of his employment with LVMG) was informed that Decedent had difficulty swallowing. Dr. Jahangir instructed that Decedent present to the emergency room at Spring Valley Hospital to be admitted in order to undergo surgery on June 5, 2020 to repair the apparent right subclavian artery.

55. On May 30, 2020, Decedent was admitted into Spring Valley Hospital with difficulty swallowing.

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56. Contrary to Dr. Jahangir's long-standing diagnosis, a May 31, 2020 CT Angiogram of Decedent's Chest showed an "Aberrant right subclavian artery…with no apparent compression or involvement of the adjacent cervical esophagus."

57. A CT scan of Decedent's neck on June 3, 2020 showed progressive irregularity to the upper esophagus with new bilateral cervical lymphadenopathy. A biopsy of an enlarged left cervical node on June 3, 2020 revealed that Decedent had Stage IVA squamous cell carcinoma.

58. On or about June 18, 2020, Decedent underwent an implantation of a feeding tube because the cancerous lesion blocked her ability to swallow.

59. On or about July 8, 2020, Decedent underwent a tracheostomy because the cancerous lesion blocked her ability to breathe.

60. A July 8, 2020 biopsy of the Hypopharynx confirmed invasive squamous cell carcinoma.

61. Thereafter, Decedent required aggressive chemotherapy and radiation to treat the cancerous lesion, which resulted in a great deal of scar tissue and a stricture of Decedent's esophagus.

62. To address the stricture of Decedent's esophagus (which would allow for the removal of the feeding tube and the trach), Decedent was required to undergo several procedures at Keck Medicine of USC.

63. On October 7, 2021, Decedent passed away and her cause of death was attributed to squamous cell carcinoma of head and neck with metastasis to cervical lymph nodes

64. On or about May 24, 2021, Oluwole Fajolu, M.D., F.A.C.S. ("Dr. Fajolu"), a Cardiovascular Thoracic Surgeon who practices in an area substantially similar to the type of practice engaged in by Dr. Jahangir (while Dr. Jahangir was in the course and scope of his employment with LVMG) at the time of the alleged malpractice, provided a declaration (as required by NRS 41A.071), which supports the allegations contained in this action. Dr. Fajolu's Declaration and CV are collectively attached hereto as Exhibit 1.

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65. In his Declaration, Dr. Fajolu, based upon his training, experience, and expertise, and further, based upon his review of salient medical records, opined to a reasonable degree of medical probability that:

> Dr. Jahangir (an employee/agent of Las Vegas Medical Group, LLC) deviated from the accepted standard of care in his care and treatment of Decedent by: (1) failing to perform a biopsy on Decedent's esophagus despite the March 19, 2019 biopsy finding of high grade dysplasia in the proximal esophagus and the July 29, 2019 abnormal finding of a "raw area" in the proximal esophagus/hypopharynx noted during the EGD that Dr. Jahangir performed; (2) incorrectly advising Decedent that "there is nothing inherently wrong with her esophagus" despite the recent diagnosis of esophageal high grade dysplasia; and (3) incorrectly determining that the cause of Decedent's dysphagia was an "external compression of the esophagus from an aberrant blood vessel, the right subclavian artery and that is the source of her symptoms which needs to be addressed," which was proven to be wrong during Decedent's hospitalization at Spring Valley Hospital.

Id., ¶ 24.

66. Collectively attached hereto as Exhibit 2 are a Declaration and CV of Judy L. Schmidt, M.D., F.A.C.P., a Medical Oncologist, which further supports the allegations contained in this action. Specifically, Dr. Schmidt provides the following opinions:

> Based upon my training and experience in Medical Oncology and further based upon my review of the records listed above, it is my opinion to a reasonable degree of medical probability that if a biopsy of Decedent's proximal esophagus was done on July 29, 2019 when Dr. Jahangir (an employee/agent of LVMG) performed the EGD, the result would have indicated (more probable than not) the presence of Stage T1a esophageal cancer.
>
> It is further my opinion to a reasonable degree of medical probability that because Dr. Jahangir (an employee/agent of LVMG) did not biopsy Decedent's proximal esophagus on July 29, 2019, assured Decedent that "there is nothing inherently wrong with her esophagus" on August 1, 2019, and Decedent's probable Stage T1a esophageal cancer went untreated for nearly ten (10) months, the cancer progressed to Stage IVA esophageal cancer in June 2020 when Decedent underwent a biopsy at Spring Valley Hospital.
>
> It is further my opinion to a reasonable degree of medical probability that, had Dr. Jahangir (an employee/agent of LVMG) biopsied Decedent's proximal esophagus on July 29, 2019 and the probable

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> Stage T1a esophageal cancer was recognized and diagnosed in or about July 29, 2019, Decedent would have (more probable than not) had the opportunity to undergo an endoscopic mucosal resection/a minor surgery of the areas involved and subsequent close ongoing monitoring.
>
> It is further my opinion to a reasonable degree of medical probability that, had Dr. Jahangir (an employee/agent of LVMG) biopsied Decedent's proximal esophagus on July 29, 2019 and the probable Stage T1a esophageal cancer was recognized and diagnosed in or about July 29, 2019, Decedent would have (more probable than not) avoided (among other things) the need for a feeding tube, tracheostomy, chemotherapy, radiation, and the multiple procedures she was required to undergo at Keck Medicine of USC to resolve the esophageal stricture caused by scar tissue due to radiation.
>
> As such, it is further my opinion to a reasonable degree of medical probability that the nearly ten (10) months delay in diagnosis and treatment caused by the failure of Dr. Jahangir (an employee/agent of LVMG) to biopsy Decedent's proximal esophagus on July 29, 2019 statistically decreased Decedent's 5-year survival by approximately 69%. Stated differently, Decedent lost approximately 47 years of life expectancy.

Id. ¶¶ 24-27, 29.

67. The underlying Complaint was filed less than three (3) years following Defendants' medical malpractice and less than one (1) year following the date Plaintiff first learned or had a reasonable opportunity to learn of the fact that the injuries and damages suffered and complained of in this Complaint were a proximate result of negligent acts or omissions to act on the part of Defendants.

FACTUAL ALLEGATIONS (ZANTAC DEFENDANTS)

68. Plaintiffs repeat and reallege the allegations above, as though fully set forth herein.

69. From November 2016 through September 2019, Decedent ingested Zantac and its various generic forms.

70. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Decedent was diagnosed with esophageal cancer, which was deemed to be her cause of death.

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71. Based on prevailing scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant N-Nitrosodimethylamine ("NDMA") causes esophageal cancer in humans.

72. As more particularly set forth herein, Plaintiffs maintain, among other things, that the Ranitidine-Containing Drugs Decedent ingested were defective, dangerous to human health, unfit and unsuitable to be advertised, marketed, and sold in the United States, were manufactured improperly, and lacked proper warnings of the dangers associated with their use.

73. NDMA is a potent carcinogen. Discovered as a byproduct in manufacturing rocket fuel in the early 1900s, today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no business being in a human body.

74. Zantac, the popular antacid medication that was used by millions of people every day, leads to the production of staggering amounts of NDMA. The U.S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 96 ng (nanograms) and yet, in a single dose of Zantac, researchers are discovering over 3 million ng.

75. These recent revelations by independent researchers have caused widespread recalls of Zantac and its generic forms both domestically and internationally, including the domestic recall by the current owner and controller of Zantac new drug applications ("NDA"). On April 1, 2020, the FDA ordered the immediate recall of all Ranitidine-Containing Drugs sold in the United States citing unacceptable and unpreventable levels of NOMA accumulation.

76. The high levels of NDMA observed in Ranitidine-Containing Drugs is a function of the ranitidine molecule: (1) the way it breaks down in the human digestive system; (2) the way it interacts with various enzymes in the human body; (3) the way it breaks down when exposed to heat, in particular, during transport and storage; and (4) the way the molecule naturally degrades, over time, into NDMA. As it stands, ingestion of Ranitidine-Containing Drugs leads to high levels of NDMA exposure that are proven to cause cancer.

I. A Brief History of Zantac and Ranitidine

77. 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

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

78. Due in large part to GSK's marketing strategy, Zantac was a wildly successful drug. 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 as 2016, Zantac was the 50th most prescribed drug in the United States with over 15 million prescriptions. The marketing strategy that led to Zantac's success for over 30 years emphasized the purported safety of the drug. Zantac has been marketed as a safe and effective treatment for infants, children, and adults.

79. Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year.

80. 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.

81. 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.

82. 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 they removed Zantac and ranitidine products from their shelves.

83. 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.

84. 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.

85. At no time did any Defendant attempt to include a warning about NDMA or any cancer, nor did the FDA ever reject such a warning. Defendants had the ability to unilaterally add an NDMA and/or cancer warning to the Zantac label (for both prescription and OTC) without prior

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FDA approval pursuant to the Changes Being Effected regulation. Had any Defendant attempted to add an NDMA warning to the Zantac label (either for prescription or OTC), the FDA would have not rejected it.

II. The Dangers of NDMA

86. NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens. NDMA is no longer produced or commercially used in the United States, except for the purpose of inducing tumors in laboratory animals.

87. 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.

88. Beginning in July 2018, the FDA has recalled several generic blood pressure medications, such as: valsartan, losartan, and irbesartan, because the medications contained nitrosamine impurities that exceeded the 96 nanogram acceptable daily threshold set by the FDA. The highest levels detected by the FDA in valsartan pills were over 20,000 nanograms per pill. In the case of valsartan, NDMA was deposited into the pill due to a manufacturing defect, and therefore, NDMA was present in only some of the valsartan containing products. For Zantac, NDMA is a byproduct of the ranitidine molecule itself, and the levels observed in recent testing show NDMA levels in excess of 3,000,000 nanograms. In addition, NDMA has been a byproduct of the ranitidine molecule since it was first marketed in the U.S. in 1983. Therefore, Zantac consumers will have been exposed to millions of nanograms of NDMA from 1983 until Zantac was recently pulled off the pharmacy shelves.

89. In animal studies examining the carcinogenicity of NDMA through oral administration, animals exposed to NDMA developed cancer in the stomach, liver, kidney, bladder, esophagus, pancreas and other organs.

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90. Alarmingly, Zantac is listed in FDA's category for birth defects, meaning it is considered safe to take during pregnancy. However, in laboratory animals exposed to NDMA during pregnancy, the offspring had elevated rates of cancer in the liver and kidneys.

91. Numerous in vitro studies confirm that NDMA is a mutagen that causes mutations in human and animal cells.

92. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous epidemiological studies exploring the effects of NDMA dietary exposure to various cancers. The exposure levels considered in these studies are a very small fraction - as little as 1 millionth - of the exposure levels from a single Zantac pill, i.e., 0.191 ng/day (dietary) versus 304,500 ng/day (Zantac).

93. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng/day.[1]

94. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[2]

95. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.[3]

III. How Ranitidine Transforms into NDMA Within the Body

96. The high levels of NDMA 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

1 Pobel et al, Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in Marseille, France, 11 EUROP. J. EPIDEMIOL. 67-73 (1995).

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

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

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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.

97. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply.[4] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[5]

98. Valisure, LLC is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO"), an accreditation recognizing the laboratories technical competence for regulatory. 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.

99. As part of its testing of Zantac and other ranitidine products in every lot tested, Valisure discovered exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 nanograms.[6] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet.

100. Valisure's testing shows over 2 million nanograms of NDMA in a 150 mg Zantac pill. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at 28,000 times the permissible limit. In terms of smoking, a person would need to smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

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4 Ogawa et al, *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney*, 264 J. BIO. CHEM. 17, 10205-10209 (1989).

5 Mitch et al, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENV. ENG. SCI. 5, 389-404 (2003).

6 US Food and Drug Administration. (updated 01/25/2019). Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, *FY19-005-DPA-S*.

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

102. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[7]

103. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present.

104. 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.

105. Antacid drugs are known to increase stomach pH and thereby increase the growth of nitrite-reducing bacteria which further elevate levels of nitrite. This fact is well known and present in the warning labels of antacids like Prevacid and was specifically studied with ranitidine in the original approval of the drug. Thus, higher levels of nitrites in patients regularly taking Zantac would be expected.

106. In fact, NDMA formation in the stomach has been a concern for many years and specifically ranitidine has been implicated as a cause of NDMA formation by multiple research groups, including those at Stanford University.

107. Existing research shows that ranitidine interacts with nitrites and acids in the chemical environment of the human stomach to form NDMA. In vitro tests demonstrate that when ranitidine undergoes "nitrosation" (the process of a compound being converted into nitroso

7 *See, e.g.*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; https://youtu.be/jzS2kuB5_wg; https://youtu.be/Z3QMwkSUlEg; https://youtu.be/qvh9gyWqQns.

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derivatives) by interacting with gastric fluids in the human stomach, the by-product created is dimethylamine ("DMA") - which is an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA, a secondary N-nitrosamine.

108. Moreover, in addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH") which can occur in other tissues and organs separate from the stomach.

109. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the esophagus. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[8]

110. Computational modelling demonstrates that ranitidine can readily bind to the DDAH-1 enzyme in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA").

111. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

112. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, prostate, stomach, esophagus, bladder, brain, colon, and prostate. This offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs, including the esophagus.

8 Ogawa et al, *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney,* 264 J. BIO. CHEM. 17, 10205-10209 (1989).

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113. The human data, although limited at this point, is even more concerning. A study completed and published in 2016 by Stanford University observed that healthy individuals, both male and female, who ingested Zantac 150 mg tablets produced roughly 400 times elevated amounts of NDMA in their urine (over 47,000 ng) in the proceeding 24 hours after ingestion.[9]

114. A 2004 study published by the National Cancer Institute investigated 414 cases of peptic ulcer disease reported in 1986 and followed the individual cases for 14 years.[10] One of the variables investigated by the authors was the patients' consumption of a prescription antacid, either Tagamet (cimetidine) or Zantac (ranitidine). The authors concluded that "[r]ecent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of esophageal cancer, and this association was independent of the elevated risk observed with gastric ulcers." Specifically, the authors note that "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to esophageal cancer risk." NDMA is among the most common of the N-Nitrosamines.

115. A 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, no effect was observed for cimetidine administered with nitrite, but ranitidine administered with nitrite resulted in a significant DNA fragmentation.[11]

116. Investigators at Memorial Sloan Kettering Cancer Center are actively studying ranitidine to evaluate the extent of the public health implications of these findings. Regarding ranitidine, one of the investigators commented: "A potential link between NDMA and ranitidine is concerning, particularly considering the widespread use of this medication. Given the known carcinogenic potential of NDMA, this finding may have significant public health implications[.]"

IV. Defendants Knew of the NDMA Defect but Failed to Warn or Test

117. During the time that Defendants manufactured and sold Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA.

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9 Zeng et al, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37 CARCINOGENESIS 625-634 (2016).

10 Michaud et al, *Peptic ulcer disease and the risk of bladder cancer in a prospective study of male health professionals*, 13 CANCER EPIDEMIOL BIOMARKERS PREV. 2, 250-254 (2004).

11 Brambilla et al, *Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance*, Nicolini C. (eds) Chemical Carcinogenesis. NATO Advanced Study Institutes Series (Series A: Life Sciences), Vol 52. Springer, Boston, MA (1982).

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Defendants failed to disclose this risk to consumers on the drug's label - or through any other means - and Defendants failed to report these risks to the FDA.

118. Going back as far as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested. This was known or should have been known by Defendants.

119. 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.

120. 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.

121. "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).

122. 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.

123. Defendants never provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

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124. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[12] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiffs believe this was intentional - a gambit by the manufacturer to avoid detecting a carcinogen in their product.

125. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[13] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk.

126. There are multiple alternatives to Zantac that do not pose the same risk, such as Cimetidine (Tagamet), Famotidine (Pepcid), Omeprazole (Prilosec), Esomeprazole (Nexium), and Lansoprazole (Prevacid).

FIRST CLAIM FOR RELIEF

(Medical Malpractice v. Medical Defendants)

127. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

128. Plaintiffs are informed and believe and thereon allege that at all times herein mentioned, Dr. Jahangir was the agent and/or employee of Defendants LVMG and/or Roe

12 Carey et al, *Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography*, 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).

13 Thomas et al, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 GUT. Vol. 28, 726-738 (1987).

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Defendants XI-XX, inclusive, and was acting within the course and scope of such agency and/or employment, in furtherance of the profit-making business of Defendants LVMG and/or Roe Defendants XI-XX, inclusive.

129. On June 13, 2019, Decedent presented to Dr. Jahangir, a Cardiovascular Thoracic Surgeon who was an employee/agent of LVMG, to address the esophageal high grade dysplasia diagnosis from a March 19, 2019 biopsy.

130. On July 29, 2019, Dr. Jahangir (while in the course and scope of his employment with LVMG) performed an endoscopy on Decedent.

131. On July 29, 2019, Dr. Jahangir (while in the course and scope of his employment with LVMG) failed to perform a biopsy of Decedent's esophagus (including the "raw area" in the proximal esophagus/hypopharynx noted in his report), which was found to have "Esophageal Intraepithelial Neoplasia with High Grade Dysplasia" in a March 19, 2019 biopsy performed by Dr. Sharma.

132. On August 1, 2019, Dr. Jahangir (while in the course and scope of his employment with LVMG) explained to Decedent that "there is nothing inherently wrong with her esophagus…."

133. Consequently, Dr. Jahangir, (while in the course and scope of his employment with LVMG) decided not to perform surgical resection of Decedent's dysplastic area in the proximal esophagus as he had previously planned, and he did not order any treatment to address Decedent's high grade dysplasia that was diagnosed by a biopsy performed by Dr. Sharma on March 19, 2019.

134. Decedent trusted Dr. Jahangir's professional opinion and assurances (which were made while in the course and scope of his employment with LVMG) that "there is nothing inherently wrong with her esophagus," that she did not have precancer/cancer in her esophagus, and that she did not need any treatment to address the high-grade dysplasia diagnosis from the biopsy performed by Dr. Sharma on March 19, 2019.

135. As a result, Decedent did not seek any medical care and treatment relating to the high-grade dysplasia diagnosis from the biopsy performed by Dr. Sharma on March 19, 2019.

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136. In providing medical care and treatment to Decedent, Dr. Jahangir and LVMG owed a duty to Decedent to exercise reasonable care.

137. Dr. Jahangir and LVMG breached their duty to Decedent by, among other things, (1) failing to perform a biopsy on Decedent's esophagus on July 29, 2019 despite the March 19, 2019 biopsy finding of high grade dysplasia in the proximal esophagus and the July 29, 2019 abnormal finding of a "raw area" in the proximal esophagus/hypopharynx noted during the EGD that Dr. Jahangir performed; (2) incorrectly advising Decedent that "there is nothing inherently wrong with her esophagus" despite the recent diagnosis of esophageal high grade dysplasia; and (3) incorrectly determining that the cause of Decedent's dysphagia was an "external compression of the esophagus from an aberrant blood vessel, the right subclavian artery and that is the source of her symptoms which needs to be addressed," which was proven to be wrong during Decedent's hospitalization at Spring Valley Hospital. ***See*** Fajolu Declaration, ***Exhibit 1***, ¶ 24.

138. As a proximate result of the negligence of Dr. Jahangir and LVMG, Decedent was diagnosed with Stage IVA esophageal cancer in June 2020. ***See*** Schmidt Declaration, ***Exhibit 2***, ¶ 25.

139. As a further proximate result of the negligence of Dr. Jahangir and LVMG, Decedent (more probable than not) lost the opportunity to undergo an endoscopic mucosal resection/a minor surgery of the areas involved and subsequent close ongoing monitoring. ***Id.***, ¶ 26.

140. As a further proximate result of the negligence of Dr. Jahangir and LVMG, Decedent would have (more probable than not) avoided (among other things) the need for a feeding tube, tracheostomy, chemotherapy, radiation, and the multiple procedures she was required to undergo at Keck Medicine of USC to resolve the esophageal stricture caused by scar tissue due to radiation. ***Id.,*** ¶ 27.

141. As a further proximate result of the negligence of Dr. Jahangir and LVMG, Decedent's 5-year survival decreased by approximately 69%. ***Id.,*** ¶ 29. Stated differently, Decedent lost approximately 47 years of life expectancy. ***Id.***

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142. As a further proximate result of the negligence of Dr. Jahangir and LVMG, Decedent had to endure extreme pain and suffering and disfigurement.

143. As a further proximate result of the negligent conduct of Dr. Jahangir and LVMG, Decedent is entitled to recover other general, special and compensatory damages in an amount in excess of $15,000.00.

144. It was necessary for Plaintiffs to retain the services of an attorney to file this action. Therefore, Plaintiffs are entitled to an award of reasonable attorney's fees and costs of suit.

SECOND CLAIM FOR RELIEF

(Gross Negligence/Recklessness v. All Defendants)

145. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

146. Plaintiffs are informed and believe and thereon allege that at all times herein mentioned, Dr. Jahangir was the agent and/or employee of Defendants LVMG and/or Roe Defendants XI-XX, inclusive, and was acting within the course and scope of such agency and/or employment, in furtherance of the profit-making business of Defendants LVMG and/or Roe Defendants XI-XX, inclusive.

147. The conduct of Dr. Jahangir and LVMG, as described herein, constitute unlawful acts and omissions, carelessness, gross negligence, and recklessness of the Defendants, and each of them, in failing to properly diagnose and care for Decedent.

148. As a direct and proximate result of the gross negligence and recklessness of Defendants, Decedent is entitled to recover other general, special and compensatory damages in an amount in excess of $15,000.00.

149. It was necessary for Plaintiffs to retain the services of an attorney to file this action. Therefore, Plaintiffs are entitled to an award of reasonable attorney's fees and costs of suit.

THIRD CLAIM FOR RELIEF

(Loss of Consortium- Jamil v. All Defendants)

150. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

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151. As a direct and proximate result of the injuries sustained by Decedent, was unable to perform her daily activities and services as a wife to her husband, Plaintiff JAMIL.

152. By reason of the injuries so inflicted on Decedent caused by the acts and omissions of Defendants, and each of them, Jamil has lost the companionship, society, love, affection, consortium, and services of his wife, resulting in general damages in an amount far in excess of $15,000.00.

153. It was necessary for Plaintiffs to retain the services of an attorney to file this action. Therefore, Plaintiffs are entitled to an award of reasonable attorney's fees and costs of suit.

FOURTH CLAIM FOR RELIEF

(Strict Liability – Design Defect v. ZANTAC Defendants)

154. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

155. Defendants designed, manufactured, marketed, promoted, sold, supplied and/or distributed Zantac.

156. Nevada common law requires manufacturers to design reasonably safe products. Defendants have a duty to use reasonable care to design a product that is reasonably safe for its intended use to prevent defects that constitute a substantial risk of foreseeable injury to persons using its products. Moreover, manufacturers stand in a superior position over consumers with regard to knowledge of, or the ability to discover and prevent, defects.

157. Zantac is defective in design and/or formulation due to its inherent risks of producing the carcinogen NDMA, thereby rendering the drug unreasonably dangerous. More specifically, Zantac is defective because the drug is made up of an inherently unstable ranitidine molecule that contains both a nitrate and a dimethylamine ("DMA") group that combine to form a known carcinogen (NDMA), which can lead to the development of cancer.

158. Defendants had a duty to use due care in designing Zantac and to disclose defects that they knew or should have known existed. In other words, Defendants had a duty to design Zantac to prevent it from reacting with itself to produce the carcinogen NDMA. Nevada law

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required Defendants to design Zantac differently. At no time was there a federal law that prohibited Defendants from submitting to FDA a different non-defective design for Zantac.

159. This defect in design and/or formulation existed at the time the drug left Defendants' possession and at the time it was sold to Plaintiff.

160. Zantac was expected to and did reach Plaintiff without a substantial change in condition in which it was sold.

161. At the time Zantac left Defendants' possession, an average consumer could not reasonably anticipate the dangerous nature of Zantac nor fully appreciate the attendant risk of injury associated with it use, including the risk of developing cancer.

162. Zantac was prescribed to and otherwise used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

163. As a direct and proximate result of Plaintiff's ingestion of Zantac, Plaintiff developed esophageal cancer.

164. That as a direct and proximate result of the Defendants' breach, Decedent suffered general, special and compensatory damages in an amount in excess of $15,000.00

165. WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF

(Strict Liability – Failure to Warn v. ZANTAC Defendants)

166. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

167. 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.

168. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Zantac to Plaintiff. Additionally, Defendants expected the Zantac that they were selling, distributing,

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supplying, manufacturing, and/or promoting to reach - and Zantac did in fact reach - consumers, including Plaintiff, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

169. 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.

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

171. 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.

172. 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.

173. 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.

174. 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.

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

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

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

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

179. 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.

180. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF

(Negligence v. ZANTAC Defendants)

181. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

182. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Zantac.

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

184. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a. In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Zantac;

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b. In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Zantac's dangerous and defective characteristics;

c. In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the ranitidine and/or Zantac;

d. In promoting Zantac in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause cancer;

e. In representing that Zantac was safe for its intended use when, in fact, the product was unsafe for its intended use;

f. In failing to perform appropriate pre-market testing of Zantac;

g. In failing to perform appropriate post-market surveillance of Zantac;

h. In failing to adequately and properly test Zantac before and after placing it on the market;

i. In failing to conduct sufficient testing on Zantac which, if properly performed, would have shown that Zantac could react with itself to produce the carcinogen NDMA;

j. In failing to adequately warn Plaintiff that the use of Zantac carried a risk of developing cancer;

k. In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of cancer associated with the use of Zantac; and

l. In failing to adequately and timely inform Plaintiff, the consuming public, and the healthcare industry of the risk of serious personal injury, namely cancer, from Zantac ingestion as described herein.

185. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

186. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, esophageal cancer. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur

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such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

187. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

SEVENTH CLAIM FOR RELIEF

(Breach of Express Warranty v. ZANTAC Defendants)

188. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

189. Through Defendants' public statements, descriptions, and promises relating to Zantac, Defendants expressly warranted that the product was safe and effective for its intended use and was designed to prevent and relieve heartburn associated with acid indigestion and sour stomach associated with acid indigestion brought on by eating or drinking certain foods and beverages.

190. These warranties came in one or more of the following forms: (a) publicly made written and verbal assurances of safety; (b) press releases, media dissemination, or uniform promotional information intended to create demand for Zantac, but which contained misrepresentations and failed to warn of the risks of using the product; (c) verbal assurances made by Defendants' marketing personnel about the safety of Zantac, which also downplayed the risks associated with the product; and (iv) false, misleading, and inadequate written information and packaging supplied by Defendants.

191. When Defendants made these express warranties, they knew the intended purposes of Zantac and warranted the drug to be in all respects safe and proper for such purposes.

192. Defendants drafted the documents and/or made statements upon which these warranty claims were based and, in doing so, defined the terms of those warranties.

193. Zantac does not conform to Defendants' promises, descriptions, or affirmations, and is not adequately packaged, labeled, promoted, and/or fit for the ordinary purposes for which it was intended.

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194. All of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiff's belief that these materials shall be produced by Defendants and made part of the record once discovery is completed.

195. As a direct and proximate result of Defendants' breach of these warranties, Plaintiff suffered serious injuries and/or side effects, including cancer and death.

196. As a direct and proximate result of Defendants' breach of the implied warranties, Plaintiff will require and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

197. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

EIGHTH CLAIM FOR RELIEF

(Breach of Implied Warranty v. ZANTAC Defendants)

198. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

199. At all times material to this action, Defendants were merchants Zantac.

200. Plaintiff was a foreseeable user of Zantac.

201. At the time Defendants marketed, sold, and distributed Zantac, Defendants knew of the intended use of the drug, impliedly warranted the drug to be fit for a particular purpose, and warranted that the drug was of merchantable quality and effective for such use.

202. Defendants knew or had reason to know that Plaintiff would rely on Defendants' judgment and skill in providing Zantac for its intended use.

203. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Zantac was of merchantable quality, safe, and effective for its intended use.

204. Contrary to Defendants' implied warranties, Zantac is neither of merchantable quality, nor safe or effective for its intended use, because the subject product is unreasonably dangerous, defective, unfit, and ineffective for the ordinary purposes for which it is used.

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205. Zantac was sold without adequate instructions or warnings regarding the foreseeable risk of harm posed by the drug.

206. In violation of Nevada law, Defendants breached their implied warranty to Plaintiff in that Zantac was not adequately tested and was not of merchantable quality, safe, or fit for its foreseeable and reasonably intended use.

207. Plaintiff could not have discovered that Defendants breached their warranty or the danger in using Zantac.

208. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff suffered serious injuries and/or side effects, including cancer and death.

209. As a direct and proximate result of Defendants' breach of the implied warranties, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

210. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

211. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

NINTH CLAIM FOR RELIEF

(Negligent Misrepresentation v. ZANTAC Defendants)

212. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

213. Defendants negligently and/or recklessly misrepresented to Plaintiff, the consuming public, and the healthcare industry the safety and effectiveness of Zantac and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Zantac.

214. Defendants made reckless or negligent misrepresentations and negligently and/or recklessly concealed adverse information when Defendants knew, or should have known, that Zantac had defects, dangers, and characteristics that were other than what Defendants had

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represented to Plaintiff, the consuming public, and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, the health care industry, and the consuming public that:

a. the defective, improper, negligent, fraudulent, and dangerous design of Zantac;

b. that ranitidine had not been adequately tested prior to product launch;

c. the connection between ranitidine and Zantac and NDMA formation;

d. that ranitidine and Zantac can produce NDMA at harmful levels;

e. that harmful levels of NDMA is carcinogenic;

f. the inadequacy of the labeling for Zantac; and

g. the dangerous effects of Zantac.

215. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

216. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, the consuming public, and the healthcare industry.

217. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, the consuming public, and the healthcare industry would rely on them, leading to the use of Zantac by Plaintiff as well as the general public.

218. At all times herein mentioned, Plaintiff was not made aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had he been aware of said facts, Plaintiff would not have taken Zantac.

219. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Zantac and relied on the absence of information regarding the dangers of Zantac which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

220. Defendants had a post-sale duty to warn Plaintiff and the general public about the potential risks and complications associated with Zantac in a timely manner.

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221. Defendants made the representations and actively concealed information about the defects and dangers of Zantac with the absence of due care such that Plaintiff and the consuming public would rely on such information, or the absence of information, in selecting Zantac as a treatment.

222. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff suffered serious injuries, including cancer.

223. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

224. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

225. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

TENTH CLAIM FOR RELIEF

(Fraudulent Concealment and/or Omissions v. ZANTAC Defendants)

[Discovery Rule and Tolling]

226. Plaintiffs incorporate by reference paragraphs each and every allegation previously made in this Amended Complaint, as if fully set forth herein.

227. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

228. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the wrongful act, cause of the injury, and/or the tortious nature of the wrongdoing that caused the injury.

229. Despite diligent investigation by Plaintiff into the cause of his injuries, the nature of Plaintiff's injuries and damages, and their relationship to Zantac was not discovered, and

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through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

230. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from of the true risks associated with their product, the nature of Plaintiff's injuries, and the connection between Plaintiff's injuries and Defendants' tortious conduct. As a result of Defendants' fraudulent concealment, Plaintiff was unaware, and could not have known or have learned through reasonable diligence that he had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

231. Defendants falsely and fraudulently represented to the medical and healthcare community, Plaintiff and the public the safety of Zantac for its intended use.

232. Defendants concealed that the design of Zantac lacked adequate safety data, that safety and efficacy of Zantac had not been established, that a carcinogenic ingredient was in Zantac in amounts sufficient to cause cancers, and that the characteristic of Zantac made it dangerous and increased the risks of injury in patients.

233. Further, in representations to Plaintiff, Defendants fraudulently concealed and intentionally omitted the statements described herein and below which were material in nature:

a. That the Defendants' product was not as safe as other products available;

b. That the risk of adverse events with the Defendants' product was higher than with other products;

c. The Defendants' product was not adequately tested;

d. That Defendants deliberately failed to inform health care providers and consumers about the carcinogenic properties of their product and/or misrepresented those properties;

e. That Defendants were aware of dangers in the Defendants' product in addition to and above and beyond those associated with other H2 blockers;

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f. That the Defendants' product was defective, and caused dangerous and adverse side effects, including but not limited to esophageal cancers at a much more significant rate than other products in the H2 blocker class;

g. That the Defendants' product was manufactured negligently;

h. That the Defendants' product was manufactured defectively; and

i. That the Defendants' product was designed negligently and designed defectively.

234. Defendants made claims and representations in their promotional materials to healthcare professionals and patients that the Defendants' product had innovative beneficial properties that increased the safety of the device.

235. The representations made by Defendants were, in fact, false and the omissions were misleading and fraudulent. When Defendants made the representations and omissions, Defendants knew and/or had reason to know that those representations were false, and the omissions were misleading, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in the representations and the dangers and health risks to users of Zantac, including Plaintiff.

236. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the Product was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff into reliance on the use of the subject product, and to cause him to purchase and/or use the subject product.

237. The information distributed to the public, the medical community, and Plaintiff by Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Defendants' product.

238. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Defendants' product.

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

240. At the time these representations and omissions were made by Defendants, and at the time Plaintiff was ingesting it, Plaintiff was unaware of the falsehood of these representations, misleading nature of omissions and statements, and reasonably believed them to be true. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

241. Plaintiff reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants that were critical to understanding the real dangers inherent in the use of Zantac.

242. In reliance upon these false representations, Plaintiff was induced to, and did use the product, thereby causing Plaintiff to sustain severe personal injuries and damages. Defendants knew or had reason to know that Plaintiff had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Defendants' product, as described in detail herein.

243. If Plaintiff would have been made aware of these purposefully suppressed and concealed facts, as set forth herein, Plaintiff would not have used or consented to the use of Zantac.

244. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff.

245. Defendants willfully, wantonly, recklessly and/or intentionally represented false, dangerous, and serious health and safety concerns inherent in the use of Defendants' product to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

246. Defendants chose to over-promote the purported safety, efficacy and benefits of the Defendants' product instead.

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247. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the product; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, and purchase the Defendants' product over others.

248. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

249. Defendants' wrongful conduct constitutes fraud and deceit and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

250. Defendant knew and had reason to know that its device could and would cause severe and grievous personal injury to the patients using the product, and that the product was inherently.

251. Per NRS 11.190(3)(d), the cause of action in this case should be deemed to accrue upon the discovery by Plaintiff herein of the facts constituting the fraud or mistake.

252. Because the documents and information necessary to plead a fraudulent concealment and/or omissions claim are peculiarly within Defendants' knowledge and/or control or are readily obtainable by Defendants, Plaintiff is unable to plead the instant claim with more particularity than that contained herein. Accordingly, pursuant *to Rocker v. KPMG LLP*, 122 Nev. 1185, 148 P.3d 703 (2006), a relaxed pleading standard should be applied and Plaintiff should be afforded the opportunity to conduct discovery relevant to such claims with leave to amend with more particularity at a later time.

253. As a direct and proximate result of the Defendants' conduct, Plaintiff has suffered serious and permanent injuries, specifically, esophageal cancers. Plaintiff has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has also incurred past pain, suffering, grief, sorrow, disfigurement and other harms and losses, and will continue to incur such damages in the future.

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254. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

ELEVENTH CLAIM FOR RELIEF
(Nevada Deceptive Trade Practices Act v. ZANTAC Defendants)
[DTPA Violations]

255. Plaintiffs repeat and reallege all prior paragraphs of the Amended Complaint as if set out here in full.

256. The acts of all Defendants described herein also constitute violations of Nevada's Deceptive Trade Practices Act, as codified in NRS Chapter 598, in that Defendants:

a. Knowingly made a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease [NRS 598.0915(5)];

b. Represented that goods or services for sale or lease were of a particular standard, quality or grade, or that such goods were of a particular style or model, where they knew or should have known that they were of another standard, quality, grade, style or model [NRS 598.0915(7)];

c. Knowingly made other false representations in a transaction affecting Plaintiff and others similarly-situated [NRS 598.0915(15)];

d. Failed to disclose a material fact in connection with the sale or lease of goods or services [NRS 598.0923(2)].

257. Per NRS 11.190(2)(d), this cause of action should be deemed to accrue when Plaintiff discovered, or by the exercise of due diligence should have discovered, the facts constituting the deceptive trade practice.

258. As a direct and proximate result of Defendants' violations of Nevada's Deceptive Trade Practices Act, Plaintiff has suffered serious and permanent injuries, specifically, esophageal cancers. Plaintiff has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has also incurred past pain, suffering, grief, sorrow, disfigurement and other harms and losses, and will continue to incur such damages in the future.

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259. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

TWELFTH CAUSE OF ACTION
(Wrongful Death)

260. Plaintiffs repeat and reallege all prior paragraphs of the Amended Complaint as if set out here in full.

261. Pursuant to NRS 41.085, Plaintiffs bring this cause of action against the Defendants for the wrongful death of Yasmin Husrom and seek all damages authorized by statute and available at law.

262. As a result of the foregoing, on October 7, 2021, Decedent died from complications proximately related to Defendants' Zantac and Medical Defendants' failure to treat and care for Plaintiff.

263. As a direct and proximate result of the breach of duty by Defendants, and each of them, as set forth above, Plaintiffs has suffered general and special damages in the past in an amount in excess of Fifteen Thousand Dollars ($15,000.00) and general and special damages in the future in an amount in excess of Fifteen Thousand Dollars ($15,000.00).

264. As a further direct and proximate result of the breach of duty of Defendants, and each of them, as set forth above, Decedent left heirs, next-of-kin and/or distributes surviving, who, by reason of Decedent's death have suffered pecuniary and/or non-pecuniary loss including, but not limited to support, income, services, and guidance of the Decedent and were all permanently damaged thereby.

265. The actions and conduct of Defendants, and each of them, as set forth above, show Defendants has been guilty of oppression, fraud, or malice, express or implied, and their agents, servants, and/or employees, were wanton, grossly negligent, reckless and demonstrated complete disregard and reckless indifference to the safety and welfare of the general public and to the Decedent in particular.

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266. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

267. As a direct and proximate result of Defendants' malicious fraudulent, and/or intentional disregard of Plaintiffs' rights, Plaintiffs are entitled to punitive damages to punish Defendants and deter similar wrongdoing by others in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

1. General damages Plaintiffs' pain, suffering, disfigurement, emotional distress, shock, loss of enjoyment of life, grief, sorrow, loss of probable support, companionship, society, comfort and consortium, and agony in an amount in excess of $15,000.00.
2. Special damages in an amount excess of $15,000.00.
3. Compensatory damages in an amount in excess of $15,000.00.
4. Consequential damages in an amount in excess of $15,000.00.
5. For full refund of all purchase costs Plaintiff paid for Zantac;
6. For Special Damages and Funeral Expenses allowed under NRS 41.085(5)(a)
7. For any penalties, including but not limited to, exemplary or punitive damages that Decedent would have recovered had she lived, allowed under NRS 41.085(5)(b)
8. Costs of suit incurred including reasonable attorneys' fees.
9. Prejudgment interest;
10. Punitive damages against ZANTAC Defendants; and

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11. Such other relief as the Court deems equitable.

DATED this 11th day of February, 2022.

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/s/ Michael Kane

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on the 11th day of February, 2022, I caused service of a true and correct copy of the foregoing **SECOND AMENDED COMPLAINT FOR COMPENSATORY AND PUNITIVE DAMAGES & DEMAND FOR JURY TRIAL** to be made by the Eighth Judicial District Court's Odyssey E-File and Serve program or by mail, upon all parties registered to use this service, in accordance with the Clark County District Court's Administrative Order No. 14-2, issued 5/9/14:

Robert C. McBride, Esq. Sean M. Kelly, Esq. **McBRIDE HALL** 8329 W. Sunset Road, Suite 260 Las Vegas, Nevada 89113 *Attorneys for Defendants* *Nauman Jahangir, M.D. and Las Vegas Medical Group, LLC*	Kelly A. Evans, Esq. Chad R. Fears, Esq. Justin S. Hepworth, Esq. **EVANS FEARS & SCHUTTERT LLP** 6720 Via Austi Parkway, Suite 300 Las Vegas, NV 89119 *Attorneys for Defendant GlaxoSmithKlineLLC*
Robert B. Friedman, Esq. **KING & SPALDING LLP** 1180 Peachtree Street, NE, Suite 1600 Atlanta, Georgia 30309-3521 -and- Julia Zousmer, Esq. **KING & SPALDING LLP** 110 N Wacker Drive, Suite 3800 Chicago, Illinois 60606 *Attorneys for Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corporation*	Bryce K. Kunimoto, Esq. Nevada Bar No. 7781 Amanda K. Baker, Esq. Nevada Bar No. 15172 **HOLLAND & HART LLP** 9555 Hillwood Drive, 2nd Floor Las Vegas, NV 89134 -and- Devin A. Moss, Esq. (pro hac vice forthcoming) **SHOOK, HARDY, & BACON LLP** *Attorneys for Defendant Walmart Inc.*
Erika Pike Turner, Esq. Nevada Bar No. 6454 **GARMAN TURNER GORDON LLP** 7251 Amigo Street, Suite 210 Las Vegas, NV 89119 *Attorneys for Defendants Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC, and Chattem, Inc.*	Fredrick H.L. McClure, Esq (pro hac vice forthcoming) **TRENAM, KEMKER, SCHARF, BARKIN, FRYE, O'NEILL & MULLIS** *Attorneys for Defendant Smith's Food & Drug Centers*
Sarah E. Johnston, Esq. (pro hac forthcoming) **BARNES & THORNBURG LLP** *Attorneys for Defendants CVS Pharmacy, Inc. and Walgreen Co.*	Jesse M. Sbaih, Esq. **JESSE SBAIH & ASSOCIATES, LTD.** The District at Green Valley Ranch 170 South Green Valley Parkway, Suite 280 Henderson, Nevada 89012 *Attorneys for Plaintiff*

/s/ Amber Casteel

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An employee of THE702FIRM

THE702FIRM
ATTORNEYS AT LAW
400 S. 7th St. #400
LAS VEGAS, NEVADA 89101
PHONE: (702) 776-3333

EXHIBIT 1

DECLARATION OF OLUWOLE FAJOLU, M.D., F.A.C.S.

Oluwole Fajolu, M.D., F.A.C.S. declares as follows:

1. I am a medical doctor licensed to practice in the State of California. I obtained my board certification in Thoracic Surgery in 1980.

2. I have been in the active practice of Cardiothoracic Surgery since 1985 in California.

3. Based on my training, experience, and expertise, I am familiar with the prevailing standards of care which are applicable to the facts and circumstances of this case.

4. I have reviewed the following records pertaining to the diagnosis and treatment of Yasmin Husrom:

-Medical records from Vishinder Sharma, M.D. (Digestive Associates, LLP);

-March 19, 2019 Valley View Surgery Center Operative/Endoscopy Report;

-Associated Pathologists Biopsy Report (specimen collected March 19, 2019);

-Medical records from Nauman Jahangir, M.D. (Las Vegas Medical Group, LLC);

-July 29, 2019 SVH Center Operative/Endoscopy Report;

-June 3, 2020 Aurora Diagnostics Surgical Pathology Report;

-Medical records and reports from Spring Valley Hospital Medical Center;

-Medical records from Hope Cancer Care of Nevada;

-Medical records from Radiation Oncology of Nevada, and

-Medical records from Keck Medicine of USC.

5. On March 11, 2019, Ms. Husrom (age 32) presented to Vishvinder Sharma, MD, a Gastroenterologist with Digestive Associates, LLP, with "worsening dysphagia to both liquids and solids."

6. On March 19, 2019, Dr. Sharma performed an esophagogastroduodenoscopy (EGD) and a biopsy of Ms. Husrom's proximal esophagus.

7. The biopsy report revealed "Esophageal Intraepithelial Neoplasia with High Grade Dysplasia" and "fragment of inflamed necrotic on the epithelium consistent with ulcer base."

8. On April 27, 2019, Ms. Husrom presented to Dr. Sharma who noted, among other things, that "CT scan of the neck performed showed effacement of the left vallecula, cervical esophagus showed thickening and she also has an aberrant right subclavian artery which courses posterior to the upper thoracic esophagus." Dr. Sharma further noted that "Histology Biopsies revealed esophageal Intraepithelial new plays [sic] a with high-grade dysplasia; in addition there was fragmented inflamed necrotic epithelium consistent with ulcer."

9. On June 13, 2019, Ms. Husrom presented to Nauman Jahangir, M.D., a Cardiovascular Surgeon with Las Vegas Medical Group, LLC. During the visit, Dr. Jahangir noted that "Her most recent endoscopy was in March of this year by Dr. Sharma who also took biopsies and this revealed high grade dysplasia of the esophagus." At that time, Dr. Jahangir was concerned about the dysplasia and determined that "She would most likely require some sort of surgical resection."

10. On July 18, 2019, Ms. Husrom returned to Dr. Jahangir. During that visit, Dr. Jahangir scheduled Ms. Husrom for an endoscopy, and he planned to perform a biopsy if a stricture is noted.

11. On July 29, 2019, Dr. Jahangir performed the endoscopy on Ms. Husrom. According to Dr. Jahangir "The mid and distal esophagus appeared to be normal without obvious lesions nor strictures" and that "A systematic examination of the esophagus was then performed from the GE junction to the pharynx. There is no area of stricture nor is there any mass

lesions seen though in the proximal esophagus/hypopharynx, there is some raw area possibly related to prior interventions but definitely no area of stenosis."

12. On July 29, 2019, Dr. Jahangir did not perform a biopsy of Ms. Husrom's esophagus (including the "raw area" in the proximal esophagus/hypopharynx noted in his report), which was found to have "Esophageal Intraepithelial Neoplasia with High Grade Dysplasia" in a March 19, 2019 biopsy performed by Dr. Sharma.

13. On August 1, 2019, Ms. Husrom returned to Dr. Jahangir. During that visit, Dr. Jahangir explained to Ms. Husrom that "there is nothing inherently wrong with her esophagus however there is external compression of the esophagus from an aberrant blood vessel, the right subclavian artery and that is the source of her symptoms which needs to be addressed."

14. On that date, Dr. Jahangir recommended that Ms. Husrom undergo reimplantation of the aberrant right subclavian artery via sternotomy with cardiopulmonary bypass at Spring Valley Hospital, which Ms. Husrom did not undergo.

15. On March 12, 2020, Ms. Husrom returned to Dr. Jahangir. At that time, Dr. Jahangir reiterated his prior diagnosis of esophageal compression due to aberrant right subclavian artery and the need for Ms. Husrom to undergo surgical repair.

16. On May 28, 2020, Dr. Jahangir was informed that Ms. Husrom had difficulty swallowing. Dr. Jahangir instructed that Ms. Husrom present to the emergency room at Spring Valley Hospital to be admitted in order to undergo surgery to repair the apparent right subclavian artery on June 5, 2020.

17. On May 30, 2020, Ms. Husrom was admitted into Spring Valley Hospital with difficulty swallowing.

18. Contrary to Dr. Jahangir's long-standing diagnosis, a May 31, 2020 CT Angiogram of Ms. Husrom's Chest showed an "Aberrant right subclavian artery…with no apparent compression or involvement of the adjacent cervical esophagus."

19. Also, a biopsy of the enlarged left cervical node revealed that Ms. Husrom had Stage IV squamous cell carcinoma of the hypopharynx with tumor extending to the cervical esophagus as well as bilateral cervical lymph nodes.

20. On June 18, 2020, Ms. Husrom underwent an implantation of a feeding tube because the cancerous lesion blocked her ability to swallow.

21. On July 7, 2020, Ms. Husrom underwent a tracheostomy because the cancerous lesion blocked her ability to breathe.

22. Thereafter, Ms. Husrom required aggressive chemotherapy and radiation to treat the cancerous lesion, which resulted in a great deal of scar tissue and a stricture of Ms. Husrom's esophagus.

23. To address the stricture of Ms. Husrom's esophagus (which would allow for the removal of the feeding tube and the trach), Ms. Husrom was required to undergo several procedures at Keck Medicine of USC.

24. Based on my training, experience, and further based upon my review of the records listed above, it is my opinion to a reasonable degree of medical probability that Dr. Jahangir (an employee/agent of Las Vegas Medical Group, LLC) deviated from the accepted standard of care in his care and treatment of Ms. Husrom by (1) failing to perform a biopsy on Ms. Husrom's esophagus despite the March 19, 2019 biopsy finding of high grade dysplasia in the proximal esophagus and the July 29, 2019 abnormal finding of a "raw area" in the proximal esophagus/hypopharynx noted during the EGD that Dr. Jahangir performed; (2) incorrectly advising Ms. Husrom that "there is nothing inherently wrong with her esophagus" despite the

recent diagnosis of esophageal high grade dysplasia; and (3) incorrectly determining that the cause of Ms. Husrom's dysphagia was an "external compression of the esophagus from an aberrant blood vessel, the right subclavian artery and that is the source of her symptoms which needs to be addressed," which was proven to be wrong during Ms. Husrom's hospitalization at Spring Valley Hospital.

25. It is further my opinion to a reasonable degree of medical probability that had Dr. Jahangir (an employee/agent of Las Vegas Medical Group, LLC) performed a biopsy on Ms. Husrom's esophagus on July 29, 2019, it would have confirmed the presence of dysplastic cells/ very early-stage cancer, and Ms. Husrom would have had the option of (among other things) undergoing an endoscopic mucosal resection/surgery of the areas involved and subsequent close monitoring.

26. Instead, due to Dr. Jahangir's deviation from the standard of care, Ms. Husrom was ultimately diagnosed with Stage IV esophageal cancer in June 2020, which required substantially more aggressive treatment. Had Dr. Jahangir not deviated from the standard of care, Ms. Husrom would have (more probably than not) avoided (among other things) the need for a feeding tube, tracheostomy, chemotherapy, radiation, and the multiple procedures she was required to undergo at Keck Medicine of USC to resolve the esophageal stricture caused by scar tissue due to radiation.

27. I reserve the right to supplement the above opinions as more information becomes available.

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28. I declare under penalty of perjury under the laws of the State of Nevada that the foregoing is true and correct.

DATED this 24th day of May, 2021.

Oluwole Fajolu M.D

Oluwole Fajolu, M.D., F.A.C.S.

Oluwole Fajolu, M.D., F.A.C.S.
Thoracic and General Surgery
Curriculum Vitae

5105 Kelvin Avenue
Woodland Hills, CA 91364
Mobile#: 818-590-0247 Office#: 818-884-5334
Email: drfajolu@aol.com

Medical School: **Calcutta Medical College,**
Calcutta University, India

Residencies: **Lagos University Teaching Hospital**
Lagos, Nigeria
General Surgery 1970-1972
Harlem Hospital
New York, New York
General Surgery 1972-1974
Columbia Presbyterian Hospital
Columbia University, New York
General Surgery 1974-1977
Long Island Jewish Hospital
New Hyde Park, New York
Cardiothoracic Surgery 1977-1979

Hospital on Staff: **Valley Presbyterian Hospital, Van Nuys March 2012 to present**

Hospital Positions at Kaiser Foundation Hospital, Woodland Hills:

Director – Continuing Medical Education, Department of Surgery from 1987 till 2009
Designing weekly educational conferences for Surgery Department – invited guest Speakers discussion of morbidities and mortalities, Quality Assurance, etc.

Member – Bioethics Committee for over 15 years.
Involved in discussing and often times resolving difficult bioethical issues e.g. End of Life; family and physicians conflicts with respect to medical care; cultural and Religious conflict issues with Medicare, etc.

Member Cancer Committee for over 15 years.
Design of algorithms that ensured less time from diagnosis to treatment of cancers. This resulted in patient's satisfaction, and measurable better outcomes; especially in breast cancer.

Chair – Biweekly Chest Conference where as the Head of Thoracic Surgery, discussing and
Determining management of diverse chest conditions with Pulmonologists, Radiologist, Pathologists, Oncologists and Internists.

Practice Litigation Support for Attorneys December 2009 to present

Expert Surgical Consultant to the Medical Board of California December 2009 to present

Expert Case Review for the Medical Board of California December 2009 to present

Skilled Wound Care – Consultant on Wounds, Gastrostomy, and Dermatologic Conditions 07/2012 to present

Cardiothoracic

- Thoracic Surgery and Oncologic Thoracic Surgery
- Minimally Invasive Thoracic Surgery (Thoracoscopy)
- Implanted over 3k pacemakers, Responsible for auto follow up

Association and Certificate: **Fellow, American College of Surgeons**

Board Certification: **American Board of Surgery 1980**
American Board of Surgery 1990 (Recertification)
American Board of Thoracic Surgery (1980)
American Board of Thoracic Surgery (1990) (Recertification)
American Board of Thoracic Surgery (Recertification_ - Till 2020

Special Interests in Practice: **Oncologic and General Thoracic Surgery**
Pacemaker Implants and Acute Follow-up
Minimally Invasive Thoracic Surgery
Oncologic Breast Surgery

Publications:

1) Fajolu O. Cloacogenic Carcinoma of the Anorectum
Journal of National Medical Association
U.S.A. Vol 63 No 1 pp 115-119 – July 1975

2) Barlow B; Fajolu O.; Leblanc W.
Hydatid Torsion Am J. Dis. Child. Vol 132 pp 1216-1217 – December 1978

3) Garvey J.W.; Mehta A; Fajolu O.; Crastnopol P.
Two New Complications of Heroin Drug Abuse
New York State Journal of Medicine 1983

4) Fajolu O. Traumatic Diaphragmatic Hernia;
Nigeria Quarterly Journal of Hospital Medicine – 1984

5) Fajolu O. Carcinoma of the lung
Self Instructional Package for the college of Medicine

University of Lagos

6) Fajolu O. Foregin Body Impaction in the Esophague
- 10 years experience in a Teaching Hospital
Journal of National Medical Association
1986 Vol. 78 No 10 pp 987-990

7) Fajolu O.; R. Braun
Spontaneous Pneumothorax as First Manifestation
Of Bronchial Carcinoma and Mesothelioma
Contemporary Surgery July 1989 Vol. 31 No 1 pp 39-42

8) I.J. Strumpf; R. Drucker; K. Anders; S. Cohen; Fajolu O.
Acute Esoinophilic Pulmonary Disease associated with
The ingestion of L-Tryptophan containing products Chest – In Press

9) Fajolu O. Chapter in Manual of Emergency Surgery;
Thoracic Emergencies 1991 pp 62-84

EXHIBIT 2

DECLARATION OF JUDY L. SCHMIDT, M.D., F.A.C.P.

Judy L. Schmidt, M.D., F.A.C.P. declares as follows:

1. I am a medical doctor licensed to practice in the states of Montana, Hawaii, and California. I obtained my board certification in Medical Oncology in 1989.

2. I have been in the active practice of Medical Oncology since 1988.

3. I have reviewed the following records pertaining to the diagnosis and treatment of Yasmin Husrom:

-Medical records from Vishinder Sharma, M.D. (Digestive Associates, LLP);

-March 19, 2019 Valley View Surgery Center Operative/Endoscopy Report;

-Associated Pathologists Biopsy Report (specimen collected March 19, 2019);

-Medical records from Nauman Jahangir, M.D. (Las Vegas Medical Group, LLC);

-July 29, 2019 SVH Center Operative/Endoscopy Report;

-June 3, 2020 Aurora Diagnostics Surgical Pathology Report;

-July 29, 2020 Steinberg Diagnostic Medical Imaging Centers PET Scan;

-Medical records and reports from Spring Valley Hospital Medical Center;

-Medical records from Hope Cancer Care of Nevada;

-Medical records from Radiation Oncology of Nevada;

-Medical records from Keck Medicine of USC;

-Declaration of Oluwole Fajolu, M.D. dated May 24, 2021; and

-Death Certificate issued October 12, 2021.

4. On March 11, 2019, Ms. Husrom (age 32) presented to Vishvinder Sharma, MD, a Gastroenterologist with Digestive Associates, LLP, with "worsening dysphagia to both liquids and solids."

5. On March 19, 2019, Dr. Sharma performed an esophagogastroduodenoscopy (EGD) and a biopsy of Ms. Husrom's proximal esophagus.

6. The biopsy report revealed "Esophageal Intraepithelial Neoplasia with High Grade Dysplasia" and "fragment of inflamed necrotic on the epithelium consistent with ulcer base."

7. On April 27, 2019, Ms. Husrom presented to Dr. Sharma who noted, among other things, that "CT scan of the neck performed showed effacement of the left vallecula, cervical esophagus showed thickening and she also has an aberrant right subclavian artery which courses posterior to the upper thoracic esophagus." Dr. Sharma further noted that "Histology Biopsies revealed esophageal Intraepithelial new plays [sic] a with high-grade dysplasia; in addition there was fragmented inflamed necrotic epithelium consistent with ulcer."

8. On June 13, 2019, Ms. Husrom presented to Nauman Jahangir, M.D., a Cardiovascular Surgeon with Las Vegas Medical Group, LLC ("LVMG"). During the visit, Dr. Jahangir noted that "Her most recent endoscopy was in March of this year by Dr. Sharma who also took biopsies and this revealed high grade dysplasia of the esophagus." At that time, Dr. Jahangir was concerned about the dysplasia and determined that "She would most likely require some sort of surgical resection."

9. On July 18, 2019, Ms. Husrom returned to Dr. Jahangir. During that visit, Dr. Jahangir scheduled Ms. Husrom for an endoscopy, and he planned to perform a biopsy if a stricture is noted.

10. On July 29, 2019, Dr. Jahangir performed the endoscopy on Ms. Husrom. According to Dr. Jahangir “The mid and distal esophagus appeared to be normal without obvious lesions nor strictures" and that “A systematic examination of the esophagus was then performed from the GE junction to the pharynx. There is no area of stricture nor is there any mass lesions seen though in the proximal esophagus/hypopharynx, there is some raw area possibly related to prior interventions but definitely no area of stenosis.”

11. On July 29, 2019, Dr. Jahangir did not perform a biopsy of Ms. Husrom’s esophagus (including the “raw area” in the proximal esophagus/hypopharynx noted in his report), which was found to have “Esophageal Intraepithelial Neoplasia with High Grade Dysplasia” in a March 19, 2019 biopsy performed by Dr. Sharma.

12. On August 1, 2019, Ms. Husrom returned to Dr. Jahangir. During that visit, Dr. Jahangir explained to Ms. Husrom that “there is nothing inherently wrong with her esophagus however there is external compression of the esophagus from an aberrant blood vessel, the right subclavian artery and that is the source of her symptoms which needs to be addressed.”

13. On that date, Dr. Jahangir recommended that Ms. Husrom undergo reimplantation of the aberrant right subclavian artery via sternotomy with cardiopulmonary bypass at Spring Valley Hospital, which Ms. Husrom did not undergo.

14. On March 12, 2020, Ms. Husrom returned to Dr. Jahangir. At that time, Dr. Jahangir reiterated his prior diagnosis of esophageal compression due to aberrant right subclavian artery and the need for Ms. Husrom to undergo surgical repair.

15. On May 28, 2020, Dr. Jahangir was informed that Ms. Husrom had difficulty swallowing. Dr. Jahangir instructed that Ms. Husrom present to the emergency room at Spring Valley Hospital to be admitted in order to undergo surgery to repair the apparent right subclavian artery on June 5, 2020.

16. On May 30, 2020, Ms. Husrom was admitted into Spring Valley Hospital with difficulty swallowing.

17. Contrary to Dr. Jahangir's long-standing diagnosis, a May 31, 2020 CT Angiogram of Ms. Husrom's Chest showed an "Aberrant right subclavian artery…with no apparent compression or involvement of the adjacent cervical esophagus."

18. A CT Scan of Ms. Husrom's neck on June 3, 2020 showed progressive irregularity to the upper esophagus with new bilateral cervical lymphadenopathy. A biopsy of an enlarged left cervical node on June 3, 2020 revealed that Ms. Husrom had Stage IVA squamous cell carcinoma.

19. On or about June 18, 2020, Ms. Husrom underwent an implantation of a feeding tube because the cancerous lesion blocked her ability to swallow.

20. On or about July 8, 2020, Ms. Husrom underwent a tracheostomy because the cancerous lesion blocked her ability to breathe.

21. A July 8, 2020 biopsy of the Hypopharynx confirmed invasive squamous cell carcinoma.

22. Thereafter, Ms. Husrom required aggressive chemotherapy and radiation to treat the cancerous lesion, which resulted in a great deal of scar tissue and a stricture of Ms. Husrom's esophagus.

23. To address the stricture of Ms. Husrom's esophagus (which would allow for the removal of the feeding tube and the trach), Ms. Husrom was required to undergo several procedures at Keck Medicine of USC.

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24. Based upon my training and experience in Medical Oncology and further based upon my review of the records listed above, it is my opinion to a reasonable degree of medical probability that if a biopsy of Ms. Husrom's proximal esophagus was done on July 29, 2019 when Dr. Jahangir (an employee/agent of LVMG) performed the EGD, the result would have indicated (more probable than not) the presence of Stage T1a esophageal cancer;[1] knowing that the cancer was high grade dysplasia on March 19, 2019 and measured 51 millimeters on July 29, 2020.[2]

25. It is further my opinion to a reasonable degree of medical probability that because Dr. Jahangir (an employee/agent of LVMG) did not biopsy Ms. Husrom's proximal esophagus on July 29, 2019, assured Ms. Husrom that "there is nothing inherently wrong with her esophagus" on August 1, 2019, and Ms. Husrom's probable Stage T1a esophageal cancer went untreated for nearly ten (10) months, the cancer progressed to Stage IVA esophageal cancer in June 2020 when Ms. Husrom underwent a biopsy at Spring Valley Hospital.

26. It is further my opinion to a reasonable degree of medical probability that, had Dr. Jahangir (an employee/agent of LVMG) biopsied Ms. Husrom's proximal esophagus on July 29, 2019 and the probable Stage T1a esophageal cancer was recognized and diagnosed on or about July 29, 2019, Ms. Husrom would have (more probable than not) had the opportunity to undergo an endoscopic mucosal resection/a minor surgery of the areas involved and subsequent close ongoing monitoring.[3]

27. It is further my opinion to a reasonable degree of medical probability that, had Dr. Jahangir (an employee/agent of LVMG) biopsied Ms. Husrom's proximal esophagus on July 29, 2019 and the probable Stage T1a esophageal cancer was recognized and diagnosed in or about July 29, 2019, Ms. Husrom would have (more probable than not) avoided (among other things)

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[1] AJCC Cancer Staging Manual, Eighth Edition 2017.

[2] www.radclass.mudr.org

[3] Merkow, R.P., et al. Treatment Trends, Risk of Lymph Nodes Metastasis, and Outcomes for Localized Esophageal Cancer. JNCI.2014;106(7) dju133doi.

the need for a feeding tube, tracheostomy, chemotherapy, radiation, and the multiple procedures she was required to undergo at Keck Medicine of USC to resolve the esophageal stricture caused by scar tissue due to radiation.

28. The five (5) year survival rate for patients diagnosed with T1a esophageal cancer is 94%.[4] On the other hand, the five (5) year survival rate for Stage IVA esophageal cancer is approximately 25% with median survival of two (2) years.[5]

29. As such, it is further my opinion to a reasonable degree of medical probability that the nearly ten (10) months delay in diagnosis and treatment caused by the failure of Dr. Jahangir (an employee/agent of LVMG) to biopsy Ms. Husrom's proximal esophagus on July 29, 2019 statistically decreased Ms. Husrom's 5-year survival by approximately 69%. Stated differently, Ms. Husrom lost approximately 48.4 years of life expectancy.[6]

30. According to the October 12, 2021 death certificate, Ms. Husrom died of hemorrhagic shock due to carotid artery pseudoaneurysm as a consequence of squamous cell carcinoma of head and neck with metastasis to cervical lymph nodes. She was 34 years old. To a reasonable degree of medical probability, the delay in diagnosis of the cancer caused her death.

31. All my opinions are held to a reasonable degree of medical probability and are based upon my training, experience and expertise as well as my review of the records listed above.

32. I reserve the right to supplement the above opinions as more information becomes available.

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[4] Tanaka, T., et al. T1 Squamous Cell Carcinoma of the Esophagus; Long Term Outcomes and Prognostic Factors after Esophagectomy. Ann Surg Onc. 2014; 21:932.
[5] AJCC Cancer Staging Manual, Eighth Edition 2017.
[6] www.ssa.gov (Life Expectancy Table).

33. I declare under penalty of perjury under the laws of the State of Nevada that the foregoing is true and correct.

DATED this 4th day of February 2022

Judy L. Schmidt, M.D., F.A.C.P.

JUDY L. SCHMIDT, M.D., F.A.C.P.

2870 St. Michael Drive, Missoula, Montana 59803
808-281-5189 | qualitycancercare@gmail.com
April 7, 2021

EDUCATION:

Lindbergh High School - Hopkins, Minnesota	1970-1974
B.A. – Chemistry – University of Minnesota, Duluth; Duluth, Minnesota	1974-1978
M.D. – University of Minnesota School of Medicine; Duluth and Minneapolis, Minnesota	1978-1982

INTERNAL MEDICINE RESIDENCY:

University of California – Davis; Davis, California	1982-1984
Martinez Veterans Hospital; Martinez, California	1982-1984
Mount Sinai and Hennepin County Medical Center – University of Minnesota; Minneapolis, Minnesota	1984-1985

HEMATOLOGY and MEDICAL ONCOLOGY FELLOWSHIP:

Mayo Clinic; Rochester, Minnesota	1985-1988

ACADEMIC HONORS:

High School:
Valedictorian, Student Council President, School Board Representative

College:
Honors in Chemistry, Teaching Assistant in Chemistry, Magna Cum Laude, National Science Foundation Grant for Research in Polychlorinated Phenols in Lake Superior

Medical School:
Scholarship received by the University of Minnesota School of Medicine, Received a grant for research using a new Immunoperoxidase Stain for the Diagnosis of Metastatic Prostate Cancer

MEDICAL LICENSURE and CERTIFICATIONS

State of Montana 6372; 92113	1988 - 2010; 2021 -
State of Hawaii MD-15691	2010 - present
State of California C-172153	2021 - present

National Board of Medical Examiners, Diplomat	1983
American Board of Internal Medicine	1984
American Board of Hematology	1988
American Board of Medical Oncology	1989
Fellow American College of Physicians (FACP)	1994

CURRENT MEMBERSHIPS

- Association of Community Cancer Centers (ACCC)
- American Society of Clinical Oncology (ASCO)

EXPERIENCE

- Missoula Medical Oncology 1988-1991
  Missoula, Montana – Medical Group Practice
- Guardian Oncology & Center for Wellness 1991-2010
  Missoula, Montana – Solo Medical Practice
- Maui Medical Group 2010-2011
  Wailuku, Maui, Hawaii – Multi-specialty Group Medical Practice
- Quality Cancer Care - Medical Consultant and Legal Expert
  Wailuku, Maui, Hawaii 2011 - present
  Missoula, Montana 2016 - present
- Signify Health 2021

HOSPITAL MEDICAL STAFF

- Missoula Community Medical Center – Missoula, Montana 1988-2010
- St. Patrick's Hospital – Missoula, Montana 1988-2010
- St. Joseph Hospital – Polson, Montana 1990-2010
- Marcus Daly Medical Center – Hamilton, Montana 1989-2010
- Barrett Memorial Hospital – Dillon, Montana 1989-2010
- St. Peter's Hospital – Helena, Montana 1989-2010
- Clark Fork Valley Hospital – Plains, Montana 1991-2010
- Maui Memorial Medical Center – Wailuku, Maui, Hawaii 2010-2011

MEDICAL COMMITTEE POSITIONS

- Clinical Instructor of Medicine, WAMI, University of Washington 1989-2010
  Seattle, Washington
- Minerva Society Member, Community Medical Center; Missoula, Montana 1989-1997
- Director, Tumor Board, St. Patrick Hospital; Missoula, Montana 1989-1993
- Board Member, Partners in Home Health Care and Hospice; Missoula, Montana 1990-1995
- Board Member, Missoula Branch of American Cancer Society; Missoula, Montana 1991-1992
- Member Ethics Committee, St. Patrick Hospital; Missoula, Montana 1991
- Member, Clinical Practice Committee, 1991-2005
  American Society of Clinical Oncology; Alexandria, Virginia
- President, Montana Society of Clinical Oncology, 1991-2005
  American Society of Clinical Oncology; Alexandria, Virginia
- Member, Medicine Committee, St. Patrick Hospital; Missoula, Montana 1992, 1994
- Member, Executive Committee, St. Patrick Hospital; Missoula, Montana 1993
- Member, Ethics Committee, St. Patrick Hospital; Missoula, Montana 1995
- Board Director, Association of Community Cancer Centers; Rockville, Maryland 2001-2005
- President, Montana Hematology/Oncology Medicare Carrier Advisory Committee 2001-2005
- Member, Medicine Committee, Missoula Community Medical Center; Missoula, Montana 2002
- Associate Editor, JCO – Journal of Clinical Oncology (Daniel Haller MD) 2002-2007
- Member, Blood Bank Committee 2003
  Missoula Community Medical Center; Missoula, Montana
- Board Member, Bristol Myers Medical Advisory Meeting; Washington, DC 2005
- Facilitator, Montana Cancer Control Coalition; St. Patrick Hospital; 2005
  Missoula, Montana
- Member Beta Group (rural practices) American Society of Clinical Oncology 2005-2008
  Quality Oncology Practice Initiative (QOPI); Alexandria, Virginia
- Board Member, Novartis Medical Advisory Meeting; East Hanover, 2006
  New Jersey
- Director, Gynecologic Oncology Tumor Board; 2009-2010
  Missoula Community Medical Center; Missoula, Montana
- Member, Tumor Board; Maui Memorial Medical Center; Wailuku, Maui, Hawaii 2010-2011

- Member, Blood Bank Committee; 2011
  Maui Memorial Medical Center; Wailuku, Maui, Hawaii
- Instructor, Genetics (Nursing Program); University of Hawaii, Maui, Hawaii 2012-2013

CONFERENCE DIRECTOR and LECTURER

"**Gynecologic Malignancies"** Missoula, Montana (October, 1991)

"Oncologic Emergencies" Missoula, Montana (November, 1991)

"Lymphoma" Missoula, Montana (July, 1993) James Armitage MD FACP FASCO

"**Overview of Cancer Statistics and Review of Oncologic Emergencies"** School of Pharmacy, University of Montana; Missoula, Montana (February, 2005)

"Breast Cancer" School of Physical Therapy, University of Montana, Missoula, Montana (2005-2006)

"Verify Your Pathology; Obtain a Second Opinion." Joni Aldrich, Cancer Support Network at W4CS.com Radio on Cancer SOS. Greensboro/Winston-Salem NC (July 2013)

"Advocacy Heals U." Joni Aldrich, Cancer Support Network at W4CS.com Radio on Cancer SOS (August 2015)

"Cancer Statistics 2019" Lahainaluna H.S. Health Class, Lahaina, Maui, Hawaii (November 2019)

RESEARCH

Polychlorinated Phenols in Lake Superior – Effluent from a Waste Treatment Plant.
University of Minnesota, Duluth, Department of Chemistry, Duluth, Minnesota 1977.

Prostate Cancer: Immunoperoxidase Histologic Diagnosis with Prostate Specific Antigen and Prostate Specific Acid Phosphatase.
University of Minnesota School of Medicine, Department of Pathology, Duluth, Minnesota, 1981.

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Mayo Clinic Proceedings, 69: 329-332, 1994.

Pathology – Implications for the Physical Therapist. Goodman, 2nd Edition, 2003, Saunders.
Reviewer for Hematology and Oncology.

AWARDS AND ACHIEVEMENTS

- **1991-2010 –** Co-Director **Guardian Angels.** A nonprofit organization Joni Landes, RN OCN and I formed to assist cancer patients in Montana to defray costs of treatment. We raised over $800,000. 100% of the money raised went directly to cancer patients.
- **1998 –** Western Montana **YMCA Salute to Excellence**, Honoree in the Category of Science.
- **September 16, 1999 – Ensuring Quality Cancer Care –** United States Senate sub-committee testimony. **Representing Rural Oncologists** for the American Society of Clinical Oncology with Senators Dianne Feinstein (California) and Connie Mack (Florida).

- **January, 2000 – Coping Magazine Professionals of the Year HERO** award with my nurse of 20 years, Joni J. Landes, RN OCN.

- **2001 –** Independent review of my clinic, Guardian Oncology and Center for Wellness (GOCW) by Kim Johnson and Associates. **Rated 'Best Clinic' in over 330** Oncology clinics evaluated.

- **2004 –** American Society of Clinical Oncology (ASCO) **Quality Oncology Practice Initiative (QOPI).** My solo Medical Oncology practice in Montana (GOCW) participated in the initial **Beta Group** representing Rural Medical Oncology Practices.

- **2004 – Mayo Clinic** award for **Excellence in Private Practice Hematology and Medical Oncology.**

- **2015-2020 – Hawaii's Top Doctors for 2015, 2016, 2017, 2018 and 2020** Honolulu Magazine.

Exhibit B

Defendant GlaxoSmithKline Motion to Dismiss

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Attorneys for Defendant GlaxoSmithKline LLC

EIGHTH JUDICIAL DISTRICT COURT

FOR THE DISTRICT OF NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as a legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor;

Plaintiffs,

vs.

LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES 1 through X; and ROE CORPORATIONS XI through XX, inclusive,

Defendants.

Case No. A-21-835385-C

Dept No. 15

DEFENDANT GLAXOSMITHKLINE LLC'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FAILURE TO STATE A CLAIM

HEARING REQUESTED

Pursuant to NRCP 12(b)(2) and 12(b)(5), Defendant GlaxoSmithKline LLC ("GSK"), hereby submits its motion to dismiss Plaintiffs' innovator-liability and predecessor-liability claims for lack of personal jurisdiction and for failure to state a claim upon which relief can be granted.

This Motion is based upon the Points and Authorities, the papers and pleadings on file, and any oral argument that may be entertained at the hearing in this matter.

DATED: February 25, 2022.

EVANS FEARS & SCHUTTERT LLP

/s/ Chad R. Fears

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

In this action, Plaintiffs Sara Elabbassy and Jamil Husrom alleges that Decedent Yasmin Husrom died from cancer as a result of taking ranitidine-containing products, including both branded Zantac and generic versions of the drug. Plaintiffs do not allege that Decedent ever took a drug manufactured or sold by GSK. Plaintiffs nonetheless seek to hold GSK liable, presumably on theories of innovator-liability and predecessor-liability. Under the theory of innovator liability, which has been rejected by the overwhelming majority of courts to consider it, the brand-name company that controls the "New Drug Application" (NDA) for a pharmaceutical product, and thus has the exclusive ability to update the drug's warning label, can be held liable for alleged deficiencies in the generic product's label, because federal regulations require the generic label to copy the branded one. And under the even broader theory of predecessor liability, which has been adopted by just one court in the country, a brand-name company can be held liable even after it transfers the NDA to a different company, if it was foreseeable that the successor would rely on the predecessor's labeling decisions.

Innovator liability and predecessor liability both radically depart from traditional tort principles by imposing liablity on a defendant for products made, marketed, and sold by a *different company*. The theories are thus incompatible with Nevada law. Even more fundamentally, however, this Court lacks personal jurisdiction over GSK in connection with Plaintiffs' innovator- and predecessor-liability claims, because none of GSK's activities in Nevada have any legal relevance to those claims. The only actions by GSK relevant to an innovator- or predecessor-liability claim are its labeling decisions, and Plaintiffs do not allege GSK made any labeling decisions in Nevada. Those claims must therefore be dismissed for lack of personal jurisdiction.

II. FACTUAL BACKGROUND

More than forty years ago, GlaxoSmithKline ("GSK") discovered ranitidine, a histamine antagonist capable of reducing the amount of acid created by the stomach. Second Am. Compl. (SAC) ¶ 77. In 1983, the FDA granted GSK's NDA and approved the sale of prescription ranitidine under the trade name "Zantac." *Id*. Within just a few years, Zantac became the most

popular prescription medication in the world, used by tens of millions to treat ulcers, gastroesophageal reflux disease, and other gastric conditions. *Id*. ¶ 78.

Zantac became available without a prescription in 1996, and generic versions of the drug became available the following year. *Id*. ¶ 79. GSK has controlled the NDA for prescription Zantac since 1983, but there is a separate NDA for over-the-counter ("OTC") Zantac. *Id*. ¶ 12. As relevant here, Boehringer Ingelheim held the NDA for OTC Zantac from December 2006 to January 2017, *id*. ¶ 13, and Sanofi has held the NDA from January 2017 to the present. *Id*. ¶ 17. Plaintiffs allege that Decedent took branded Zantac and generic ranitidine from November 2016 through September 2019. *Id*. ¶ 69.

III. LEGAL ARGUMENT

A. The Court Lacks Personal Jurisdiction Over Innovator-Liability and Predecessor-Liability Claims.

1. The Court Lacks General Jurisdiction Over GSK.

There are two species of personal jurisdiction: general (or "all-purpose") jurisdiction and specific (or "case-linked") jurisdiction. A court may exercise general jurisdiction over an out-of-state defendant, meaning jurisdiction without regard to the facts of a particular lawsuit, only if its "affiliations with the State are so continuous and systematic as to render it *essentially at home* in the forum State." *Daimler AG v. Bauman*, 571 U.S. 117, 122 (2014). Except in the most unusual case, where the defendant is a corporation, its place of incorporation and principal place of business are the only states where general jurisdiction exists.[1] *See Daimler,* 571 U.S. at 137 ("With respect to a corporation, the place of incorporation and principal place of business are 'paradig[m] . . . bases for general jurisdiction.'") (citation omitted).

[1] The Supreme Court has recognized that in an "exceptional case," general jurisdiction may be appropriate in a state other than the place of incorporation or principal place of business. As an example, the Court cited *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952), in which a foreign company had temporarily moved its headquarters during World War II—in effect relocating its principal place of business for the duration of the war. *Daimler AG v. Bauman*, 571 U.S. 117, 139 n.19 (2014). Here, GSK's contacts with Nevada are in no way analogous to *Perkins*.

Here, GSK is not incorporated in Nevada and does not have its principal place of business in the state. SAC ¶ 11. Because Plaintiffs do not—and cannot—allege that GSK is "essentially at home" in Nevada, this Court lacks general jurisdiction over GSK.

2. The Court Cannot Exercise Specific Jurisdiction Over GSK in Connection with Innovator-Liability Claims.

This Court lacks specific jurisdiction over the Plaintiffs' "innovator-liability" claims, which are based on the consumption of generic ranitidine made by other companies. Only two states have adopted innovator liability, and Nevada is not one of them. *See T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018). As explained below, this Court should reject innovator liability on the merits if it reaches the question. But the key, objectionable feature of innovator liability—that it holds a company responsible for products manufactured and sold by a *different company*—also gives rise to a threshold jurisdictional problem that Plaintiffs cannot overcome.

"[S]pecific jurisdiction is proper only when the cause of action arises from the defendant's contacts with the forum." *Fulbright & Jaworski v. Eighth Jud. Dist. Ct.*, 131 Nev. 30, 37 (2015). The Supreme Court recently stressed in *Ford Motor Company v. Montana Eighth Judicial District Court*, 141 S. Ct. 1017 (2021), that this relatedness requirement "incorporates real limits." *Id*. at 1026. It is Plaintiffs' burden to allege that the defendant has sufficient suit-related contacts with Nevada to support specific jurisdiction. *See Fulbright*, 131 Nev. at 35.

The only actions by a brand-name company that "relate to" an innovator-liability claim are its labeling decisions, because the Brand Defendant's control of the generic label is the sole basis for holding the Brand Defendant liable for injuries caused by another company's drugs. When the California Supreme Court recognized innovator liability, it identified the brand-name company's "failure to update and maintain the warning label" as the conduct giving rise to liability. *T.H.*, 407 P.3d at 34. The Court referred to the theory it recognized as "warning label liability," and explained that "a brand-name drug manufacturer owes a duty of reasonable care in ensuring that *the label* includes appropriate warnings, regardless of whether the end user has been dispensed the brand-name drug or its generic bioequivalent." *Id*. at 22 (emphasis added). The

only basis the Court gave for extending brand-name manufacturers' duty of care to generic consumers was that "the same warning label must appear on the brand-name drug as well as its generic bioequivalent." *Id*.

Similarly, the first line of the Massachusets Supreme Judicial Court opinion recognizing a form of innovator liability made clear the holding rested on the fact that "[u]nder Federal law, a manufacturer of a generic drug must provide its users with a warning label that is identical to the label of the brand-name manufacturer." *Rafferty*, 92 N.E.3d at 1209. Because the brand-name manufacturer effectively controls the label copied by generic manufacturers, the court decided to permit a generic consumer to bring "a common-law recklessness claim against the brand-name manufacturer if it intentionally failed to update the label on its drug, knowing or having reason to know of an unreasonable risk of death or grave bodily injury." *Id*.

After examining these decisions in detail, the federal district court handling the *Zantac* MDL concluded that "[t]he nature of an innovator-liability claim … compels" the conclusion that "only those activities that relate to the brand-name manufacturers' labeling decisions" could support specific jurisdiction. *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 2021 WL 2682602, at *14 (S.D. Fla. June 30, 2021). That was so because the "only conduct that gives rise to [innovator-liability] claims is Defendants' alleged failure to update the warning label." *Id*. The MDL court rejected the plaintiffs' argument that the brand-name companies' alleged misrepresentations regarding their own products in the forum states could support specific jurisdiction, because "[s]uch misrepresentations … are not necessary to state a misrepresentation claim premised on the innovator-liability theory" and thus do not "give rise to 'jurisdictionally relevant' contacts between the brand-name manufacturers and the forum." *Id*. If activities with no relevance to the plaintiffs' innovator-liability claims, such as the brand-name companies' "marketing and sales contacts relating to their own products," could support specific jurisdiction, then "the phrase 'relate to' would have no 'real limits'"—contradicting the Supreme Court's admonition in *Ford*. *Id*. (quoting *Ford*, 141 S. Ct. at 1026).

This Court should reach the same conclusion as the MDL court: innovator-liability plaintiffs cannot establish specific jurisdiction over GSK in Nevada because the only actions

relevant to the innovator-liability theory—GSK's labeling decisions—took place in other states. Because Plaintiffs cannot establish personal jurisdiction over GSK for any claims based on consumption of generic ranitidine, any innovator-liability claims must be dismissed.

Any other result would violate the basic notions of "fair play and substantial justice" underlying personal jurisdiction. *Arbella Mut. Ins. Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark*, 122 Nev. 509, 512 (2006). Due process requires "fair warning" that a defendant's activity would require it to litigate claims like the plaintiff's in the forum state. *Ford*, 141 S. Ct. at 1025 (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)). Put another way, specific jurisdiction is grounded on a *quid pro quo*: in exchange for the privilege of conducting business in a state, the non-resident defendant agrees to litigate any resulting disputes in the state. As the Supreme Court has explained, it is reasonable to require an out-of-state corporation "to respond to a suit brought to enforce" obligations incurred when it "exercises the privilege of conducting activities" there. *Int'l Shoe Co. v. State of Wash., Office of Unemp. Comp. & Placement*, 326 U.S. 310, 319 (1945).

When GSK marketed and sold its own branded, prescription Zantac in Nevada, it received the protection of the State's laws and tacitly consented to the possibility of litigation when its own products were used by Nevada residents. But it was the *generic* manufacturers that made independent decisions to sell generic ranitidine products in Nevada, received all the benefits from the sale of those products, and incurred all of the corresponding obligations. GSK and Nevada do not have "reciprocal obligations" relating to generic ranitidine, because GSK had no control over and did not benefit from the generic manufacturers' decisions to sell their products in Nevada. *Ford*, 141 S. Ct. at 1030. In short, it would be grossly disproportionate and fundamentally unfair to subject GSK to litigation in Nevada based on other companies' decisions to sell their products there. That result would also violate the Supreme Court's repeated holdings that specific jurisdiction must be based on "contacts that the defendant *himself* creates with the forum States," and not the "unilateral activity of another party." *Walden v. Fiore*, 571 U.S. 277, 284 (2014) (quoting *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 417 (1984)).

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3. The Court Cannot Exercise Specific Jurisdiction Over GSK in Connection with Predecessor-Liability Claims.

The Court does not have personal jurisdiction over GSK with respect to predecessor-liability claims for the same reason it lacks personal jurisdiction with respect to innovator-liability claims—because GSK did not make any labeling decisions in Nevada. In *T.H.*, the California Supreme Court held that, in some circumstances, a brand-name company could remain liable for alleged defects in a drug's label after transferring the NDA to a new company because it is "reasonably foreseeable that a successor drug manufacturer could continue to use the same label it inherited, even when the label was deficient." 407 P.3d at 42–43. Under *T.H.*—the only decision to *ever* recognize predecessor liability—the only reason a predecessor company could be liable for products sold by a successor company is that the successor company reasonably relied on the predecessor's original label. As with innovator-liability claims, therefore, the only actions by GSK that "relate to" a predecessor-liability claim are GSK's labeling decisions, and GSK made no labeling decision in Nevada. For the same reasons given above with respect to innovator-liability claims, therefore, the predecessor-liability claims brought by Plaintiffs should be dismissed for lack of specific jurisdiction.

B. Innovator Liability Is Incompatible with Nevada Law

Even if Plaintiffs could establish that the Court had jurisdiction to consider claims against GSK alleging injuries caused by other companies' generic products, Plaintiffs' claims would fail on the merits. "[T]he overwhelming national consensus—including the decisions of every [federal] court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product." *In re Zantac(Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1175, 1195 (S.D. Fla. 2020) (quoting *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013)). That conclusion is compelled by "traditional common law tort principles under which a manufacturer is liable for injuries caused by *its own* product[s]," not those of other companies. *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 865 (W. Va. 2018) (quoting *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013) (emphasis added)).

Accordingly, the four courts that have addressed the question have all held that "Nevada law does not support imposing liability on a brand-name defendant for a generic manufacturer's product." *In re Zantac*, 510 F. Supp. 3d at 1218 (citing *Baymiller v. Ranbaxy Pharm., Inc.*, 894 F. Supp. 2d 1302, 1310 (D. Nev. 2012); *Moretti v. Wyeth, Inc.*, 2009 WL 749532, at *3 (D. Nev. March 20, 2009), *aff'd* 579 F. App'x 563 (9th Cir. 2014)). "Under Nevada law, a plaintiff who asserts a strict liability claim must establish that the defendant manufactured or sold the specific product that allegedly injured the plaintiff." *Baymiller*, 894 F. Supp. 2d at 1310; *see Allison v. Merck & Co.*, 110 Nev. 762, 767 (1994) (holding that a plaintiff must establish that his injury was "caused by a defect in the product, and that such defect existed when the product left the hands of the defendant"). And Plaintiffs may not bring any sort of negligence claim against GSK regarding generic products, because "only the manufacturer or seller of an allegedly defective product owes a duty of care to the purchaser." *Moretti*, 2009 WL 749532, at *5 (D. Nev. 2009) (citing *Kite v. Zimmer*, 2006 WL 3386765, at *5 (D. Nev. March 20, 2009)); *see Dow Chem. Co. v. Mahlum*, 114 Nev. 1468, 1486 (1998) ("The duty to disclose requires, at a minimum, some form of relationship between the parties."). Because GSK did not make the generic products that allegedly injured Decedent, and because GSK had no relationship of any kind with Decedent in connection with those generic products, Plaintiffs cannot make out an innovator-liability claim against GSK under Nevada law.

This Court should join the overwhelming national consensus, as well as the smaller but unanimous consensus of courts applying Nevada law, and hold that innovator-liability claims are not viable in Nevada. A manufacturer is liable only for injuries caused by its own products, not products made by other companies.

C. Predecessor Liability Is Incompatible with Nevada Law

Even if this Court were to break with the national and Nevada consensus rejecting innovator liability, it should decline Plaintiffs' invitation to take a huge step further and become only the second court in the country to recognize "predecessor liability." Plaintiffs concede that GSK did not hold the NDA for OTC Zantac at a time when Decedent was using Zantac or a ranitidine-containing generic product. *See* SAC ¶¶ 13, 17. Yet Plaintiffs nonetheless seek to hold

GSK liable, presumably on a theory of predecessor liability, according to which a brand-name company can be held liable even after it transfer the NDA to a different company, if it was foreseeable that the successor would rely on the predecessor's labeling decisions.

The California Supreme Court has adopted predecessor liability, but that holding is an outlier even among the small number of courts that have recognized innovator liability. Neither Massachusetts nor Alabama (before the legislature overturned the state Supreme Court's decision) made the former brand-name manufacturers of a drug liable for labeling deficiencies they have no ability to correct. *See Rafferty*, 92 N.E. 3d 1205; *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014). The ruling was even controversial on the California Supreme Court itself. Three justices who otherwise joined the majority opinion dissented from the holding that "would extend indefinitely a drug manufacturer's duty to warn the customers of its successor, even after sale of the product line." 407 P.3d at 48 (Corrigan, J., dissenting). As the dissent observed, that "theory of 'predecessor liability' represents a substantial and unprecedented expansion of tort duties." *Id*. "[P]redecessor liability for failure to warn ha[d] never before been recognized by *any* court, in any jurisdiction" and "[t]o the extent the theory ha[d] been raised, courts across the country ha[d] universally rejected it." *Id*.

Predecessor liability does not make sense even if one accepts the logic of innovator liability. As explained above, the sole rationale for innovator liability is that the generic company is required by federal regulations to copy the branded product's label. But after a company transfers the NDA to a new company, it no longer has any ability to change the generic *or* the brand-name label. The successor company that holds the NDA is the only one that can make updates to the label. The successor company thus "assumes the responsibility to update the warning label if and when reasonable evidence demonstrates a link to a serious health hazard," and the predecessor manufacturer has "a right to presume successors will perform their duty and follow the law." *Id*. at 50.

There is also no policy rationale for predecessor liability. Imposing the duty has no regulatory benefits because, again, it is "*impossible* for predecessor companies to discharge" because they have "*no ability* to change the product's labeling and thus no effective way to control the warnings given to consumers." *Id*. at 49, 50. There are also significant downsides to recognizing

predecessor liability, such as "encourag[ing] over-warning by drug manufacturers" who, knowing that they will be liable for deficiencies in the label even after they lose control of the NDA, will have an incentive to warn about "potential adverse side effects that have only the barest support in evolving scientific literature." *Id*. at 51. Imposing liability on predecessor manufacturers also has "the perverse effect of diminishing successor corporations' incentive to update labels as scientific evidence develops" because it allows the successor companies to share the costs of tort suits with predecessors who no longer have any ability to alter the label. *Id*. at 52.

In sum, even if this Court were to find it had jurisdiction over GSK in this suit, and became the first court applying Nevada law to recognize innovator liability, it must dismiss all claims against GSK based on consumption of OTC products because the they rest on a theory of predecessor liability that is incompatible with the logic of innovator liability itself, not to mention the fundamental principles of Nevada law.

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IV. CONCLUSION

For the foregoing reasons, GSK respectfully requests the Court dismiss the claims against GSK for lack of personal jurisdiction or, in the alternative, for failure to state a claim.

DATED: February 25, 2022.

EVANS FEARS & SCHUTTERT LLP

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CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I certify that I am an employee of EVANS FEARS & SCHUTTERT LLP, and that on the 25th day of February, 2022, I caused the foregoing document entitled **DEFENDANT GLAXOSMITHKLINE LLC'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FOR FAILURE TO STATE A CLAIM** to be served upon those persons designated by the parties in the E-Service Master List for the above-referenced matter in the Eighth Judicial District Court eFiling System in accordance with the mandatory electronic service requirements of Administrative Order 14-2 and the Nevada Electronic Filing and Conversion Rules.

/s/ Faith Radford
An Employee of Evans Fears & Schuttert LLP

Exhibit C

Plaintiff Husrom Opposition to Motion to Dismiss

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DISTRICT COURT
CLARK COUNTY, NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as the legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor;

Plaintiffs,

vs.

LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC.; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES I through X; and ROE CORPORATIONS XI through XX, inclusive,

Defendants.

Case No.: A-21-835385-C
Dept No.: 15

PLAINTIFFS' OPPOSITION TO DEFENDANT GLAXOSMITHKLINE LLC'S MOTION TO DISMISS

Hearing Date: April 20, 2022
Hearing Time: 9:00 a.m.

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I. INTRODUCTION.

This Court should exercise specific personal jurisdiction over Defendant GlaxoSmithKline LLC ("GSK") and allow Plaintiffs to proceed on their innovator liability claims. GSK's jurisdictional arguments misread *Ford Motor Co. v. Mont. Eighth Judicial Dist. Court*, 141 S. Ct. 1017, 1024 (2021). *Ford* was issued to correct a misunderstanding: Plaintiffs' cause of action need not "arise from" GSK's tortious conduct (which it claims took place in other states). Rather, Plaintiffs must show only that their claims "relate to" GSK's contacts—which they do by showing "an affiliation between the forum and the underlying controversy." *Id.* at 1026 (quoting *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1780 (2017)). Because GSK exploited Nevada's market, it is on "clear notice" that it is "subject to jurisdiction in the State's courts when the product malfunctions there." *Ford*, 141 S. Ct. at 1030.

GSK also asks this Court to rule that Plaintiffs' innovator liability claims fail as a matter of law. But the common law of Nevada is that the "responsibility for injuries caused by defective products is properly fixed *wherever* it will most effectively reduce the hazards to life and health inherent in defective products that reach the market." *Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (emphasis added). Following this principle, brand-name manufacturers like GSK are in the best position to "effectively reduce" these risks. Under federal law, brand-name manufacturers control the contents of generic manufacturer's labels, and generic manufacturers *cannot* change them. Applying bedrock tort principles, the risk of loss should fall on the responsible party. Here, that party is GSK.

Lastly, GSK creates something it calls "predecessor liability" and paints it as a novel theory. In reality, GSK is just asking this Court to hold that it cannot be held liable for actions it took a long time ago (and that other entities should have corrected in the meantime). But this is essentially a defense of intervening or superseding cause—in other words, GSK must save this argument for summary judgment or the jury. As the California Supreme Court has recognized, this type of defense cannot be adequately assessed "before a factual record has been developed." Thus, GSK's motion should be denied.

II. COUNTERSTATEMENT OF FACTS.

Ranitidine, better known as Zantac, was developed by GSK and approved for prescription use in 1983. (Second Am. Compl. at ¶ 77.) Zantac was a wildly successful drug. (*Id.* at ¶ 78.) Due to GSK's marketing strategy, 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 GSK's sales of $3.98 billion. (*Id.*) Even as late as 2016, Zantac was the 50th most prescribed drug in the United States with over 15 million prescriptions. (*Id.*)

The marketing strategy that led to Zantac's success for over 30 years emphasized the purported safety of the drug. (*Id.*) Zantac has been marketed as a safe and effective treatment for infants, children, and adults. (*Id.*) And GSK, through its constant television campaigns, marketed Zantac as safe to use when consuming foods containing high levels of nitrates—like tacos, pizza, and the like. (*Id.* at ¶ 102.) Because GSK promoted the drug as being safe, Zantac became available without a prescription in 1996. (*Id.* at ¶ 79.) Generic versions of the drug (ranitidine) became available the following year. (*Id.*)

From the beginning, however, GSK knew that ranitidine causes cancer. (*Id.* at ¶¶ 117–26.) Plaintiffs reference studies by GSK in 1981 and 1987 that, they allege, were purposefully distorted so that GSK could mask any potential cancer risk. (*Id.* at ¶¶ 124–25.) GSK failed to disclose the risk to the FDA or the American public so that it could continue to profit.

Plaintiffs are a Nevada family suing over the death of a loved one. *See* (Second Am. Compl. ¶¶ 2–8.) The decedent contracted esophageal cancer and died after taking both the branded and the generic versions of Zantac—a drug that was marketed by GSK as a way to *treat* gastroesophageal reflux disease—from November 2016 to September 2019. (*Id.* at ¶¶ 11, 69.) Plaintiffs allege that GSK cultivated a market in Nevada for the product and derived substantial revenue from this state. (*Id.* at ¶¶ 33–35.) The decedent lived in Nevada, was subjected to GSK's marketing in Nevada, presumably believed GSK's misrepresentations that the drug was safe in Nevada, took both the branded and generic Zantac drugs bearing GSK's warning label in Nevada, and died in Nevada. (*See generally id.*)

III. ARGUMENT.

A. This Court May Exercise Jurisdiction Over Innovator Liability Claims.

A Court may exercise "specific jurisdiction" over a defendant that has taken "some act by which it purposefully avails itself of the privilege of conducting activities within the forum State." *Ford Motor Co. v. Mont. Eighth Judicial Dist. Court*, 141 S. Ct. 1017, 1024 (2021). Purposeful availment occurs where a "defendant deliberately 'reached out beyond' its home—by, for example, 'exploiting a market' in the forum State." *Id.* at 1025. The plaintiff's claims "must arise out of *or relate to* the defendant's contacts" with the forum. *Id.* (emphasis added).

1. The "Arising Out Of" Test is Different from the "Related To" Test.

GSK's argument is based on a fundamental misreading of the Supreme Court's recent decision in *Ford*. In *Ford*, the Supreme Court clarified that there are two different ways that a plaintiff may demonstrate "purposeful availment." First, the plaintiff may show "aris[ing] out of" jurisdiction—an inquiry that "asks about causation." *Id.* But if the plaintiff cannot make a "causal showing," he can still satisfy the requirements of purposeful availment by showing that his claims "relate to" the defendant's contacts with the forum. *Id.* It is this second test—the "relate to" test—that Plaintiffs in this case have satisfied.

This second test "contemplates that some relationships will support jurisdiction without a causal showing." *Id.*; *Ayla, Ltd. Liab. Co. v. Alya Skin Pty. Ltd.*, No. 20-16214, 2021 U.S. App. LEXIS 25921, at *18 n.5 (9th Cir. Aug. 27, 2021) ("We clarify that our precedents permit but do not require a showing of but-for causation to satisfy the nexus requirement."). Rather, the "relate to" inquiry focuses on whether there is a "strong relationship among the defendant, the forum, and the litigation." *Ford*, 141 S. Ct. at 1028. Importantly, "regularly marketing" a product in a state puts a defendant on "clear notice" that it will be "subject to jurisdiction in the State's courts when the product malfunctions there." *Id.* at 1030.

2. GSK Conflates the Two Distinct Jurisdictional Tests Outlined in Ford.

GSK repeatedly conflates the "arising out of" and "related to" tests, contrary to the holding in *Ford*. Br. at 5:14–18 (conflating the phrase "arises from" with the "relatedness requirement"); 6:16–17 (claiming that only conduct that "gives rise" to claims can "relate to" those claims); 8:12–14 (purporting to apply the "relate to" test while actually applying the "arising out of" test). GSK applies only the standard for "arising out of" jurisdiction, narrowly examining only the one cherry-picked fact it believes is the "but-for" cause of Plaintiffs' cause of action—GSK's labeling decisions, which it claims to have carried out in other states.

Such an analysis completely misses the factors that Supreme Court found relevant in *Ford*. There (as here), the defendant argued that it had "designed" and "manufactured" the relevant product outside the forum. *Ford*, 141 S.Ct. at 1023. And there (as here), the defendant had not sold the product that injured the plaintiff in the forum. *Id.* As a result, Ford argued that there was no specific personal jurisdiction. *Id.* The Court disagreed.

In *Ford*, the Supreme Court did not first winnow down the relevant jurisdictional facts to only those aspects of the defendant's conduct that were allegedly tortious. Rather, the Court asked whether there was "'an affiliation between the forum and the underlying controversy,' without demanding that the inquiry focus on cause." *Id.* at 1026. And an "affiliation" may occur where the plaintiff is injured by a product in a state and the defendant has made "efforts" to "serve, directly or indirectly, the market" in that state. *Id.* at 1027 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

Thus, so long as there is at least some "affiliation between the forum and the underlying controversy," a defendant cannot complain that the exercise of personal jurisdiction "offend[s] traditional notions of fair play and substantial justice." *Id.* After all, if a defendant does not wish to be sued in a certain state, it can "structure [its] primary conduct to lessen or avoid exposure to a given State's courts," for example by declining to do any business in that state. *Id.* at 1025. But when a company "exercises the privilege of conducting activities within a state—thus enjoy[ing] the benefits and protection of [its] laws—the State may hold the company to account for related misconduct." *Id.*

GSK—much like the defendant in *Ford* argued its manufacturing processes took place outside the forum—argues here that Plaintiff's innovator liability claims are not sufficiently tied to Nevada because GSK's labeling decisions allegedly took place in another state. While that may be true, the Supreme Court's holding in *Ford* cautions against such a myopic view of the relevant facts. Rather, the Court reasoned that the plaintiffs "might never have bought [the products], and so these suits might never have arisen, except for Ford's contacts with their home States." *Id.* at 1029. And Ford's development of the forum state as a market "might turn any resident of [the forum] into a Ford owner." *Id.* Adopting an expansive view of the type of contacts that lead to personal jurisdiction, the Court reasoned:

> The plaintiffs here did not in fact establish, or even allege, such causal links. Nor should jurisdiction in cases like these ride on the exact reasons for an individual plaintiff 's purchase, or on his ability to present persuasive evidence about them. But the possibilities listed above—created by the reach of Ford's Montana and Minnesota contacts—underscore the aptness of finding jurisdiction here, even though the cars at issue were first sold out of state.

Id. at 1029. GSK, by insisting that the only relevant jurisdictional fact is where it undertook its labeling decisions, applies the flawed analysis *Ford* set out to correct.

3. GSK's Development of the Nevada Market and Misrepresentations in the Forum Give Rise to Personal Jurisdiction.

Here, GSK, just like the defendant in *Ford*, created a market for its product in the forum state through its advertising and misrepresentations. GSK's misrepresentations that ranitidine is safe and effective occurred throughout the state of Nevada, and GSK poured millions of dollars into marketing the drug in Nevada. The decedent, who at all relevant times lived in Nevada, relied on those misrepresentations and took ranitidine—both in its branded Zantac form and in its generic form—for years there. And when she developed cancer, as was reasonably foreseeable to GSK given what it knew about Zantac and generic ranitidine, she suffered in Nevada and was treated at a clinic in Las Vegas. Under *Ford*, then, there is a sufficient "affiliation between the forum and the underlying controversy" for the exercise of personal jurisdiction.

This is true even though Plaintiff never ingested a drug GSK manufactured. In those states that have recognized innovator liability, to establish personal jurisdiction, the plaintiff is not required to show that the defendant's labeling decisions took place in the forum state. For instance, in *Quinn-White v. Novartis Pharm. Corp.*, the Court reasoned that "[a]lthough Plaintiff Quinn-White did not ingest Defendant's drug, Plaintiff alleges that her California-based physician reviewed and relied on Novartis's label and its warnings in California, where Novartis marketed its drugs." No. CV 16-4300 PSG (AGRx), 2016 U.S. Dist. LEXIS 201328, at *7 (C.D. Cal. Oct. 7, 2016). Thus, *Quinn-White*, in a decision that harmonizes with *Ford*, held that the plaintiff's reliance on a misrepresentation in the forum state, together with the defendant's decision to market its drugs in that state, is sufficient to allege personal jurisdiction. *Id.* Because the defendant marketed its drugs in California, it had "availed itself of California's legal system and could reasonably expect to litigate claims related to its drugs in California." *Id.*

This Court should avoid the analytical error made by the MDL court. The MDL court began the "relate to" test by taking a narrow view of the facts, concluding that "the Defendants' only conduct that *gives rise* to Plaintiffs' claims is Defendants' alleged failure to update the warning label for brand-name ranitidine products, not the alleged misrepresentations about the safety and efficacy of Zantac that Defendants made in the course of sales and marketing activities." *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1192, 1212–13 (S.D. Fla. 2021) (emphasis added). Inevitably, then, the MDL court reasoned that specific jurisdiction over innovator liability theory claims could *only* be proper where labeling decisions had taken place. *Id.* But by looking only at the conduct that "gives rise" to the cause of action, the MDL court conflated the "arising out of" and "relate to" tests. The MDL court thus fell into exactly the type of "but-for causation" thinking that *Ford* held was too narrow.

Plaintiff alleges that GSK developed a market for ranitidine in Nevada; caused misrepresentations regarding ranitidine to be made in the forum; and caused the decedent's injuries in Nevada when she took both branded and generic Zantac. In the end, by "conducting so much business in" Nevada, GSK has "enjoy[ed] the benefits and protection of" its laws—"the

enforcement of contracts, the defense of property, the resulting formation of effective markets." *Id.* at 1030. Those benefits give rise to "reciprocal obligations for the Defendants under state law," notably the obligation not to make negligent misrepresentations; and breaching those obligations "relates to" the negligent misrepresentation claims, allowing Nevada courts to hold GSK accountable consistent with the Constitution and Due Process. *Id.*

Lastly, as explained below, there is no separate theory of "predecessor liability." Plaintiffs seek to hold GSK liable for its misrepresentations concerning branded Zantac, but this is not a novel legal theory. Rather, the phrase "predecessor liability" is a label that GSK has placed on its own affirmative defenses of intervening or superseding cause. Because "predecessor liability" is just another name for GSK's affirmative defenses—GSK's assertions regarding this supposed "theory" of liability do not change the personal jurisdiction analysis.

B. Innovator Liability is Based on Fundamental Principles of Nevada Tort Law.

Nevada is a notice pleading state. *McGowen v. Second Judicial Dist. Court of Nev.*, 432 P.3d 220, 225 (Nev. 2018) ("Nevada has not adopted the federal 'plausibility' pleading standard."). Thus, to succeed on a motion to dismiss for failure to state a claim, the defendant must show that, after every reasonable inference is drawn in the plaintiff's favor, "it appears beyond a doubt that the plaintiff could prove no set of facts that would entitle him to relief." *Munda v. Summerlin Life & Health Ins. Co.*, 127 Nev. 918, 923, 267 P.3d 771, 774 (2011). With this in mind, we turn to Plaintiffs' theories of liability.

Under the theory of "innovator liability," a brand-name manufacturer of a drug may be held responsible for the contents of a generic manufacturer's warning label because, under federal law, the generic manufacturer is *required* by to copy the brand-name manufacturer's label. *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1210 (Mass. 2018) (citing 21 U.S.C. § 355(j)(2)(A)(v) & (j)(4)(G)). Because federal law only requires the generic manufacturer to copy the brand-name manufacturer's label, many of Plaintiffs' state law failure-to-warn claims against the generic manufacturer are impliedly preempted by federal law. *PLIVA, Inc., v. Mensing*, 564 U.S. 604 (2011).

Courts have recognized that this is fundamentally unfair to the plaintiff. For instance, in *Franzman v. Wyeth, Inc.*, a Missouri court acknowledged (in applying Kentucky law to the case before it) that there was "inherent unfairness [in] first substantially preempting a consumer's tort claims against the generic manufacturer, and next concluding that the same consumer's tort claims are also barred against the brand-name manufacturer responsible for the product design, formula, dosage, labeling and warning that are at the core of the consumer's claims." 451 S.W.3d 676, 691 (Mo. Ct. App. 2014). And the Sixth Circuit has recognized the "basic unfairness" of the "classic 'Catch 22'" that occurs where the plaintiff cannot sue the *generic* manufacturer for failure to warn because that company didn't design the label, but also can't sue the *brand-name* manufacturer because it didn't make the product the plaintiff consumed. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013) (applying Tennessee law).

In *Franzman* and *Strayhorn*, however, state law products liability statutes prevented the Courts from adopting the "innovator liability" theory. *See Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1221 (Mass. 2018) (distinguishing cases finding no duty because those were "resolved under the products liability statutes of other States"). And the federal case law presented by GSK is not persuasive, as those decisions were "issued by Federal courts that are constrained in their interpretation of State law in the absence of clear guidance from State appellate courts." *Id.* This Court must, relying on Nevada tort principles, reach its own conclusion.

Where—as here—no legislative scheme bars application of the theory, judges have applied traditional tort law principles to properly allocate the risk of loss onto the party in the best position to prevent the harm (the brand-name manufacturer). *See, e.g.*, *Rafferty*, 92 N.E.3d at 1221; *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18 (Cal. 2017); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014), *superseded by statute*, Ala. Code § 6-5-530(a); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010). While the name GSK uses for Plaintiffs' theory—"innovator liability"—may be relatively recent, the principles underpinning it are well-established.

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So-called "innovator liability" is based on the commonsense principle that liability for injuries should be assigned those parties who are in the best position to avoid them. *Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (The "responsibility for injuries caused by defective products is properly fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market.").

In *Allison*, the Nevada Supreme Court explained that when considering whether to permit the plaintiff's theory of liability, the Court should consider "public interest" principles. *Id.* at 953. The Court reasoned that these "public policy considerations . . . were put well by Professor Prosser in the noted law review article, 'The Fall of the Citadel':

> The public interest in human safety requires the maximum possible protection for the user of the product, and those best able to afford it are the suppliers of the chattel. By placing their goods upon the market, the suppliers represent to the public that they are suitable and safe for use; and by packaging, advertising and otherwise, they do everything they can to induce that belief . . . .

Id. (citing 50 Minn. L. Rev. 791, 799 (1966)). The Court further endorsed this vision of Nevada's common law tort principles, explaining that "[t]his concept of 'public interest' is the guiding principle of our present opinion." *Id.* Indeed, Nevada law has viewed products liability law in this light for over fifty years. *See Stackiewicz v. Nissan Motor Corp.*, 686 P.2d 925, 926–27 (Nev. 1984) (providing an overview of the evolution of products liability law in Nevada); *Shoshone Coca-Cola Bottling Co. v. Dolinski*, 420 P.2d 855, 857 (Nev. 1966) (adopting the California Supreme Court's expansion of strict liability doctrines).

Recently, Nevada has reaffirmed its commitment to providing the "maximum possible protection" for consumers and has rejected attempts to narrow liability. *Ford Motor Co. v. Trejo*, 402 P.3d 649, 655 (2017) (not requiring the plaintiff to proffer evidence of an alternative feasible design). In *Trejo*, the Court recognized the "unique position of manufacturers" in "establishing the reasonable expectations of a product that in turn cause consumers to demand that product." *Id.* at 529–30. Moreover, the Court has not shied away from following California's lead in products liability cases. *Shoshone*, 420 P.2d at 857. There is, accordingly, no reason for this Court to reject Plaintiffs' "innovator liability" theory.

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Rather, following the principle laid out in *Allison*, this Court should assign responsibility for injuries "*wherever* it will most effectively reduce the hazards to life and health inherent in defective products that reach the market." *Allison*, 878 P.2d at 952 (emphasis added). The best, and likely only, way to "effectively reduce the hazards to life and health" arising from inadequate or otherwise defective generic drug labels is to hold the brand-name manufacturer (who exercises complete control over the contents of the drug label) liable for injury resulting from its failure to properly warn of known risks. Indeed, this is the same logic that California relied on when it found a brand-name manufacturer liable for an inadequate drug label included with a generic drug. *See T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 32 (Cal. 2017) ("The brand-name drug manufacturer is the only entity with the unilateral ability to strengthen the warning label. So a duty of care on behalf of all those who consume the brand-name drug or its bioequivalent ensures that the brand-name manufacturer has sufficient incentive to prevent a known or reasonably knowable harm.").

Nothing in GSK's case law is to the contrary. Rather, the three federal cases that GSK cites all stem from the same original mistake, with each subsequent case parroting the error. In the unpublished decision *Moretti v. Wyeth, Inc.*, the federal Court misread *Allison* to hold that only the manufacturer of a product could be liable to a consumer. No. 2:08-cv-00396-JCM-(GWF), 2009 U.S. Dist. LEXIS 29550, at *9–10 (D. Nev. Mar. 20, 2009).

Of course, that is not at all what *Allison* held. In that case, the Nevada Supreme Court stated that under general tort principles, liability should be assigned "*wherever* it will most effectively reduce the hazards to life and health inherent in defective products that reach the market." *Allison*, 878 P.2d at 952 (emphasis added). Under the facts of that *particular* case, the risk of loss was most appropriate allocated to the manufacturer. But *Allison* never held that only the manufacturer of a specific item could be liable for damages.

Later, a federal Court relied on *Moretti* in *Baymiller v. Ranbaxy Pharm., Inc.*, to reach the same conclusion—again without properly considering the theory of liability allocation set forth in *Allison*. 894 F. Supp. 2d 1302, 1311 (D. Nev. 2012). The mistake thus took root.

The MDL Court, in a cursory analysis, reasoned that *Moretti* and *Baymiller* were appropriate "data" for predicting that the Nevada Supreme Court would reject "innovator liability." *In re Zantac*, 510 F. Supp. at 1219. And given the 50-state task before it, no one can fault the MDL court for doing this. But the opinion hardly constitutes persuasive authority.

GSK also cites in passing to *Dow Chem. Co. v. Mahlum*, where the Court stated that "[t]he duty to disclose requires, at a minimum, some form of relationship between the parties." 114 Nev. 1468, 1486 (1998). While this quote, at first blush, favors GSK's position, the "duty to disclose" analyzed in that case pertained only to fraudulent concealment claims—not to claims sounding in negligence. 114 Nev. at 1486. In *Mahlum*, Dow Chemical had entered into a venture with another company, Dow Corning, to provide the latter with testing related to silicone breast implants. Dow Chemical apparently never, however, marketed or sold any breast implants to anyone. When the plaintiff was injured by Dow *Corning's* breast implants, the Court held that she could not recover against Dow *Chemical* for fraudulent concealment because she did not have a "fiduciary" or "special" relationship with that company. *Id.* at 1486–87. She could (and did), however, recover against both companies on a negligence theory. *Id.* at 1491–92.

Nothing in *Mahlum* precludes Plaintiff from recovering from GSK in this case. Here, unlike in *Mahlum*, both parties freely admit that the generic manufacturers were required by law to copy GSK's product label. Thus, there is a direct causal link between GSK's misrepresentations and the labeling on the product Plaintiff ingested. And because Plaintiffs' theory of liability sounds in negligence, not fraud, no special duty is required.

Moreover, GSK had a duty created by federal law to disclose to the public any defects in its drug. *Rafferty*, 92 N.E.3d at 1209 ("the manufacturer must also show that the proposed warning label for the drug is accurate and adequate." (citing 21 U.S.C. § 355(b)(1)); *see also Local Union No. 400 of the Int'l Union of Operating Eng'rs v. Bosh*, 715 P.2d 36, 41 (Mont. 1986) (applying federal law when considering duties in the state law context). And once GSK "assumed the duty to supervise and exert control" over the New Drug Application, "it had to do so in a reasonably prudent manner." *Wright v. Schum*, 781 P.2d 1142, 1146 (Nev. 1989).

Lastly, GSK engaged in widespread advertising directed to the public at large to convince consumers that ranitidine was safe. GSK's negligence with respect to the initial New Drug Application, together with its failure to correct its misstatements for years despite a duty created by federal law, constitute exactly the kind of negligent undertaking that the Court allowed the plaintiff to recover for in *Mahlum*. Thus, *Mahlum* is of no help to GSK.

C. So-Called "Predecessor Liability" is Not a Separate Theory.

GSK also urges this Court to reject what it styles "predecessor liability," which GSK defines as the theory "according to which a brand-name company can be held liable even after it transfer the NDA to a different company, if it was foreseeable that the successor would rely on the predecessor's labeling decisions." (Def's Br. at 10.) But this is not a separate theory of liability. Rather, it is a term pejoratively used by the dissent in *T.H. v. Novartis Pharm. Corp.*, and that does not appear to have been used in any other opinion. 407 P.3d 18, 47–48 (2017) (Corrigan, J., dissenting).

What Justice Corrigan referred to as "predecessor liability" was merely one aspect of innovator liability—the California Supreme Court's holding that "a brand-name manufacturer's sale of the rights to a drug does not, as a matter of law, terminate its liability for injuries foreseeably and proximately caused by deficiencies present in the warning label prior to the sale." *Id.* at 47. But whether the parties that subsequently owned the NDA are at fault (and are thus a superseding or intervening cause cutting off the causal chain back to GSK's original labeling decisions) are issues of fact that cannot be decided on a motion to dismiss.

As the majority explained, "significant moral blame attaches to the failure to warn about a drug's risks when the brand-name drug manufacturer knew or should have known about those risks. The fact that the brand-name manufacturer has since exited the market does not alter the calculus." *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 46–47 (Cal. 2017). The actionable conduct "occurred while the manufacturer still had control over the warning label," and although it "can be difficult to assess the full extent of moral blame before a factual record has been developed," this does not mean that the jury will not be up to the task. *Id.*

Plaintiffs in this case allege that GSK knew *from the beginning* that ranitidine causes cancer. GSK cannot shed itself of liability for its misrepresentations concerning its own product—Zantac—by selling off the product line, knowing that thousands of its customers will die of cancer. Moreover, GSK would have derived a concrete benefit from concealing the risks of Zantac while selling off the rights to over-the-counter versions of the drug—an "inflat[ed] sales price of the NDA." *Id.* After all, GSK would not have made money from exiting the over-the-counter market for Zantac if no one had been willing to purchase the rights to manufacture and sell it, which would have been the case if GSK had made the truth known about its product.

Lastly, GSK's arguments regarding economic incentives are unpersuasive. Juries are free to apportion blame among manufacturers, distributors, and others, and punitive damages exist to prevent companies from attempting to "pass off" responsibility for grave societal harms to other parties. And GSK's theory—that the sale of a New Drug Application prospectively cuts off a manufacturer's liability moving forward—creates a perverse incentive for companies like GSK to conceal defects in their drugs and then sell them off to limit their liability for what they know. Such an approach defies not only reason, but also the policy of this State of providing the maximum level of protection to the end user.

IV. CONCLUSION.

For the above reasons, GSK's motion to dismiss for lack of personal jurisdiction and failure to state a claim should be denied.

DATED this 25th day of March, 2022.

THE702FIRM

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CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of March, 2022, I caused service of a true and correct copy of the foregoing **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT GLAXOSMITHKLINE LLC'S MOTION TO DISMISS** to be made by the Eighth Judicial District Court's Odyssey E-File and Serve program, upon all parties registered to use this service, in accordance with the Clark County District Court's Administrative Order No. 14-2, issued 5/9/14:

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/s/ Amber Casteel

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Exhibit D

Defendant GlaxoSmithKline Reply in Support of Motion to Dismiss

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Attorneys for Defendant GlaxoSmithKline LLC

EIGHTH JUDICIAL DISTRICT COURT

FOR THE DISTRICT OF NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as a legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor;

Plaintiffs,

vs.

LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES 1 through X; and ROE CORPORATIONS XI through XX, inclusive,

Defendants.

Case No. A-21-835385-C

Dept No. 15

DEFENDANT GLAXOSMITHKLINE LLC'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FAILURE TO STATE A CLAIM

HEARING DATE: April 20, 2022

HEARING TIME: 9:00 a.m.

I. INTRODUCTION

Faced with a unified set of precedents rejecting their claims on both jurisdictional and merits grounds, Plaintiffs are forced to argue that nearly every court to consider the questions raised by GSK's motion to dismiss has reached the wrong answers. But the fault does not lie with the courts that have rejected innovator- and predecessor-liability claims like the Plaintiffs; the fault lies with the claims themselves.

First, Plaintiffs cannot establish specific jurisdiction for their innovator- or predecessor-liability claims because GSK did not engage in any conduct in Nevada that is legally "related to" those claims. As the MDL court held, a manufacturer's labeling decisions are the only conduct legally relevant to an innovator-liability claim, and Plaintiffs do not allege GSK made any labelling decision in Nevada.

Second, the federal courts that have addressed innovator-liability claims brought under Nevada law are correct that Nevada—like every state that has not expressly adopted innovator liability—adheres to the "traditional common law tort principles under which a manufacturer is liable for injuries caused by *its own* product[s]," not the products of its competitors. *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013). Plaintiffs' characterization of their innovator-liabilty claims as negligent misrepresentation claims does them no favors. Innovator-liability claims will fail under *any* negligence theory because brand-name manufacturers simply do not owe a duty of care to consumers of other companies' products. Negligent misrepresentation is a particularly bad fit for innovator liability under Nevada law, moreover, because negligent misrepresentation requires an affirmative misstatement (which Plaintiffs have not alleged) and is limited to claims resulting in pecuniary loss.

Third, even if this Court were to break with the national and Nevada consensus and recognize innovator liability, it should not take the extra step of recognizing predecessor liability. Because GSK never held the NDA for OTC Zantac during the years Plaintiff consumed the product, all claims against GSK must be dismissed for this reason alone.

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II. LEGAL ARGUMENT

A. The Court Lacks Personal Jurisdiction Over Innovator-Liability and Predecessor-Liability Claims.

Plaintiffs acknowledge that their innovator-liability theory depends entirely on the fact that "the generic manufacturer is *required* by [federal law] to copy the brand-name manufacturer's label." Opp. at 7 (emphasis in original). The only reason a brand-name manufacturer can be sued for injuries allegedly caused by generic products is that the brand-name manufacturer, as the NDA holder, effectively controls the contents of the generic label. The only actions relevant to an innovator-liability claim, therefore, are the brand-name company's labeling decisions. The labeling decisions are the only actions by the brand-name manufacturer that allegedly affect the generic consumer, and the central dispute in an innovator-liability case is whether those labeling decisions were made negligently. As the MDL court put it, after examining the two state supreme court decisions adopting innovator liability, "the core conduct that constitutes the rationale for … the theory of innovator liability" is the "brand-name manufacturer's labeling decisions regarding its own product." *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1192, 1213 (S.D. Fla. 2021); *see T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 34 (Cal. 2017) (the conduct giving rise to innovator liability is the "failure to update and maintain the warning label"); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1209 (Mass. 2018) (the culpable conduct in an innovator-liability case is the "intentional[] fail[ure] to update the label").

It follows, then, that the only actions that "relate to" an innovator-liability claim for purposes of specific jurisdiction are the defendant's labeling decisions regarding the brand-name product. *Ford Motor Company v. Montana Eighth Judicial District Court*, 141 S. Ct. 1017, 1026 (2021). Because the sole basis for an innovator-liability claim is the brand-name manufacturer's control of the label, nothing else the brand-name company does matters. If a plaintiff does not allege the brand-name manufacturer made labeling decisions in the forum state, therefore, she has not alleged forum contacts that "relate to" an innovator-liability claim, and there is no basis for specific jurisdiction. *See In re Zantac*, 546 F. Supp. 3d at 1214 ("Plaintiffs conceded at the Hearing that they do not allege that Defendants made labeling decisions related to brand-name

ranitidine products in California or Massachusetts. As such, Plaintiffs' claims, as alleged, do not 'arise out of or relate to' Defendants' alleged activities within those forums.").

Plaintiffs attempt to manufacture a basis for specific jurisdiction on the ground that GSK "created a market for its product in [Nevada] through its advertising and misrepresentations." Opp. at 5. But any alleged misrepresentations GSK made in Nevada regarding its own products have nothing to do with Plaintiffs' innovator-liability claims. As the MDL court held when considering this exact question, alleged "misrepresentations made in the course of sales and marketing" are "not necessary to state a misrepresentation claim premised on the innovator-liability theory" and thus "do not give rise to 'jurisdictionally relevant' contacts between the brand-name manufacturers and the forum." *In re Zantac*, 2021 WL 2682602, at *14 (quoting *Walden v. Fiore*, 571 U.S. 277, 289 (2014)). In other words, the brand-manufacturer's marketing of its own product is legally irrelevant to an innovator-liability claim. Even if GSK had *never* marketed or sold Zantac in Nevada, Plaintiffs would still be pursuing an innovator-liability claim on the ground that GSK controlled the NDA and was thus responsible for the contents of the label on the generic products the decedent purchased.

GSK's marketing of Zantac in Nevada is legally irrelevant to Plaintiffs' innovator-liability theory, and thus does not "relate to" those claims. That conclusion follows from *Ford*, which made clear that "the phrase 'relate to' incorporates real limits, as it must to adequately protect defendants foreign to a forum." *Id*. The MDL court explained that it was "compel[ed]… to establish those 'real limits,' for purposes of specific personal jurisdiction, as only those activities that relate to the brand-name manufacturers' labeling decisions regarding their own product" *In re Zantac*, 2021 WL 2682602, at *14. If activities with no relevance to the plaintiff's innovator-liability claim, such as the brand-name companies' "marketing and sales contacts relating to their own products," could support specific jurisdiction, then "the phrase 'relate to' would have no 'real limits.'" *Id*. Indeed, if a plaintiff could establish specific jurisdiction for a particular claim just by pointing to some sort of activity by the defendant in the forum state, no matter how irrelevant to the claims at issue, the distinction between specific and general jurisdiction would

collapse. An out-of-state defendant could be sued in the forum state for any reason, so long as they had some sort of minimum contact with the state.[1]

Defendants do not conflate the "arise out of" and "relate to" tests, as Plaintiffs argue, and neither did the MDL court. There is no dispute that, after *Ford*, a plaintiff need not show that the defendant's activities in the forum state were the but-for cause of his injuries. But there is also no dispute that a plaintiff must show the defendant's in-state activities "relate to" the plaintiff's claims. And if the phrase "relate to" is to have any "real limits," it cannot encompass activities that have no legal relevance to the claims at issue. *Ford*, 141 S. Ct. at 1026.

The fact that GSK's contacts with Nevada are irrelevant to Plaintiffs' innovator-liability claims distinguishes this case from *Ford*. In that case, the two plaintiffs had brought product-liability suits in Minnesota and Montana alleging that two models of Ford vehicles—the 1996 Explorer and 1994 Crown Victoria—were defective. *See id*. at 1023. Ford argued it was not subject to specific jurisdiction because the plaintiffs had purchased their cars outside the forum states, and thus there was no causal link between the plaintiffs' claims and Ford's activities in Minnesota and Montana. Ford had designed the cars in Michigan, manufactured them in Kentucky and Canada, and sold them to the plaintiffs in Washington and North Dakota. *See id*. The particular cars at issues only reached the forum states through the plaintiffs' unilateral actions.

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[1] This loose approach to personal jurisdiction is exemplified by *Quinn-White v. Novartis Pharmaceuticals*, 2016 WL 11519285 (C.D. Cal. Oct. 7, 2016), the only decision cited by Plaintiffs that found personal jurisdiction in an innovator-liability case. The court began its brief analysis by finding general jurisdiction over the out-of defendant based on the fact that the company was registered in California, had a California office and research center, and had often litigated in California courts. *See id.* at *2. That conclusion is clearly inconsistent with the Supreme Court's holding that even a "substantial, continuous, and systematic course of business" in the forum state does *not* make an out-of-state defendant subject to general jurisdiction. *Daimler AG v. Bauman*, 571 U.S. 117, 138 (2014). The court also found specific jurisdiction (in one sentence of analysis) because the plaintiff's doctor had relied on the label on the defendant's own product (a fact not alleged in this case), but the court did not grapple with the fact that any statements the defendant itself made in California were completely irrelevant to the innovator-liability theory. *See Quinn-White*, 2016 WL 11519285 at *2.

The Supreme Court held that the absence of but-for causation was not fatal, and that Minnesota and Montana could exercise specific jurisdiction over Ford because the company "had advertised, sold, and serviced those two car models in both States for many years." *Id*. at 1028. It did not matter that Ford happened to have sold the specific cars that injured the plaitiffs in others states, because Ford knew that its activities in Minnesota and Montana could give rise to the exact type of product-liability suits the plaintiffs had brought. Ford "enjoy[ed] the benefits and protection" of Minnesota and Montana law when it marketed and sold the Crown Victoria and Explorer in those states, and it incurred a "reciprocal obligation[ ]" to defend the safety of those vehicles in Minnesota and Montana courts. *Id*. at 1029-30 (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 319 (1945).

Here, GSK enjoyed the benefits of Nevada law when it marketed and sold Zantac in the state, and GSK incurred the reciprocal obligation to defend the safety of its products in Nevada courts. But when GSK marketed and sold Zantac in Nevada, it did not incur any obligation to defend the safety of its *competitors'* generic ranitidine. The only reason GSK could even arguably be held responsible for its competitors' products is that GSK controlled the label for generic ranitidine—but none of GSK's labeling decisions took place in Nevada. Because none of GSK's activities in Nevada have any relevance to innovator-liability or predecessor-liability claims, those claims must be dismissed for lack of personal jurisdiction.

B. Innovator Liability Is Incompatible with Nevada Law

1. Nevada Courts Adhere to the Traditional Tort Principle that a Manufacturer Is Liable Only for Injuries Caused by Its Own Products.

Every court to consider the question has concluded that Nevada law is consistent with "the overwhelming national consensus" that "a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product." *In re Zantac(Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1175, 1195 (S.D. Fla. 2020) (quoting *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013)). Contrary to Plaintiffs' suggestion, that overwhelming consensus is not restricted to states with "products liability statutes" that inhibit courts' ability to apply "traditional tort law principles." Opp. at 8. Courts reject innovator liability for precisely

the opposite reason—because "traditional common law tort principles" dictate that a manufacturer is liable for injuries caused by its own product[s]," not those of other companies. *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 865 (W. Va. 2018) (quoting *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013).

Plaintiffs have not cited a single Nevada case breaking with the traditional rule that a manufacturer is not liable for injuries allegedly caused by other companies' products. Plaintiffs attempt to cast doubt on the federal decisions rejecting innovator liability under Nevada law by trying to cabin the Nevada Supreme Court's statement in *Allison v. Merck & Co.*, 110 Nev. 762, 767 (1994), that a plaintiff must "establish that his injury was caused by a defect in the product, and that such defect existed when the product left the hands of the defendant" to the facts of that case. *See* Opp. at 10. But the principle that a plaintiff cannot sue a defendant for injuries caused by another company's products finds support in many other Nevada cases. For example, in *Sanchez ex rel. Sanchez v. Wal-Mart Stores, Inc.*, 125 Nev. 818 (2009), the Nevada Supreme Court held that a pharmacy did "not owe a duty of care" to third parties injured by a pharmacy customer driving under the influence of prescription drugs because the pharmacy had "no direct relationship" with the injured parties, who were "unidentifiable members of the public … unknown to the pharmacies." *Id*. at 821, 825; *see also DeBoer v. Sr. Bridges of Sparks Fam. Hosp.*, 128 Nev. 406, 410 n.3 (2012) (quoting *Sanchez* and observing that "in Nevada, there is no duty to protect a person from the harmful conduct of a third party unless … 'a special relationship exists between the parties or between the defendant and the identifiable victim.'").

Here, as in *Sanchez*, the decedent was an unidentifiable member of the public with whom GSK had no relationship. GSK thus owed no duty of care to the decedent, and had no legal responsibility to protect her from the allegedly harmful conduct of the third-party generic companies that manufactured and sold the ranitidine products that she purchased. Plaintiffs' innovator-liability claims therefore fail as a matter of law.

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2. Plaintiffs Cannot Bring Negligent Misrepresentation Claims Under an Innovator-Liability Theory.

As the federal courts have recognized, the Nevada Supreme Court's holding in *Dow Chemical Co. v. Mahlum*, 114 Nev. 1468, 1486 (1998) that "[t]he duty to disclose requires, at a minimum, some form of relationship between the parties" also supports the principle that manufacturers simply do not owe a duty of care to consumers of other companies' products. Plaintiffs argue that *Mahlum* is irrelevant because a duty to disclose is an element of a fraudulent concealment claim, and Plaintiffs' theory "sounds in negligence, not fraud." Opp. at 11. More specifically, Plaintiffs make clear elsewhere in their brief (as they did not in their complaint) that they conceive of their innovator-liability claims as "negligent misrepresentation claims." *Id*. at 7.

Negligent misrepresentation claims are still predicated on the existence of a duty of care, like all negligence claims, so they fail for the reasons given above. *See Sanchez*, 125 Nev. at 824 ("[T]o prevail on a negligence claim, a plaintiff must establish … the existence of a duty of care."). But Plaintiffs' negligent misrepresentation claim also fails for two independent reasons specific to that particular theory.

First, Plaintiffs have not stated a valid negligent misrepresentation claim because they have not alleged that GSK made affirmative misstatements, as opposed to omissions, on the label for Zantac. The Nevada Supreme Court has adopted section 552 of the Second Restatement of Torts, which provides that one who "supplies false information for the guidance of others in their business transactions is subject to liability for pecuniary loss." *See Reynolds v. Tufenkjian*, 136 Nev. 145, 152 (2020). Section 552 "by its own terms requires an affirmative misstatement, not just a non-disclosure." *McLachlan v. N.Y. Life Ins. Co.*, 488 F.3d 624, 630 (5th Cir. 2007). Nowhere in their complaint do the Plaintiffs identify a specific false statement in the label for Zantac and generic ranitidine products.

Second, the Nevada Supreme Court has "limited claims for negligent misrepresentation to only those claims resulting in pecuniary loss." *Reynolds v. Tufenkjian*, 136 Nev. 145, 152 (2020). "Given that negligent misrepresentation claims in Nevada only arise out of pecuniary

loss, it is clear that the nature of such a claim is not to recover for a personal injury, but instead is more akin to a claim seeking recovery for a loss of property." *Id*. Even if Plaintiffs' innovator-liability negligent misrepresentation claims were viable, then, Plaintiffs' potential recovery would be limited to the decedent's "out-of-pocket losses." *Id*. (quoting *Goodrich & Pennington Mortg. Fund v. J.R. Woolard, Inc.*, 120 Nev. 777, 782 (2004)). The Plaintiffs' demand for compensation for decedent's injuries and death would therefore be subject to dismissal.

C. Predecessor Liability Is Incompatible with Nevada Law

Plaintiffs claim that GSK's arguments against predecessor liability—according to which a brand-name company can be held liable for the generic product's label even *after* it has relinquished the NDA—are simply restatements of GSK's affirmative defenses of intervening or superseding cause. *See* Opp. at 7. Not so. GSK's argument is that, even if this Court breaks with the consensus and recognizes innovator liability, it should adopt the position of the dissent in *T.H. v. Novartis*, 407 P.3d 18 (Cal. 2017), and hold that a brand-name manufacturer's liability for injuries allegedly caused by the generic label necessarily ends when a new company acquires the NDA.

That result follows from the logic of innovator liability itself. As GSK explained in its opening brief, when a brand-name manufacturer transfers the NDA to a new company, it no longer controls the generic label. The successor company is the only one that can change the label, and by acquiring the NDA it "assumes the responsibility to update the warning label if and when reasonable evidence demonstrates a link to a serious health hazard." *Id*. at 50 (Corrigan, J., dissenting). Any innovator-liability claim should lie only against the company that was actually in a position to change the label that reached the generic consumer.

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IV. CONCLUSION

For the foregoing reasons, GSK respectfully requests the Court dismiss the claims against GSK for lack of personal jurisdiction or, in the alternative, for failure to state a claim.

DATED: April 13, 2022.

EVANS FEARS & SCHUTTERT LLP

/s/ Chad R. Fears

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CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I certify that I am an employee of EVANS FEARS & SCHUTTERT LLP, and that on the 13th day of April, 2022, I caused the foregoing document entitled **DEFENDANT GLAXOSMITHKLINE LLC'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FOR FAILURE TO STATE A CLAIM** to be served upon those persons designated by the parties in the E-Service Master List for the above-referenced matter in the Eighth Judicial District Court eFiling System in accordance with the mandatory electronic service requirements of Administrative Order 14-2 and the Nevada Electronic Filing and Conversion Rules.

/s/ Faith Radford
An Employee of Evans Fears & Schuttert LLP

Exhibit E
Hearing Transcript of April 20, 2022

Electronically Filed
5/4/2022 1:07 PM
Steven D. Grierson
CLERK OF THE COURT

RTRAN

DISTRICT COURT

CLARK COUNTY, NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as the legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor, Plaintiffs, vs. LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC.; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES I through X; and ROE CORPORATIONS XI through XX, inclusive, Defendants.	CASE#: A-21-835385-C DEPT. XV

Case Number: A-21-835385-C

BEFORE THE HONORABLE JOE HARDY
DISTRICT COURT JUDGE
WEDNESDAY, APRIL 20, 2022

RECORDER'S TRANSCRIPT OF MOTION HEARING

APPEARANCES:

For the Plaintiff:	MICHAEL C. KANE, ESQ. BRANDON BORN, ESQ. ADAM KRAUSE, ESQ. JONATHAN HILTON, ESQ.
For the Defendant Sanofi US Services and Chattem:	ERICA PIKE TURNER, ESQ. DANIEL PARISER, ESQ.
For the Defendant Boehringer Ingelheim Pharmaceuticals:	ANNEKE SHEPARD, ESQ. DAVID KOCH, ESQ.
For the Defendant GlaxoSmithKline:	JUSTIN HEPWORTH, ESQ. COLE CARTER, ESQ.
For the Defendant Las Vegas Medical Group:	SEAN M. KELLY, ESQ.

RECORDED BY: MATTHEW YARBROUGH, COURT RECORDER

Las Vegas, Nevada, Wednesday, April 20, 2022

[Case called at 11:21 a.m.]

THE MARSHAL: A-835385, Jasmin Husrom v. Las Vegas Medical Group LLC.

THE COURT: Let's go left to right, my left, state your appearances.

MR. KANE: Good morning, Your Honor. Michael Kane, and Brandon Born, on behalf of Plaintiffs, we also have two counsel appearing via BlueJeans who had not -- they are pending pro hac with the State bar, but have not formally filed it with the Court.

THE COURT: Okay. And who are they, just so we add them on.

MR. KANE: They can go ahead and state their appearances,

THE COURT: Okay.

MR. KANE: Your Honor, I appreciate it.

MR. KRAUSE: Adam Krause for the Plaintiff.

MR. HILTON: Jonathan Hilton from Hilton Parker, LLC, Ohio attorney bar number is 0095742, for Plaintiff.

THE COURT: Okay, good morning.

MS. TURNER: Good morning, Your Honor. Erika Pike Turner, of Garman Turner Gordon, on behalf of the Defendant, Sanofi US Services, Sanofi-Aventis U.S. LLC and Chattem, Inc. And I have with me Dan Pariser, we do have a motion to associate Mr. Pariser as counsel, on the calendar.

THE COURT: Yeah. So that's good. We actually have that motion, so thank you. And how do you say your name again?

MR. PARISER: It's Pariser, Your Honor.

THE COURT: Oh, I didn't mean to throw you under the bus, honestly, I just did. And say it again, I apologize.

MR. PARISER: Sure it's like the city of Paris with an "ER" at the Pariser

THE COURT: Pariser, okay.

MS. SHEPARD: Anneke Shepard on, on behalf of the Boehringer Ingelheim Defendant.

MR. KOCH: And David Koch for the same Boehringer Defendants. I think there's three of them, we just appeared this morning, so I don't know all of their names yet.

THE COURT: Okay.

MR. HEPWORTH: Good morning, Your Honor. Justin Hepworth from Evans Fears & Schuttert on behalf of Glaxosmithkline. With me is Cole Carter, he has a pending motion for proc hac vice application that we filed earlier this month, and we're hoping that we could advance that today; there have been no oppositions filed.

THE COURT: Okay. You all can sit down. If you can find a chair, or you're welcome to stay standing too. Let's do the pro hacs first. Mr. Pariser's motion set for today, I don't think there was any opposition; is that fair?

MS. TURNER: There was no opposition, Your Honor. And we filed a notice of non-opposition and attached an order. I have that

form of order with me today. I don't know your preference, if you want us to send it --

THE COURT: Electronic, yeah.

MS. PIKE: I'll submit it to Ms. Rivera.

THE COURT: That motion's granted for Mr. Pariser.

And, Mr. Carter, is there a hearing already pending, or do you know?

MR. CARTER: I can't remember if there was a hearing pending or not, Your Honor.

MS. SHEPARD: I think there maybe is.

MR. CARTER: I think there is.

THE COURT: Does anybody object to that?

MR. KANE: No, Your Honor. We don't object, with the caveat, obviously no objection. However, we would ask that Mr. Hendricks [phonetic] be able to, to argue one of the motions here today, via BlueJeans, who wrote the opposition and has prepared to do that, understanding, Your Honor, if he is the not allowed to, or if there's no stipulation reached by the parties here that that dance, then we're still ready to move forward.

THE COURT: Any response?

MS. TURNER: Your Honor, on behalf of the Sanofi Defendants, we don't have any opposition.

[Court and Clerk confer]

THE COURT: So does anybody object to, and I forget which attorney on Plaintiff's side was mentioned,

MR. KANE: Mr. Hilton --

THE COURT: Hilton.

MR. KANE: -- Your Honor.

THE COURT: Anybody object to him arguing?

MR. PARISER: No objection, Your Honor.

MR. KANE: For the Court's application for the Defense's education as well, he's going to be arguing specifically as in regards to the innovator of liability theories, brought up in the motion to dismiss by GSK.

THE COURT: So that sounds like potentially a lawyerly way of saying, are you splitting the argument?

MR. KANE: I'm going to address an argument that needs to be addressed prior to the innovator argument, and that's going to be addressed by Mr. Hilton.

THE COURT: So the answer to my question?

MR. KANE: Yes.

THE COURT: Yes.

MR. KANE: I'm sorry, Your Honor.

THE COURT: And I heard one Defense say no objection to him arguing today. Anybody else have any objection?

MS. SHEPARD: No objection.

THE COURT: Okay. On the pro hacs, just because this can come up sometimes as some of you may know, once you're pro hac'd into the case, including if you're arguing this morning pending a pro hac, I have jurisdiction over you as if you were admitted to practice in the

laws of the State Nevada, and that includes whether or not you withdraw as counsel in the cases, some of you may be aware; everybody understand that?

MR. KRAUSE: Yes, Your Honor.

MR. HILTON: Yes. Thank you, Your Honor.

THE COURT: Well, thank you. And --

MS. TURNER: And Your Honor, our proposed order includes the *Quinn* language.

THE COURT: Oh, good. Thank you. So on the pending ones, put that same language in your proposed orders, so that way everybody knows -- like maintain jurisdiction over attorneys that are pro hac, and -- okay.

So this might demonstrate some ignorance, but are there any other motions that are unopposed and/or mooted, that we should address before we get to the substantive motions?

MR. KANE: Not that I'm aware of, Your Honor.

MR. PARISER: No, Your Honor.

THE COURT: Okay,

MR. KRAUSE: Your Hour, this is Adam Krause for the Plaintiff. I don't anticipate arguing today, but my pro hac is also pending. I don't know if anyone has a problem with me arguing, but I don't anticipate arguing, but I am here on BlueJeans, in the background, as well for the Plaintiff. But I just wanted to give you a heads up, I don't anticipate speaking, but I wanted to bring that to the Court's attention.

THE COURT: Okay. Okay. Thank you. Bear with me a

minute. So I think we have a motion to sever by the Brand Defendants, a motion to dismiss and/or strike by the Brand Defendants. And if I can just call them JSK's motion to dismiss; are there any other motions pending? Good.

MR. KANE: No, Your Honor, you're done.

THE COURT: Okay. Let's do the, and this is unusual for me because I reviewed them in a different order, but let's do the Brand Defendant's motions first, and then JSK's after those. Do Brand Defendants have a preference between their two motions.

MR. PARISER: If you don't mind, Your Honor, I'd like to start with the motion sever.

THE COURT: Okay. Bear with me.

And I guess there is a joinder. So if I forget if there's any parties filed a joinder to any of the motions try and chime in before we turn it over to the other side, if the joining party wants to add anything. Then, Mr. Pariser, go ahead.

MR. PARISER: Thank you, Your Honor. May I approach the Podium, or do you prefer that I --

THE COURT: Yeah.

MR. PARISER: -- argue from counsel table.

THE COURT: -- that's a great question. Either the table or podium is fine by me. So whatever works better for you is fine.

MR. PARISER: Thank you, Your Honor. I appreciate that. And, again, it's Daniel Pariser, representing the Sanofi Defendants, but also arguing on behalf of the Brand Defendants for purposes of this

motion.

So, Your Honor, I'd like to just start off with framing briefly the legal standard, and in particular, Your Honor, bringing the Court's attention to a recent Nevada Supreme Court case, which is cited in our papers, but there's not much elaboration. So I think it's just worth a moment of the Court's attention. And that's the *A Cab, LLC* case, *A Cab v. Murray*, 501 P.3d 961, came out in December of 2021.

I do happen to have a copy of the opinion if it would be helpful for the Court to pass it up, but obviously only if the Court thinks that would be helpful.

THE COURT: No. If you have a printed copy that would be great.

MR. PARISER: Certainly Your Honor,

THE COURT: And show it to the other side, just in case.

MR. PARISER: May I approach?

THE COURT: Yes. Thank you. Thank you.

MR. PARISER: Thank You, Your Honor.

So I think that this case is noteworthy for few reasons. First of all, it is, as the case itself, acknowledges the first authority from the Nevada Supreme Court, articulating the basics of the standard for joinder and severance in this State, and what the Court does, and this is on page 973 to 974, is adopt a Federal standard out of this Sixth Circuit called the "Parchment" factors" and it lists out five factors there.

Two of them are the familiar factors that we see from the language of Rule 20 itself, which require common issues of law and

fact -- or fact rather, and the other is a common transaction or series of transaction or occurrences. But the standard also includes a number of what I will characterize as "discretionary factors," including serving the interests of judicial economy, and if you look at factor Number 5 it's whether different witnesses and documentary proof are required for separate claims, and I think those discretionary factors, so to speak, are going to be important in deciding this motion.

The other thing I'd just like to highlight about this case is really the holding, it's pretty unusual. This is a case alleging wage and hour violations against a taxicab company, and the principal of the company is also named. So obviously in that sort of situation, you have an overlap of common issues. You certainly have the same transaction or occurrence, and yet the Nevada Supreme Court affirmed the Court's decision to sever the case in its discretion, to further the interests of judicial economy.

So I just think that this case is important to emphasize the discretion that the Court has in that regard, whether or not, and I know the parties disagree on that, but whether or not there are in fact common issues of law in fact, or claims that arise from the same transaction or series of transactions.

So with the *A Cab* case in mind, and those factors in mind, I want to turn to case at hand, and I want to start Your Honor with the issue of sort of separate versus overlapping evidence if you will, which is the fifth Parchman Factor, because I think that's very telling in this case. And in particular, Your Honor, here, we have a complex drug product

liability set of claims, which involves significant evidence that has no commonality or overlap whatsoever with the medical malpractice claims in this case; and I'd just like to unpack that for a minute or two.

So we have a number of Brand Defendants that are included here, and that's a little unusual because this drug, Ranitidine, has changed hand over the years and different defendants held the marketing authorization rights. So GSK developed the drug and held the rights to the prescription form of the product, Boehringer Ingelheim held over-the-counter rights for 2016, which was the first year the Plaintiff alleges use, my client, Sanofi, then took over the over-the-counter rights.

So in order to prove their case, the Plaintiffs essentially have to put in liability cases against all of those Defendants, which is going to involve presumably liability experts, certainly documentary proof, company witnesses, none of which is going to be in common with the medical malpractice claims.

That's just the beginning though, because then they also have to prove medical causation, and if you break that down further in a drug product liability case like this, that's quite a bit of evidence. First, you have the question of general causation. Van Ranitidine even in the abstract cause cancer, and that's going to require expert testimony, review of epidemiology and the like; none of which is common to the medical malpractice case.

They're also going to have to prove specific causation, even assuming in the abstract, the drug can cause cancer, did it cause the decedent's cancer, and that is also going to require expert evidence and

proof. For instance, we know from the complaint that the Plaintiff suffered from dysplasia of the esophagus, which is essentially a pre-cancerous condition caused by gastro esophageal reflux, and presumably that's -- there's going to be a question of whether that is what really caused her cancer, again, involving medical expert testimony, not going to be common to the medical malpractice case.

And with regard to the legal issues, there's no commonality at all, really. For example, the threshold issue of preemption, that's going to be product liability, legal defense, not going to be a product -- not going to be a defense for the medical malpractice claim.

So when you, when you look at *A Cab* in particular and the discretion the Court has, and the amount of overlapping evidence in that case, clearly here, that Parchman Factor strongly favors severing the claims.

So next, Your Honor, I want to turn to this sort of judicial efficiency and economy prong. And I think the key point here is that there is already a Federal multidistrict litigation addressing product liability claims arising from Ranitidine use and claims of cancer. And if severance is granted, the Defendants will remove the product liability case to Federal Court, it'll get transferred to the MDL. And that MDL, which is in the Southern District of Florida, its very purpose is to effectuate efficiencies by coordinating pretrial discovery of similar claims; that's why it's there.

And so Judge Rosenberg who presides over that proceeding, she's handled document discovery with millions of pages of documents

produced, overseeing deposition discovery. If you just look at the Brand Defendants, over 70 depositions have been taken, in the aggregate of the Brand Defendants who are named in this case, and she has already ruled on for threshold preemption motions and can handle further motions down the road.

So clearly, Your Honor, from our perspective, that enhances judicial economy, it respectfully will save this Court work, it will certainly save the Defendants having to do duplicative discovery, potentially be subject to inconsistent rulings. And although the Plaintiffs don't see it that way, I would submit it also will serve the serve the Plaintiffs' interest in efficiency because they can rely --

THE COURT: I have a sneaky suspicion they will --

MR. PARISER: I --

THE COURT: -- disagree as you stated, but --

MR. PARISER: I imagine they will. But I think it's important to point out that counsel who has just associated today already has cases in the MDL. Based on my count they've got 24 cases already in the MDL, so I feel like the prejudice argument may be -- I understand their position --

THE COURT: Overstated.

MR. PARISER: Perhaps, Your Honor.

THE COURT: Okay.

MR. PARISER: So with regard to both of those Parchman factors, I think the question is clear. Now I want to turn to the Parchman factor about whether these claims arise from the same transaction, or

occurrence of a series of transaction or occurrences. The Plaintiffs rely very heavily on some case law, including an opinion by Magistrate Judge Koppe from the Federal Court, which also cites a few different cases.

But those cases also recognize there's a completely different line of authority, which we cite in our papers. And Your Honor, I just think that this inquiry there's no -- there's no magic line, it's really largely in the Court's discretion and the Court can choose which cases to follow. I think the *A Cab* decision says the Court has discretion to do what it wants.

The thing that I point out to the Court in particular is that the cases the Plaintiffs rely on are much simpler. They largely involve successive car accidents, or slip and falls, I think that there's an industrial accident or two, but they don't involve facts such as you have here, with a large MDL with complex product liability claims. And they don't certainly involve cases involving multiple defendants and a drug that's been on the market for decades. So I do think that the better line of cases to follow here are the line of cases we cite involving MDL claims.

And then finally, Your Honor, and then I'll be happy to answer any questions or turn over the floor. With regard to Plaintiffs' argument that they're going to be prejudiced by sort of the trying the empty chair problem, I just don't think that that holds water because in a sense, if the cases are severed, they get two bites at the apple, because under Nevada Law you can't allocate fault to non-parties, so they can essentially potentially obtain full recovery from either trial.

And in fact, Your Honor, the *A Cab* case acknowledges exactly that; this is on page 974. What the Court says is:

"Most prominently, the District Court sought to facilitate settlement and judicial economy by severing the alter ego claims, particularly because if the drivers collected the full amount of their judgment against the corporate defendants, there would be no need to proceed with the claims against *Nady*,"

who was the individual defendant. So I don't think that objection suffices to avoid severance.

And, Your Honor, that's all I have for now unless the Court has questions.

THE COURT: No questions. Thank you very much.

MR. PARISER: Thank you.

THE COURT: I can't -- okay, go ahead.

MR. BORN: Good morning, Your Honor, Brandon Born on behalf of Plaintiffs.

THE COURT: Good morning.

MR. BORN: Defendants appear to argue that the existence, the very existence of the MDL completely overrides any standards that are, are set forth in Rule 20. They cited *Coughlin*, a Ninth Circuit case had said the Court may sever if [indiscernible] is not satisfied. The motion very specifically hones in on Rule 20, and like wants to claim that there's no similar transaction occurrence or series of occurrences.

Here, the Plaintiffs filed suit against the medical Defendants

and Zantac Defendants, alleging they are successive tortfeasors contributing to the same ultimate injury. The same, a series of occurrences contributed to Ms. Husrom's death from esophageal cancer. The majority approach, which has been applied before in the *Gonzales* case in 2014, to evaluate proper joinder, find its proper where alleged successive tortfeasors contributed to the same injury; and that is exactly what's alleged in the second amended complaint.

Specifically this majority approach was adopted and applied Nevada and Federal Courts in *Gonzales v. Walmart*. They found conclusions reached in cases applying majority rule are consistent with the Rule 20's liberal application which is mirrored by an RCP 20.

Further, *Gonzales* rejected the requirement for the common basis of liability between claims, as successive tortfeasors. So the necessary prima facie elements to prove a medical malpractice case vs. a products liability case do not actually override the fact that there is a series of occurrences committed by successive tortfeasors that committed, that caused Ms. Husrom to suffer the ultimate injury of death from esophageal cancer.

The, the majority approach actually arose out of a medical -- a product liability vs. medical malpractice, subsequent medical malpractice case, and that's Williams -- Wilson v. Famatex.

The majority approach has been applied to premise liability in a successive motor vehicle collision, which requires different facts to prove negligence on those claims, so it's not dispositive that the basis for liability are different.

Instead the same transaction occurrence or series of occurrence tests focuses on related activities and similarity in factual background. And Gonzales says, "The rule is satisfied where the injuries from successive tortfeasors are to the same area of the body," which we have alleged here is Ms. Husrom's esophagus.

It's satisfied where the first injury is aggravated by the second tortfeasor, which is exactly what the Plaintiffs allege, that the medical malpractice failure to diagnose and failure to treat her esophageal cancer aggravated the underlying esophageal cancer that was caused by her consumption of Zantac.

There's a consideration of proximity and time, and here we have alleged forth in the complaint that the claims are intertwined because of proximity. Ms. Husrom took Zantac as set forth in the complaint from November 2016 through September 2019, and her treatment with Dr. Jahangir began in July of 2019. So there's significant overlap of the time when she was taking Zantac and when she began treatment, which ultimately the medical malpractice claim is premised upon

The Court's indulge, Your Honor.

THE COURT: Sure, sure.

[Counsel confer]

MR. BORN: And going towards the judicial economy, and there was a discussion of *A Cab* with the witnesses, Dr. Jahangir would have to be necessarily called as a witness, both in the Nevada case and the Southern District of Florida case, should the claims be severed?

The ultimate injury is, is the same. It's alleged that excessive tortfeasors contributed to her death from esophageal cancer, and there's just no way to sever that from the series of occurrences, and when the injuries actually occurred. Again, there is a common question of law and common questions of fact. The common question of law ultimately and specifically has been addressed by Defendants of the empty chair defense, and their position is premised on a motion in limine trial order from *Bard*, which ultimately states that there's no -- yeah. *Phillips v. C.R. Bard* goes to say --

THE COURT: Let me pause you on that, because I don't remember -- I mean, there was a lot of stuff. Where should I be looking, because that case doesn't ring a bell?

MR. BORN: I know it's addressed at the end of their reply.

THE COURT: Okay.

MR. BORN: In discussing the judicial economy.

THE COURT: Okay. Bear with me a minute.

MR. BORN: And this is what the contention of no empty chair --

THE COURT: So hold on one second. I'm trying to find --

MR. BORN: Page 6, Your Honor --

THE COURT: Okay. Of their request?

MR. BORN: The second full paragraph.

THE COURT: Pause for a moment.

[Pause]

THE COURT: Okay. Go ahead.

MR. BORN: And so this is in -- this citation is in response to Plaintiffs' citation of *Banks v. Sunrise Hospital*, their opposition, in which it sets forth that the empty chair defense is permitted in Nevada, specifically in a medical malpractice case, finding that a party may -- the jury on the verdict form may apportion percentages to non-parties, and also that they can find a non-party completely responsible and completely liable for the ultimate condition.

And so here that's the prejudice that Plaintiffs will suffer, should the cases be severed, and they proceed through separate trials, where the medical Defendants can essentially say the fault -- the cause of her death was actually the esophageal cancer, and there's nothing I could have done to have treated timely. And going to the multi-district litigation and them saying, well, she would have -- she wouldn't have died if not for the treatment, the failure to treat from the medical malpractice defendants.

So ultimately severing the case, permits an empty chair defense in both forums, that the Plaintiffs would have to overcome. And that's set forth in the *Sunrise v. Bank's* case that we have set forth in our opposition that was not acknowledged in the reply.

So ultimately that is the similar question of law, and the law states for this similar question of law or fact that there only needs to be one commonality, and the one commonality is going to be that the apportionment of liability, and that's especially important in this case because the medical Defendants have already raised their 11 affirmative defense in their answer, which indicates their intention to argue that

Plaintiffs' injuries and damages were caused in whole, or in part by other parties; who in this case would be the Zantac Defendants.

There are also common issues of fact where it relates to whether or not she has pre-existing conditions, which ultimately would be raised by both Defendants likely at trial. Further the examination of judicial efficiency and fundamental fairness, which is part of the analysis of whether or not cases should be severed.

The Defendants advanced the argument that the mere existence of the MDL for Zantac-related lawsuits is dispositive. Severance would force Plaintiffs, and it's important to note who the parties are in this case. In this case, the Plaintiffs are Ms. Husrom's surviving husband, and her surviving four minor children. The Defendants are pharmaceutical companies with much greater resources than the Plaintiffs in this matter.

THE COURT: And the Brand Defendants, right?

MR. BORN: Correct.

If forcing two separate cases would duplicate evidence and testimony, especially where it comes to the children being deposed for the grief and sorrow for the loss of their mother, the father being deposed for the loss of -- grief and sorrow for, in consortium, for the loss of Ms. Husrom. Potentially severance may deprive Plaintiffs of the full recovery as highlighted by the -- for the previous argument regarding the empty chair defense.

The MDL is essentially a foster system for cases that to be consolidated, with commonalities, and there's no timeline that has been

set forth. The medical malpractice case would very likely be decided on, well prior to the trial ever being heard in the MDL. Ms. Husrom's case doesn't fit the mold for the MDL, and as there is a claim for successive tortfeasors, with the MDL, it should be limited to just claims against Zantac.

THE COURT: Well, thank you very much.

MR. BORN: The Court's indulgence.

THE COURT: Sure.

[Counsel confer]

MR. BORN: And, further every medical treater, every medical provider for Ms. Husrom prior to her untimely passing would have to be deposed twice in both litigations, would have to testify twice at trial. Essentially discovery would be duplicated for her own medical providers as to the causation of her death in two separate forums across the country, which would greatly put the cost on Plaintiff and her surviving family to fund the litigation in two separate forums.

THE COURT: Okay. So that -- thank you.

The last portion about discovery. I mean, I'll ask both sides probably the same type of question. I mean, in terms of duplicating discovery, both sides have brought that up, but isn't it fair to say that either the parties could stipulate or the Court could order if you can't stipulate, you know, a deposition, for example the other side, said, oh, you know, all these depositions have already been taken.

And you're saying, well, the providers would need to be deposed twice, couldn't that be addressed by an order of stipulation on

both sides? Does that question make sense? You look like you want to answer it --

MR. KANE: Yes --

THE COURT: And if so that's okay.

MR. PARISER: -- Your Honor. It could be obviously taken care of pursuant to a stipulation. The problem is -- you run into, is you take the deposition one time, if you're a defendant foreseeably, and then another attorney takes a look at, he forgot to ask X, Y, and Z. We get another bite at the apple then going to do that. I mean, that's going to be taken advantage of a hundred percent without a court order.

But Your Honor is correct in the sense that if there is a court order that we will use depositions without duplicative discovery, then it makes sense to stay right here in Clark County where Ms. Husrom died and not make the family fly in a litigated case in the Southern District of Florida for 10 to 30 days outside of their home while grieving their death of their wife and mother.

So, yes, Your Honor, it is correct in that sense.

THE COURT: Thank you. Thank you.

And Mr. Pariser, any rebuttal?

MR. PARISER: Yes, Your Honor.

First to address the Court's last point, in no way would the family members be required to fly to Florida, the depositions could certainly be done and are typically done where they're located, and even trial wouldn't happen in Florida, the case at the end of coordinating discovery would be remanded back to the District of Nevada for trial.

But certainly, Your Honor, we don't want to do duplicative work that we don't need to, I'm sure we can work with counsel or Plaintiffs to try to coordinate. I think my overall point is not that there's no commonality between the cases, but that the differences vastly overwhelm the commonality. So you're, you're talking about, you know, a lengthy trial about which very little evidence is in common to the different sets of claims.

And then just briefly, Your Honor, on the point about the trying the empty chair, I know we didn't cite it for that proposition in our papers, and for that, I apologize, but the *A Cab* case, which I read to the Court during my opening remarks, I think fully addresses that concern. And I just add that at least as I understood Plaintiffs' counsel articulate what their worry is about trying the empty chair, it wasn't a situation where one party would try to completely blame the other party for the full extent of the Plaintiffs' damages.

For instance, I don't see how the Brand Defendants could say that negligence and the part of the medical providers caused the decedent's cancer. So I don't think that that concern is frankly a real one. And unless Your Honor has questions, that's all I have.

THE COURT: No questions. Thank you very much.

MR. PARISER: Thank you.

THE COURT: The Court's going to deny without prejudice, both the motion and any accompanying joinders for all the reasons in the opposition, but to be more focused, I guess, under you know, the NRCP 20 (a) as well as NRCP 21, the cases that the Court most focused

on the *Cummings*' case, the *Gonzales*'case, the *Wilson* case candidly did not focus so much on *A Cab* until argument, but definitely on *A Cab*, given that it goes through the factors which the Court should definitely consider. And the Court does have discretion, and Mr. Warren, you're going to prepare the order, somebody from your office prepare it and submit to everybody else for review and approval.

Put my reasons in there, incorporate your arguments and the Court's reasons, but also again, more specifically the Court looked at 20(a) and 21, the *Cummings*' case, *Gonzales*, *Wilson*, *A Cab*. There are you know -- it's a totality of the circumstances under the Court's discretion analysis, and may as a discretion, it's not a shall type of thing, but the claims the medical malpractice versus the product liability claims, do, you know -- the Court acknowledges and put this in the order, they are not 100 percent the same transaction or occurrence that, I'll acknowledge that. But they do generally rise you know, out of the same type of occurrence, which as Plaintiff pointed out, I did write down, but the ultimate issue is the death of decedent. How do you say his last name, Husrom? Husrom, okay.

MR. KANE: Husrom.

THE COURT: Okay. There definitely some common questions of law or fact you know, and I'm quoting some that's in the *A Cab* case itself, it doesn't say, you know, all questions have to be in common, says some, and there are clearly some here.

Settlement of the claims and judicial economy, I appreciate Defendants' argument to understand it, but respectfully disagree that

that factor -- all the factors do overall support denial at least at this early stage of the motion, you know, trying one case versus two cases generally that's economical.

Whether prejudice would be avoided if severance were granted, you know, a lot of these factors do cut both ways, I'll acknowledge that, including this one. But it seems to me that the totality of the circumstances, again, is best served, keeping the cases together here. And that factor, whether prejudice would be avoided if severance were granted could favor, and put this in the could favor severance, but the other factors do not.

Whether different witnesses and documentary proof are required for separate claims, some are some are not, many of the important ones in terms of Plaintiff's claims, both on the medical malpractice claim and the product liability claims are the same witnesses and evidences. Plaintiff points out if there's a preexisting issue, that's going to come up in both cases. If there are damages allegedly caused by other parties, whether it's, you know, the brand or the GSK Defendant pointing fingers at the medical malpractice defendant or vice versa, to have them all in the same trial serves judicial economy and cuts against severing as requested.

Discovery already performed in the MDO presumably, it could -- emphasis on both those words -- be used in this case. And there are all sorts of remedies that we can fashion to avoid duplication, if needed. Additionally, the Court notes that we do presume that jurors will follow instructions given. And there's another potential remedy to

any potential confusion, et cetera. It would be through jury instructions and the like.

So put all the reasons in there. Make it detailed. Submit it to everyone else for review.

MR. KANE: Yes, Your Honor.

THE COURT: Next up, Brand Defendants -- bear with me a moment. You know, it might make more sense to hear GSK's motion because -- and again, as you may have heard, I don't have a law clerk. So I'm reading everything, which I did anyway, but without the assistance of a law clerk. But there's a large portion of -- or at least a portion of Brand Defendants based on the same arguments in GSK.

MR. PARISER: Your Honor, from our perspective, it would make sense for the GSK motion to go first --

THE COURT: Okay.

MR. PARISER: -- principally, because it's a threshold jurisdictional question.

THE COURT: Yeah. Thank you. Let's do that.

So GSK's motion to dismiss for lack of personal jurisdiction and failure to state claim. I've reviewed that, Plaintiff's opposition, Defendant's reply. Remind me of your name again.

MR. CARTER: Thank you, Your Honor. Cole Carter for GSK.

THE COURT: Oh, Mr. Carter. Okay. Thank you. Go ahead.

MR. CARTER: So the arguments contained in GSK's motion to dismiss all stem from one feature of this litigation, which is that the Plaintiffs are attempting to hold GSK liable for injuries that were

allegedly caused by products that were made and sold by other companies. In fact, GSK had not sold over-the-counter Zantac for 18 years by the time that the Decedent began using the product in 2016.

So the -- the Plaintiffs are proceeding under a very broad theory of innovator liability that's only been adopted with the breath advocated for by the Plaintiffs by one court in the country. And that theory is not viable in Nevada for three independent reasons.

The first, which is a threshold issue, is that there -- a Nevada state court does not -- or -- or federal court does not have personal jurisdiction over GSK to adjudicate innovator liability claims, to adjudicate claims based on injuries that were caused by other companies' products. We -- of course there are two types of personal jurisdiction, general and specific. I'll agree there's no general jurisdiction here. GSK is not a Nevada company. So personal jurisdiction can only be appropriate if there's specific jurisdiction over GSK, which requires that the claims arise out of or relate to GSK's contacts with the State of Nevada. And nothing that GSK has ever done in Nevada, relates to the Plaintiffs' innovator liability claims.

The sole basis for the innovator liability theory is that by federal law, a generic label is required to copy the brand name label, so the theory goes. The brand name defendant effectively controls the contents of the generic label and can be held responsible for any deficiencies in the generic label. That's the theory. So on that theory, the only actions by the brand name company that are affecting -- that are harming and affecting the Plaintiff, the actions that bring them within the

scope of an innovator liability claim are labeling decisions, are actions that affect that label that the generic consumer is ultimately going to review and rely upon. And the Plaintiffs do not allege and cannot allege that GSK made any labeling decisions in the State of Nevada. What they can allege is that GSK marketed and sold its own products many years ago in Nevada. But those alleged misrepresentations and marketing and on the label of GSK manufactured Zantac have nothing at all to do with the innovator liability theory.

And the MDL court in Florida looked at this issue in great detail. It canvassed innovator liability case law. It applied the Supreme Court's recent personal jurisdiction decision in *Ford*. And it concluded that the only actions that relate to an innovator liability claim are those labeling decisions. And alleged misrepresentations in the forum state with respect to a brand defendant's own products are simply irrelevant.

And to put the finest possible point on this, if GSK had --

THE COURT: Let me pause you. Is this the In Re: Zantac --

MR. CARTER: Yes.

THE COURT: -- 510(3)(d) 1175?

MR. CARTER: That's correct, Your Honor.

THE COURT: Okay. Thanks.

MR. CARTER: Just to -- to put the finest possible point on this, if GSK had never sold Zantac in Nevada, if it had never marketed Zantac in Nevada, under Plaintiff's theory they would still have an innovator liability claim against GSK because as long as GSK had at some point controlled the label for Zantac, and then some other

company made the decision to sell generic ranitidine, or according to their even broader theory, a later version of over-the-counter Zantac, GSK would be liable for that other company's sales in Nevada purely because of labeling decisions that GSK had made years in the past. So the -- the -- GSK's exposure to innovator liability claims in the State of Nevada is entirely in third parties' hands.

And the Supreme Court has made clear repeatedly that third parties actions cannot subject a defendant to personal jurisdiction because there has to be a quid pro quo between an out-of-state defendant that decides to business in the state. And then it accepts a reciprocal obligation to defend itself in relation to that business. And if it's true that GSK could have never sold Zantac in the State of Nevada, yet Plaintiffs would still have innovator liability claims against GSK, then as the -- as the MDL court put it, if this relatedness requirement means anything -- excuse me, if that were true, the relatedness requirement would not mean anything. If it means anything, it has to mean that actions that bear no legal -- or have no legal bearing on the theory that's asserted, those actions do not relate to the claims at issue.

THE COURT: I think I understand what you're arguing. But in terms of your argument of hey, under Plaintiffs' theory, you know, hypothetically speaking I think is what you're saying is GSK could have never marketed or sold Zantac in Nevada, and yet still be potentially subject -- still be subject to jurisdiction in Nevada. And that can't be the case. But I mean, that hypothetical isn't what's happened, right, because GSK did -- I mean, at least at this early stage, you know, when I'm under

a motion to dismiss, I have to assume, you know, like that GSK did market and sell Zantac in Nevada, right?

MR. CARTER: Correct. Correct, Your Honor.

THE COURT: Okay.

MR. CARTER: So the -- the point of the hypothetical is to illustrate that the sale of Zantac by GSK in Nevada does not relate to the innovator liability claims. That's -- that's the test for specific jurisdiction. And the innovator liability theory depends -- it's just to illustrate the point that the only thing that -- that matters from innovator liability theory is the defendant's control of the label.

THE COURT: Uh-huh.

MR. CARTER: So in a world where GSK never sells Zantac in Nevada, but then some other company decides to sell Zantac in Nevada, the innovator liability theory, it's -- it's still valid if -- you know, we of course have objections to it. But on its own terms, it doesn't matter that -- two -- two of those claims -- those innovator liability claims, it makes no difference whatsoever that GSK never sold its product in Nevada. So what the hypothetical does is show that actions that GSK took with respect to its own products in Nevada many years ago have no relation -- do not relate to in any way the Plaintiffs' innovator liability claims.

And as the MDL court said after looking at all -- all of the case law and applying forward, if this relate to requirement has any meaning at all, it has to mean that completely irrelevant actions -- irrelevant that is under the -- the legal theory the Plaintiffs themselves are asserting -- that

they have chosen to assert, completely irrelevant actions cannot be a basis for specific jurisdiction. So unless Your Honor has more questions on the personal jurisdiction issue, I'll move on to the merits.

THE COURT: Yeah. Go ahead. Thank you very much.

MR. CARTER: So with respect to innovator liability -- and you know, of course we make this distinction in our briefs, which is really just for convenience sake between innovator liability and predecessor liability, which we see as an extension of innovator liability. But I want to focus here just on the core of the theory on -- on innovator liability. And three federal courts have now addressed this issue. Two in Nevada, one was the MDL court in Florida. And we think they've gotten this right. And the *Moretti* opinion in 2009 by Judge Mann, in particular, I think contains everything -- almost everything that's needed to -- to dispose of the issue.

There are sort of two fundamental reasons as I see it why innovator liability on the merits is not a viable theory in Nevada. The first is a sort of fundamental barrier to the theory. And that's that a manufacturer simply does not owe any duty of care to its customers competitors. This is clear. It's stated -- it has a fairly clear statement in the *Allison* Supreme Court case that the parties discuss in their briefs. But that -- that conclusion also follows from the general duty of care test that the Nevada Supreme Court annunciated in the *Sanchez* case, which we cite in our reply. And what that case says is that a defendant does not owe a duty of care -- or excuse me, does not have a duty to prevent a third party -- to prevent harm caused by a third party if the defendant

doesn't have a relationship with the plaintiffs who are being injured by that third party.

And that's precisely the situation we have here. The Plaintiffs are alleging that products that generic or other brand manufacturers sold to the Decedent injured the Decedent. And GSK is just a completely unrelated third party with respect to the Decedent. GSK had no relationship with her at all. So that's sort of the fundamental objection to innovator liability. There just is no duty of care that GSK owes to someone with whom it had no relationship and who was a customer of its competitors.

The -- the second set of problems relates to the specific claim that Plaintiffs have chosen to fit their innovator liability theory into, which as they say in their opposition is negligent misrepresentation. So there's just a baseline black letter law problem with that which is that you cannot bring a negligent misrepresentation claim in Nevada to recover for personal injuries. The Nevada Supreme Court has made that clear many times in the *Reynolds* case we cite in our reply and in many other decisions that are cited in that case. So this case just falls out of the gate on a negligent misrepresentation theory because negligent misrepresentation can -- you can only recover for pecuniary damages incurred in a business transaction.

The second problem, although that would of course be enough on its own, is that negligent misrepresentation requires an affirmative misstatement. And what's alleged here is an omission, a failure to include certain information about risks on the label for Zantac.

So there -- there are two specific problems with negligent misrepresentation, both of which are fatal even if you get past this sort of fundamental tort principal that a manufacturer just does not owe a duty of care to its customers and competitors with whom it has no relationship.

And so just very briefly, our final point is even if the Court disagreed about personal jurisdiction and decided that Nevada would in fact recognize -- the Nevada Supreme Court would in fact recognize innovator liability, it shouldn't take the further step, which is necessary to hold GSK liable in this case, to recognize what the dissent in the *T.H. v. Novartis* case the California Supreme Court described as predecessor liability.

And this -- what -- what predecessor liability is is holding a brand name defendant liable potentially in perpetuity even after it has divested the rights to the drug and transferred them to a new company, which may have transferred to another company and another company, as happened here. And as soon as it divests itself of the rights, the brand name defendant no longer has any ability to change the label that the Plaintiff is complaining about.

And if innovator liability has any justification, it's that the company that actually sells the product that allegedly harmed the Plaintiff couldn't make the change that the Plaintiff wanted to see in the label and that the brand name company was the only company in a position to do that. But that's only true when the brand name company actually has what's called the NDA, when it has the ability to go through

this regulatory process and potentially make a change to the label. Once that's taken away, there's no justification for innovator liability. The brand name defendant can't do what the plaintiff would have wanted to see it to do. It couldn't have created the label that the brand name -- that the Plaintiff claims would have complied with state law.

THE COURT: So then on that, what you're saying is -- and definitely correct me if I'm wrong -- that like in this case, GSK assigns its right to another company, which assigns so on and so forth. And then we get to a point in time where Plaintiff takes, you know, whatever version of -- say a generic version of -- or my way of personally calling it, GSK once those rights -- once it no longer has those rights can't even quote on quote fix what Plaintiff's complaining of. Is that --

MR. CARTER: That's exactly right, Your Honor.

THE COURT: Okay.

MR. CARTER: And if there's -- if there's any innovator liability claim, it should be only against the brand name defendant that actually had the ability to change the label at the time, and indeed the duty under Nevada law to change the label at the time the Plaintiff actually consumed the product. That would be the innovator -- of course, we don't think there should be an innovator liability remedy at all for the reasons discussed. But if there were to be one on the terms of the theory itself, it should only lie against the company that actually had the ability to make that change. So unless the Court has further questions --

THE COURT: No. Thank you very much.

MR. KANE: Thank you, Your Honor. I'm going to address the allegations set forth in the claim. And then my colleague, Mr. Hilton, is going to address the -- the arguments made by counsel regarding the innovator liability. And Your Honor, I'm focusing to begin --

THE COURT: So let me pause you. Maybe ask first if -- if you can tag team.

MR. KANE: Oh, Your Honor, can we -- can we split the argument as -- as I just requested.

THE COURT: Is there any objection?

MR. CARTER: No, Your Honor.

THE COURT: Okay. Go ahead.

MR. KANE: Thank you, Your Honor. And I apologize for that.

THE COURT: That -- no, that's okay.

MR. KANE: And Your Honor, I left the copy of the complaint on my desk when I was walking over here and so I'm looking at my phone. I don't want you to think I'm texting or emailing right in front of Your Honor.

THE COURT: We'll see how good your eyes are.

MR. KANE: So Your Honor, based on our second amended complaints --

THE COURT: Bear -- let me pull it up too while we're referring to it. What date was it filed, if you can see?

MR. KANE: 2/11/22.

THE COURT: And Your Honor, I'm going to start with paragraph number 11 on page 3.

MR. KANE: And Your Honor, I'm going to start with paragraph number 11 on page 3.

THE COURT: Okay.

MR. KANE: It says,

"Based on the information and belief that all times relevant hereto Defendant, GSK, is a Delaware liability corporation at all times relevant hereto GSK manufactured and distributed in the United States, Zantac, a drug used to treat gastroesophageal reflux disease."

Paragraph 12,

"Since 1983, Defendants, GSK, LLC, and GSK, collectively GSK and its predecessors, have controlled the prescription Zantac new drug application. The causes of action set forth against all Zantac defendants, including Sanofi and GSK are causes of action as set forth in the body of the complaint for products liability, negligence, and the others."

Your Honor, based on the face of the complaint, the allegations are the GSK did produce, design, manufacture, sell the exact Zantac that Ms. Husrom ingested during the course of the three years that she did ingest it, both generic and branded, as set forth in the complaint. Defendants know in Nevada, when dealing with personal jurisdiction issues, affidavits may be attached even at the early stages of a motion to dismiss. There is no affidavits attached. Therefore, there is no factual disagreement set forth other than representations that are outside of the pleadings by counsel and cannot be taken into

consideration, certainly not without an affidavit. I don't even think we get to this argument quite frankly, Your Honor, based on the pleadings of innovator liability, which I guess it's not specifically laid out as a cause of action, nor is there any language specific to innovative or predecessor liability in that complaint.

And so based on the pleadings as set forth in the second amended complaint and the devoid of any affidavits, either for personal jurisdiction or innovator liability or to dispute the factual allegations set forth in our complaint, we believe that the motion has to be denied at this stage.

THE COURT: So your argument is essentially, hey, you're limited to the four corners of our is it first amended or --

MR. KANE: Second amended, Your Honor.

THE COURT: Second -- second amended complaint. And there are exceptions to that, potentially one of which may be declarations and/or potential other evidence related to jurisdiction. But the moving parties did not attach it?

MR. KANE: That's correct, Your Honor.

THE COURT: Okay. And then, I assume your colleague will be arguing essentially in the alternative and/or as to the substance of the rest?

MR. KANE: That's correct, Your Honor.

THE COURT: Okay.

MR. KANE: With the Court's indulgence and allowance.

THE COURT: Sure.

MR. KANE: Thank you.

MR. HILTON: Thank you, Your Honor. This is Jonathan Hilton for the Plaintiffs. Can everyone hear me okay?

THE COURT: Yes. At least I can, so you're good.

MR. HILTON: Okay. All right. Perfect. Well, I want to be sure the other side can, as well. So I'd -- I'd like to start with the -- the hypothetical that was posed on the other side regarding personal jurisdiction. And I -- I want to bring it up just to highlight that the argument that GSK is making is essentially the same one that the unsuccessful defendant made in the *Ford* case argued last year and -- and decided by the U.S. Supreme Court. The basic contention is that even if you removed the conduct that directly gives rise to the cause of action, and you look at that and you just consider that, and you say, even if GSK had never done anything in Nevada, Plaintiff would still have this potential cause of action.

And I think it is true, but it's also irrelevant. The point here is that under *Ford*, GSK created a market for Zantac. And Plaintiff, based on this market that was created, then ended up consuming the generic. There were labeling decisions that were made elsewhere. And that is the conduct potentially that you could say gives rise to the claim. But in *Ford*, the U.S. Supreme Court was very clear that the language gives rise to is different than simply saying relates to. And the kinds of actions that relate to the creation of a market and the eventual consumption of the drug by the Plaintiff are the kinds of facts that are relevant when it comes to that relate to inquiry.

So similarly in *Ford*, Ford had not manufactured the cars at issue in Montana. Ford had not itself put those cars into the forum. But at this -- and you could say the same thing about Ford's position. Even if you removed all of the conduct that Ford had that was related to Montana, there would still be a cause of action against Ford for its manufacturer of those vehicles.

But when we talk in those terms, the question then is -- has to do with the specific facts that give rise to the claim as opposed to those that relate to. And when it comes to the related to inquiry, what's relevant there is whether there was marketing into the forum and whether the -- and in this case, whether the misrepresentations made it into the forum.

I do want to bring up one additional case that just very recently came out of the Southern District of California. It's a -- a decision on this very issue that came out just eight days ago. I believe that Mr. Kane has a copy -- a paper copy of the decision. And that case is called *Whaley*. Does Mr. Kane have the copy of that case?

MR. KANE: Your Honor, I do have a copy. I only have one copy, unfortunately. I can give it to the judge -- I can give it to Your Honor if you want it.

THE COURT: Give it to the other side and I can pull it up. Just bear with me a moment. What's the citation?

MR. HILTON: So the decision, which I have not found published to Lexis yet -- but the case is *Whaley*. It's W-H-A-L-E-Y, et al. v. Merck, M-E-R-C-K.

THE COURT: Do you have like a -- sorry. I have Westlaw. Do you have -- do you have any citation or --

MR. HILTON: Unfortunately, I don't know that it's been published to Lexis or Westlaw yet.

THE COURT: Okay.

MR. HILTON: I could attach it -- or I could have a -- a supplemental authority filed, and I could attach it to that. I can also give you the case number in the Southern District of California.

MR. KANE: And if helpful, I could also email it to the Court or to the clerk as well, too. And I could do that right now, if helpful, Your Honor.

THE COURT: I'll just hear your argument on it, I guess.

MR. HILTON: Okay. Thank you, Your Honor. We'll do something then to get that case, which just very recently came out before the Court. But I think the argument in it and the reasoning that the Court gives, which importantly essentially disagrees with what the MDL decided in the Zantac litigation is that when the defendant -- in this case it was Merck, which made Singulair, a brand name allergy drug. But when the defendants create a brand name drug, there's actually one product that has two components. There is the drug itself, and then under the FDA scheme, there's also the warning label. And these two go hand in hand under the federal statutory scheme. And -- and they're part in parcel. And when you recognize innovator liability, you're recognizing a cause of action that has to do with one part of that product package, which is the warning label.

So what the Court reasoned in Whaley is that there was a drug, in this case, Singulair, the brand name, that was promoted and marketed in California. Part of that was the warning label. And that warning label, which tags along with the generic drug that came into California and that mirrors it. But that warning label is part of the product that brand name manufacturer is pushing into the forum.

So in this case, if you think about it and you conceptualize it that way, there is a product that's being sent into Nevada by GSK or -- or that was sent into Nevada, that being the warning label. And that also can bend over a little bit to the analysis talking about duty and the need for a relationship in terms of the one who is consuming a generic product is actually consuming something that was -- in a sense that was made by the brand name manufacturer, which is that warning label.

So at -- at this point, before we move on to address the duty concerns, I'd like to invite the Court's questions on personal jurisdiction to make sure that I've made all of these points understood, too.

THE COURT: Thank you for asking. I -- I don't have any questions on that.

MR. HILTON: Thank you. So I'd like to turn next to innovator liability and duty. And I think that when we talk about the -- what gives rise to a legal duty and when do courts imply a legal duty, I think it's important to remember why these cases exist. Innovator liability claims exist because as many of the federal courts that have analyzed this and often have gone the other way depending on the state's laws, but they've realized that there's a fundamental unfairness about the

plaintiff's position in these kind of claims.

The generic manufacturer can turn around and point the blame on the brand name manufacturer. And they can say, well, it really isn't our fault that there was a defective warning label, we're required by federal law to copy what the brand name manufacturer put in front of the FDA. But meanwhile, if a court holds that there is no innovator liability theory, then that makes it very difficult or impossible for a Plaintiff to then seek relief from the party that's most at fault, which is the party that wrote and designed the warning label, despite what it already knew about its product.

When we think about Nevada law and what direction it should take, I think that what the Defense at GSK tries to do is come through old decisions and find small snippets that relate to the idea of well, the product was manufactured by the defendant, and it was sold to the plaintiff. But those cases aren't really applicable to a very new scenario. And if you interpret the *Allison* case that both parties cite for the proposition that -- and really what it says is that the Court should find and imply a legal duty on the party that's in the best position to avoid the harm.

In this case, that really is GSK. The generic has trouble finding a way to avoid it. In this case, it's GSK who has the knowledge and that writes the label and that goes to the FDA with it. So in that sense, I think that that's the way that these kinds of new situations are analyzed. So I think looking at cases and trying to -- to parse out language from them that don't really have to do with this very unique

federal statutory scenario, I don't think that that is very illuminating.

So I do want to turn then to the concept that as GSK has represented, they believe it's black letter law that on a negligent misrepresentation claim you can only recover for a business injury and you can only recover a -- a money loss -- a pecuniary loss. And they get that, I believe, out of the same *Moretti v. Wyeth* case that in our brief we heavily criticized and really tried to go through and show that the federal court in that case didn't do a good job interpreting Nevada law.

I think what's happened in the cases that GSK cites is that the Court in those cases was looking at Section 552 of the Restatement Second of Torts. That's titled "Information Negligently Supplied for the Guidance of Others." But based on where it's located in the Restatement and then also, what the text of it actually says, it's clear that that section only has to do with business torts.

There's a different section of the Restatement, which is Section 310 of the Restatement Second, and it's called "Conscious Misrepresentation Involving Risk." And that section says that an actor who makes a misrepresentation is subject to liability to another for physical harm which results. And I've abbreviated it slightly there. But if you actually read the cases that GSK cites, I didn't see anything where the Nevada Supreme Court analyzed that section in depth and then flat out rejected it. Instead, the cases that are cited tended to lean more towards the Section 552 category and so on. So I'm not sure that the black letter law is nearly so established on that point as GSK believes. When it -- well, and I'd invite the Court's questions on that point, as well.

THE COURT: No questions.

MR. HILTON: Okay. The one thing that I would add there is that to GSK's statement that there has to be an affirmative misrepresentation that's made at some point, well, I -- I contend there is one. GSK represented to the FDA that the product was safe. And it affirmatively supplied the warning label. So in that sense, there -- there is a misrepresentation and that is that the product is safe, other than as stated in the warning label.

So I'd last like to address predecessor liability. As we have indicated in our brief, we're not sure that this is actually so much of a real -- a real theory. The -- the term predecessor liability is not something that many courts have been using. But I think just to give our own analogy, I would put it this way. Suppose that I'm a landowner and I put a dangerous and deadly boobytrap on my land. And I know that anyone who crosses over the land and falls into my trap has a severe risk of death. Now, let's say that I planted this 30, 40 years ago. Then I go and I sell the land to the next landowner. Sure, it's possible that I even tell the landowner, or maybe I don't. And then that landowner goes and sells the land, and then sells the land again. And then one day, an unsuspecting person walks into the boobytrap.

Now, I don't think the mere fact that I sold the land or that I sold the -- even the boobytrap itself, if I sold it to someone else along the way, I don't think that that necessarily is going to cut off my chain of liability. In a scenario like that, the defendant in that case, you know, being me if I was the one who planted this boobytrap, would try to argue

that well, each succeeding landowner should have found the booby trap or removed it and so on. But this just ignores the plain reality that if I planted a boobytrap a very long time ago, I could -- even if I couldn't walk onto the land without trespassing and remove the boobytrap, I could certainly tell people about it. I could report it to the government.

In this case, GSK could have whistle blown or someone could have whistle blown about what was going on to the FDA even if they couldn't change the label. I could certainly publish it.

THE COURT: So -- so --

MR. HILTON: Go ahead.

THE COURT: My apologies. I do have another motion still, and I do have a settlement conference at 1:30. So maybe a couple more minutes to wrap up your argument, or --

MR. HILTON: Oh, thank you, Your Honor. I'm actually done.

THE COURT: Okay.

MR. HILTON: I've addressed -- I've addressed the four substantive points, and unless you have any questions about the predecessor liability, I believe I've made my point clear on that.

THE COURT: All right. Thank you very much.

Mr. Carter.

THE WITNESS: Thank you, Your Honor.

MR. CARTER: I'll try to be brief, Your Honor. First, I want to start with the factual allegations that -- that the other side raised in the second amended complaint, that GSK did manufacture and sell Zantac. But critically, does not prescription Zantac as the complaint. It says,

paragraph 12, I believe it was -- yes, it says, "Since 1983, GSK and its predecessors have controlled the prescription Zantac NDA." And then it goes on in paragraph 13 to say that, "Boehringer Ingelheim held the NDA for over-the-counter Zantac from 2006 to 2017." And then in paragraph 17, that Sanofi held it from January '17 through the present.

So there's a distinction between prescription and over-the-counter Zantac. And every indication in the complaint is that the Plaintiff took over-the-counter Zantac. Retailers are named, which are over the counter. Zantac would be sold; there is no allegation that I seen -- if Plaintiffs can direct me to it. I, of course, would -- excuse me. I have not seen any allegation in this complaint that the Plaintiff -- the decedent took prescription Zantac.

And perhaps most critically, we brought a motion to dismiss, it said very clearly, we're moving to dismiss these claims because the Plaintiff never actually consumed our products, and there's no allegation of the counter statement of facts, or elsewhere in the opposition saying, no, actually, we did -- the Plaintiff actually did take your product.

There's defensive innovator liability, but there's no dispute of the factual premise that these claims are predicated on, injuries allegedly caused by products produced by other companies. So I don't think this complaint actually does allege that GSK produced the products that this Plaintiff consumed because GSK did not control over-the-counter Zantac. And in any event, I think any arguments about the fact it was forfeited by not being raised in the Plaintiff's opposition to the motion to dismiss.

Secondly, even if there were that allegation, this Court would

still have to reach an individual liability issue because personal jurisdiction -- even on personal jurisdiction because it's assessed -- personal jurisdiction is assessed claim-by-claim. There has to be a basis for a specific jurisdiction for each claim brought on the complaint when those claims rest on different factual premises, and here, they do. One would rest on the direct sale to the Plaintiff, and one would rest on this individual liability theory that we've been discussing.

So I just want to say very briefly, we talked about *Ford* in our replies, so I don't believe at a point, but we are not making the same argument that was rejected in *Ford*. In *Ford*, the car company was selling the exact same models that were at issue in the state, and it knew that the conduct that it was rising -- doing in the state could get rise to the exact same types of products.

Here, the stuff -- what GSK was doing in Nevada, selling its own products, has absolutely nothing to do with types of claims the Plaintiffs are bringing. And I could extend, you know, my hypo even further. If GSK had never sold Zantac anywhere, if it had just controlled the label, and it does -- never happened in practice, of course, but if it had just decided not to actually sell the product, but then the patten lapsed and generics started selling it, GSK would still be liable for under an innovator liability theory.

So the sales and marketing are just are totally irrelevant, and GSK, if this court were to find personal jurisdiction, it would be on the basis of third-party actions over which GSK has no control, which we submit would not be consistent with Supreme Court precedent.

The *Whaley* case, I, of course, has have not had much time to --

THE COURT: I wouldn't worry about it.

MR. CARTER: Okay.

THE COURT: It was presented, but not -- didn't really have an opportunity to even look at it this morning, so --

MR. CARTER: And I just want -- I do want to say though on the merits briefly, on the affirmative representation point, we are not simply overreading a ready opinion. Nevada law is very clear that misrepresentation claims are limited to pecuniary damages. And in fact, they're -- I -- opposing counsel said that he thought that his prior decisions have just, you know, been expounded on 552, section of the statement. They had this other section; I think that's incorrect.

If you look at the *Reynolds v. Tufenkjian* decision in 2020, this other, broader form of liability is squarely rejected. I'll read the passage because it's completely on point. "In so doing" -- the prior sentence says that the Nevada Supreme Court is adopting section 552, and this is at page 152, and 136 Nev. 152.

> "In so doing, Nevada rejected the somewhat broader liability that other jurisdictions recognize that allows negligent misrepresentation claims to proceed when the alleged damages, the risk of physical harm, rather than pecuniary loss."

And it goes onto say, "Under this more loaded approach, Nevada law only recognizes negligent misrepresentation claims in the

context of business transactions." That is as direct a rejection of the broader theory the Plaintiffs want to proceed under that I think could possibly be asked for.

I also heard no answer to the point that -- from *Sanchez*, that a defendant owned -- it was a duty of care to prevent harm caused by a third party if there's a relationship between the defendant and the plaintiff, which we don't have here. And I would point out that the label that reached the plaintiff, which is what we should be analyzing for the purposes of this misrepresentation claim, and opposing counsel did not say that that label itself has any false statements. They focused instead on submissions to the FDA. So the management misrepresentation theory simply does not work under Nevada law, even if this court were to find jurisdiction.

THE COURT: Thank you very much.

So the negligent misrepresentation portion, I'm going to have to take under advisement because I -- based on the arguments, I did not review that in preparation for today, as much as I needed to.

But the remainders for that, I'll take under advisement. But the remainder of the motion to -- GSK's motion to dismiss is denied without prejudice. I do certainly acknowledge that somewhat, the Court, me, being in the position of trying to do my best at figuring out what I think the Nevada Supreme Court, and/or the U.S. Supreme Court would do under these exact facts and circumstances. There are splits of authority.

Mr. Hilton, you, or someone from your side is going to

prepare this order. Put my reasons in there, including what I've already stated so far.

So there's a split of authority in there on the cases, on the issue, or many of the issues, but there's no necessarily controlling law exactly on point. And so I do my best to figure out what I think the Nevada Supreme Court, and/or U.S. Supreme Court would do on a case exactly on point.

And here, I think they would, at this early stage, uphold the denial without prejudice. The personal jurisdiction at this early juncture, I'm looking at the four corners of the complaint, as pointed out and argued by Plaintiff. There was no evidence, whether a declaration, affidavit or otherwise with the motion that would potentially shift the burden to the Plaintiff at this early juncture.

So I accept all facts as pleaded in the complaint as true. Nevada certainly is in notice pleading states still. It does not follow the implausibility or plausibility federal standard, and at this early juncture, it does appear that Plaintiff has adequately pleaded facts sufficient to have a personal jurisdiction over GSK.

To go further, the Court finds a persuasive, and/or controlling on some of the points. The *Pliva*, or *Pliva*, I don't know how you pronounce it, P-L-I-V-A case, the Ford case, the Rafferty case, the *T.H. v. Novartis* case, the *Allison v. Merck* case, I, you know, all due respect, to the MDL judge, I think the Nevada Supreme Court would, at least at this early stage, hold otherwise, and so although I -- and I did read a lot of these cases in their entirety, but I think the Nevada Supreme Court would

depart from the ruling in the MDL court case and the In Re Zantac case, at least at this early junction in a motion to dismiss.

I do believe and rule and reason that the innovator, to the extent it needs to be reached at this early stage, or that Nevada would follow the cases that find innovator liability and use that as a means to obtain or hold jurisdiction, personal jurisdiction in a case like this.

The pre-*Pliva* cases are not super persuasive, and all -- even pre-*Ford* cases -- *Pliva* and *Ford* seem to clarify some things that weren't necessarily accounted for in cases that came before them.

Oh, the other case I find persuasive, the In Re -- however you say it, *Fluoroquinolone* case out of the District of Minnesota. I mean, *Ford*, with the United States Supreme Court case, just over a year ago, quote, "When a company like Ford serves a market for a product in the state, and that product causes injury in the state to one of its residents, the state's courts may entertain the resulted suit," closed quote.

The product in this case, I do agree with Plaintiff's argument. Again, this is all without prejudice, that the product here is the actual drug itself in the company label. And I understand Defendant's follow-up argument that, hey, Plaintiff did not take any of GSK's Zantac, but one, I'm limited to the face of the complaint itself. But two, alternatively, I think the Nevada Supreme Court would follow those cases that do the innovator liability analysis to find jurisdiction for reasons that are gone into great detail in Plaintiff's opposition.

Again, I do need that negligent misrepresentation, I need to take a further look at it. But the other failure to state a claim, I -- again,

assuming all facts as pleaded as true, which I do stay claims under Nevada law upon which relief may be granted. So put all that in there. Okay.

MR. HILTON: Thank you, Your Honor. On the negligent misrepresentation claim, I wondered if we could have leave to file a surreply, simply in that the arguments over the -- which restatement provision controls, I believe are further --

THE COURT: So if I -- if I look at it further and I think I need further briefing, I'll do a minute order, but otherwise, I'll just take it under advisement. Let's give me in chambers, two weeks out. In chambers on this is to remind me if I haven't done it yet, and to be clear, there's a decent chance I'll have to push it out further than that. But two weeks in chambers.

THE CLERK: May 4th, 2022 in chambers.

MR. HILTON: Thank you, Your Honor.

THE COURT: Okay. Brand defense motion to dismiss and/or strike.

MR. PARISER: Again, this is Daniel Pariser. I represent Sanofi on this motion. I'm speaking for all the brand defendants. Your Honor, I know we're short on time. I'll try to be brief and just hit the high points, and not every argument for every claim.

I think the first -- the first point I'd like to address briefly is a fundamental failure of pleading here, and that is the failure to articulate in the complaint, which products specifically the Plaintiff used over which time periods, which really leaves the Defendants in the dark as to

the claims here.

THE COURT: Yeah. So on that thought, I mean, Nevada, in those pleadings state, and I understand exactly what you're saying, but I mean, the Supreme Court is pretty clear, so unless you can address that, I mean --

MR. PARISER: Sure. I mean, Your Honor, obviously, there's no case directly on point with this particular language, but I think in this -- in this circumstance, if you look at what's pleaded, it's one sentence. From November 2016 through September 2019, the decedent adjusted Zantac and its various generic forms. The problem is that doesn't tell you which Defendant's product they adjusted.

And as you heard from counsel, my client, Sanofi, never manufactured prescription product. If they -- if the Plaintiff only took prescription product, whether it's generic or branded, my client shouldn't be in the case. The same for Boehringer Ingelheim. The reverse is true. If she only took -- if she only took OTC product, why is GSK in the case? Under these circumstances, and with all of these innovator liability claims that you heard a lot about, which we don't even know what they're claiming -- I think in this circumstance, it's certainly within the Court's discretion to order some clarity in this complaint.

I just think it's a fundamental issue. And it goes to more than just the strict liability claims. If you look at some of their other pleading failures like the failure to plead what the warranty was, I mean, you can't even get to what the warranty was if there wasn't a purchase of a particular defendant's product. So it's really a fundamental problem

here that I think it would serve everyone to get some clarity on early. And I'd ask the Court to --

THE COURT: Tell me about the fraudulent concealing claim, because that's the one that I really -- I mean, that's potentially, at least, a different standard.

MR. PARISER: Yes, certainly some pleading with particularity can acquire there, and I think that claim fails for a number of reasons. I mean, one is the fundamental one I just indicated, which has just not been pleaded. For instance, as to Sanofi, what -- whether he -- the Plaintiff even purchased Sanofi product.

But I think the more fundamental problem for that claim is that the courts have required that there be a special relationship, typically fiduciary duty, although it doesn't have to be, in order to sustain that sort of claim. And that just hasn't been -- it just hasn't been pleaded here.

And you know, again, I recognize this is a notice pleading state, but I just --

THE COURT: Well, on that it's not. That's why I asked --

MR. PARISER: Right.

THE COURT: -- because you know, the word you mentioned is in the -- I mean, particularity, that if it's a misrepresentation claim, which that appears to be, then it's a different standard.

MR. PARISER: Right. Your Honor is absolutely correct. And I think for that claim, the failure to allege a special relationship, failure to even indicate which products were purchased are fatal to that claim.

THE COURT: Okay.

MR. PARISER: With respect to the warranty claims, again, really briefly, I think this is a straightforward issue. There is a statute right on point that requires pre-suit notice. We've cited it in our papers. And really, the Plaintiffs only -- I'm sorry, it's NRS 104.2607, 3(a), "The buyer must, within a reasonable time after the buyer discovers or should have discovered any breach, notify the seller of breach or be barred from any remedy."

I think the Plaintiffs made argument in response is that it doesn't apply to consumers, shouldn't apply to consumers, or shouldn't apply to this particular consumers specific circumstances. But the language of the statute is the language of the statute. The legislature could have written in exceptions if it wanted to and it didn't. And I just think the language of the statute controls on that point. We also cited a few cases. Plaintiffs cited none going the other way, so I think that's a pretty clear straightforward issue.

In the interest of time, obviously I'll address whatever the Court wants, but just briefly on the pre-emption issue on the design defect claim, I just -- I think it's actually pretty straightforward, but maybe requires a little bit more explanation. And I think -- I'm sure the Court has read it. I commend to the Court that the MDL judge's decision at 512 F.3rd. 1278, but essentially, Your Honor, the standard for federal pre-emption, which is a threshold issue that court's routinely deal with on the pleading stage, the basic test the Supreme Court has articulated is that if the state law claim imposes a duty, that the defendants cannot

satisfy without FDA's prior approval, then the claim is pre-empted.

So the Plaintiffs here for design defect, what they're basically alleging is that the design of the molecule is defective. And you can see that in the complaint itself, paragraph 157, the Plaintiffs say Zantac is defected because the drug is made up of an inherently unstable [indiscernible] molecule. And they go onto explain that that degrades.

And so essentially what the Plaintiffs are requiring here is that Defendants redesign the molecule, and that is something they concede cannot be done without FDA's prior approval. That's at page 11, lines 18 and 19 of their opposition brief. They say changing that formulation of an approved pharmaceutical drug is a major change requiring FDA approval.

And I mean, that makes sense because if you change the molecule, you're basically created a new drug, and you can't market a new drug without FDA's blessing or you're going to be in some real trouble.

And so the authority cited in the briefs, Your Honor, is uniformly in support of the Defendant's position here, not just the MDL judge's decision, but also the *Quanusky* [phonetic] case out of the District of Nevada, the *Yates* [phonetic] case out of the Sixth Circuit, and a number of other cases that we cited.

Plaintiff's arguments in response, I think are two-fold. One, they say, okay, but if you look at *Wyatt vs. Levine* [phonetic], the labeling claim should survive. I just think that's neither here nor there. They pleaded two separate strict liability claims, so that doesn't say they're a

design defect claim.

And then finally, they point to this supposed exception for Ms. Brandon [phonetic]. And if you look at the MDL court's decision, the judge shot down that argument quite quickly, essentially saying that no case recognizes that exception. And certainly the Plaintiffs don't cite any case, and that's at 512 F.3d. at 1294.

And I could just quote you what the MDL judge says. She says, "No court has adopted the theory that impossibility pre-empts can be avoided by showing that a drug is misbranded under federal law." And the reason for that, Your Honor, is because, again, the Supreme Court's test is whether the defendants could have unilaterally made the change that the state court duty required. And whether or not there was misbranding, it just wasn't --

THE COURT: What page was that one on?

MR. PARISER: Certainly.

THE COURT: Sorry.

MR. PARISER: It is at 1294.

THE COURT: Oh, I think I'm looking at a different -- what's the full citation?

MR. PARISER: It's 512 F.3d. at 1294.

THE COURT: Okay. Thank you.

MR. PARISER: Yes, Your Honor. And just very briefly, to close on that point, if the Plaintiffs were right, that it was enough to avoid pre-emption, that you could say a drug is dangerous to health, and that gets you out of the pre-emption box, I mean, there'd basically be no

pre-emption left, because that's what's alleged in, essentially every drug case.

So just before I sit down, in terms of Plaintiff's request for leave to amend, I'll just flag that there are a couple -- few defects here that really are not curable, that pre-emption and design defect claim, the fraudulent concealment issue we talked about because they -- I don't see how they could possibly allege a special duty in a case like this, and certainly the failure to provide pre-suit notice for the express and implied warranty claims.

With respect to lack of product I.D., Your Honor, I think the point here that we make is I've not heard anything from Plaintiffs about what they would plead, and if they actually do have information about which product was taken when. I just haven't heard that from them, and I think absent some representation in that regard, I'm not sure how they can proceed with the case. So that's all I have for now, Your Honor.

THE COURT: Thank you very much.

Oh, go ahead if you're the one arguing it.

MR. KANE: I'm going to be brief, Your Honor. I'm going to go backwards since it's freshest in my mind. So dealing first with the pre-emption argument. The state court has made it very clear, the first analysis is to identify what the state court duty imposes onto the brand manufacturer or the defendants and this case, and then see it as a conflict of the federal law.

So one thing that I did not see set forth in the moving papers, or did not hear during the arguments in front of you, Judge, today, is

what that state duty was or is. I still don't know. So how can we perform an analysis of pre-emption if we don't know that duty. We set forth a duty in our complaint, what we believe it to be, and that's that they have a duty under state law duty, under the fifth claim of relief; that would be on page 29, starting at paragraph 166. I'm sorry, paragraph 120 -- or paragraph forth claim for relief, Your Honor. Paragraph 156.

THE COURT: Okay.

MR. KANE: It's -- I believe that the Nevada common law requires manufacturers to design reasonably safe products and not put unreasonably safe products into the chain of commerce that are going to hurt individuals here in Clark County.

Nowhere that I've saw in the moving papers, or had I heard in the oral argument here today is that we have a state law duty imposed upon the Defendants that they need to change a drug, that they need to change warning labels. I'm unaware of any common law here in Nevada that that would apply here in this case.

And other than what we've set forth here, I don't know what other state law analysis we'll have going to the federal regulations that they've cited in their case, or cited in the moving papers.

Last point on that is that generally these are decided in the summary judgment stage because there is information that we need to get what we don't have. Generally in a case like this, they'll attach filings that they had with the FDA, so we know when they tried, if they tried, and that changes the warning labels to the product design, to the actual construction of anything else. We don't have that in this case. These are

all things that we're probably going to get in discovery, but even then, there's no specific common law questions that would conflict with the federal. And by all means, that they would be parallel to each other.

The concealment, Your Honor, if you dismiss it, we'd ask that you just dismiss it without prejudice. And as we go through discovery, we get a specific set of facts that we can set forth, we will amend or move the Court to amend with that. If you find that we didn't specifically plead that specifically to each individual defendants and our statements that were made on specific dates, we don't believe that it's that stringent. We believe we certainly plead it with more specificity than is required under the notice pleading here in Nevada, but I'm going to leave that up to Your Honor to make a decision. We just ask without prejudice that you do that.

Breach of warranty of use -- this is a UCC argument. I want to get a little timeline here. August 17, we associate into the case. September 20th of 2021, we stipulate to amend to add the Zantac defendants. She died on October 7th. So she found out she may have a potential claim against the Zantac defendants, September 20th of 2021. During that time she was on hospice. She ultimately dies a month later. What -- how is she going to put them on notice. And aren't they already on notice on tens of thousands of claims that have been brought against them over the course of -- almost in every state across the country? It's just a -- it's a very interesting argument. I'll give them that, but with really no application here in our opinion, Your Honor. And if it was, it would be feudal because there would be no way she could have put

them on notice at that point.

Then finally, I think there was one more. Did I miss? Was there one? Oh, the first one. The -- oh, let me see, lack of product identification. Your Honor, this commonly here in Nevada, that that's information you get through discovery. We're not going to always have that information. We plead -- and unfortunately, for some reason, over the counter and brand were taken out of the second amended complaint, or omitted for some reason, but we'll amend that it -- the allegation has always been that -- and during discovery, this will be set forth, is that she took over-the-counter prescription, brand and generic Zantac here in Clark County over the course of three years.

But we have specific -- we have pled it under the notice requirement properly in order for them to be able to identify it and know what the allegations are in this company, among others.

Thank you, Your Honor.

THE COURT: Thank you.

UNIDENTIFIED SPEAKER: I'll be very brief, Your Honor. On the issue of the statewide duty, I don't think the Court needs to look any further than the complaint itself. Paragraph 158, the allegation is, and I'm quoting, "In other words, Defendants had a duty to design Zantac to prevent it from reacting with itself to produce the carcinogen and DNA." That's exactly what we cannot do without FDA prior approval. And to the extent that counsel is suggesting the Defendants could simply have removed the product from the market or not sell it Nevada, that stop selling argument in response to pre-emption has been directly rejected

by the United States Supreme Court in the *Mutual Pharmaceutical Company vs. Bartlett* case at 570 U.S. 472. I'm quoting from page 475.

> "The Court of Appeals solution that Mutual should simply have pulled Sulindac from the market in order to comply with both state and federal law is no solution. Rather, adopting the Court of Appeals stop selling rationale would render impossibility, pre-emption a dead letter, and work a revolution in this court's pre-emption case law."

And then finally, Your Honor, on the warranty claim, I understand and appreciate the timeline the Plaintiff's counsel supplied, but I think the Plaintiff's just -- the statue doesn't allow for exception. It's clear on its face, and those claims should be denied as well.

Thank you, Your Honor.

THE COURT: Well, thank you very much.

So the fraudulent concealment, which is, what number? Does anybody remember? Tenth claim for relief. It is certainly not as currently pleaded in compliance with the particularity for a requirement under NRCP 9(b). Even if it -- let's see. And 9(b), the particular requirement certainly would apply to the fraudulent concealment.

Tenth claim for relieve, Plaintiff has asked for an opportunity to amend, but at the same time, has not complied with, and it hasn't really been argued, but has not provided a proposed amended pleading to comply with the requirement either, so it makes it a little difficult for me, you know, whether to dismiss or give opportunity for relief to amend; dismiss without prejudice, to be clear. I mean, that's -- that's

what it would be. There are also other issues raised, and one of them even acknowledge, perhaps by Plaintiff's counsel in terms of over-the-counter versus prescription and being a little more clear, and to be clear, however, Nevada is a notice pleading state, and a lot of the issues raised in the motion, you know, under the notice pleading standard fail; don't merit dismissal.

So in all candor, I'm struggling a little in terms of do I say, okay, Plaintiff file a third amended, and then I have Defendants respond to that? Or something else? Let me ask, do Plaintiffs want to pursue a fraudulent concealment claim? Or do --

MR. KANE: Your Honor, candidly, with the information that we have right now, if we had more information regarding the allegation set for the fraudulent concealment, the tenth cause of action, we would have done that. So the --

THE COURT: Okay.

MR. KANE: -- like I said, Your Honor, if we find that information throughout the course of discovery, we'll move the Court to allow us to amend.

THE COURT: Okay.

MR. KANE: We amended, pretty much with --

THE COURT: Yeah. Okay. And that's understandable. So the Court will grant part and deny in part, both without prejudice, Defendant's motion to dismiss and/or strike the fraudulent concealment, tenth claim for relief, dismissed without prejudice. The negligent misrepresentation claim, I'm taking under advisement still. The

remainder, our due stay claims upon which relief may be granted under Nevada law, at least at this early juncture, and therefore, it's denied without prejudice for the reasons stated in the opposition.

Do you want to prepare that order, because you got at least part of it granted?

UNIDENTIFIED SPEAKER: I'm happy to, Your Honor.

THE COURT: Okay. Submit it to Plaintiffs and -- well, submit -- circulate on your side first and then to the other side.

Is that all?

UNIDENTIFIED SPEAKER: It is for me, Your Honor.

THE COURT: Okay.

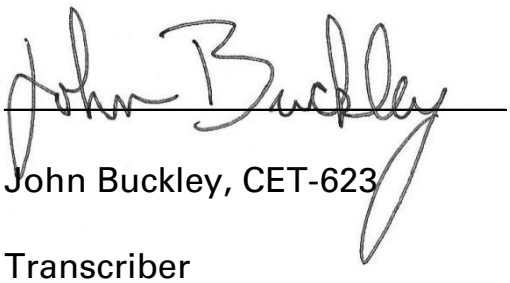
MR. KANE: Thank you, Your Honor.

THE COURT: Thank you.

[Proceedings adjourned at 1:20 p.m.]

* * * * *

ATTEST: I do hereby certify that I have truly and correctly transcribed the audio/video proceedings in the above-entitled case to the best of my ability.



John Buckley, CET-623

Transcriber

Date: April 26, 2022

Exhibit F

Plaintiff Husrom Notice of Entry of Order Denying Defendant GlaxoSmithKline Motion to Dismiss

NOE
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DISTRICT COURT

CLARK COUNTY, NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as the legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor,

Plaintiffs,

vs.

LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC, GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC.; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES I THROUGH X; AND ROE CORPORATIONS XI THROUGH XX, INCLUSIVE,

Defendants.

CASE NO. A-21-835385-C
DEPT. 15

NOTICE OF ENTRY OF ORDER DENYING DEFENDANT GLAXOSMITHKILINE LLC'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FAILURE TO STATE A CLAIM

TO: ALL INTERESTED PARTIES.

PLEASE TAKE NOTICE that an ORDER DENYING DEFENDANT GLAXOSMITHKILINE LLC'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FAILURE TO STATE A CLAIM was filed on September 9, 2022, a copy of which is attached hereto.

DATED this 9th day of September 2022.

THE702FIRM

/s/ Michael Kane

MICHAEL C. KANE, ESQ.
Nevada Bar No. 10096
BRADLEY J. MYERS, ESQ.
Nevada Bar No. 8857
400 S. 7th Street, Suite 400
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Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of September, 2022, I caused service of a true and correct copy of the foregoing **NOTICE OF ENTRY OF ORDER DENYING DEFENDANT GLAXOSMITHKILINE LLC'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FAILURE TO STATE A CLAIM** to be made by the Eighth Judicial District Court's Odyssey E-File and Serve program, upon all parties registered to use this service, in accordance with the Clark County District Court's Administrative Order No. 14-2, issued 5/9/14:

ROBERT C. MCBRIDE, ESQ. SEAN M. KELLY, ESQ. **McBRIDE HALL** 8329 W. Sunset Road, Suite 260 Las Vegas, Nevada 89113 *Attorneys for Defendants* *Las Vegas Medical Group, LLC &* *Nauman Jahangir, M.D.*	KELLY A. EVANS, ESQ. CHAD R. FEARS, ESQ. JUSTIN S. HEPWORTH, ESQ. **EVANS FEARS & SCHUTTERT LLP** 6720 Via Austi Parkway, Suite 300 Las Vegas, NV 89119 *Attorneys for Defendants* *GlaxoSmithKline LLC*
ERIKA PIKE TURNER, ESQ. **GARMAN TURNER GORDON LLP** 7251 Amigo Street, Suite 210 Las Vegas, Nevada 89119 *Attorneys for Defendants* *Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC, and Chattem, Inc.*	ANDREW T. BAYMAN, ESQ. (pro hac vice forthcoming) ROBERT B. FRIEDMAN, ESQ. *(admitted pro hac vice)* **KING & SPALDING LLP** 1180 Peachtree Street, NE, Suite 1600 Atlanta, GA 30309-3521 JULIA ZOUSMER, ESQ. (admitted pro hac vice) **KING & SPALDING LLP** 110 N Wacker Drive, Suite 3800 Chicago, IL 60606 *Attorneys for Defendants Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim USA Corporation*

/s/ Sofia Chacon

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CLERK OF THE COURT

ORDER

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DISTRICT COURT

CLARK COUNTY, NEVADA

SARA ELABBASSY, as Special Administrator of the ESTATE OF DECEDENT HUSROM, deceased; JAMIL HUSROM, individually and as the legal guardian for KHULOD HUSROM, a minor, SALIH HUSROM, a minor, FATIMA HUSROM, a minor, and MOHAMMED HUSROM, a minor,

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LAS VEGAS MEDICAL GROUP, LLC; NAUMAN JAHANGIR, M.D.; GLAXOSMITHKLINE, LLC, GLAXOSMITHKLINE, PLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; BOEHRINGER INGELHEIM CORPORATION; SANOFI US SERVICES, INC.; SANOFI S.A.; SANOFI-AVENTIS U.S. LLC; CHATTEM, INC.; SMITH'S FOOD & DRUG CENTERS, INC.; WALMART, INC.; CVS PHARMACY, INC.; WALGREEN CO. d/b/a WALGREENS; DOES I THROUGH X; AND ROE CORPORATIONS XI THROUGH XX, INCLUSIVE,

Defendants.

CASE NO. A-21-835385-C
DEPT. 15

ORDER DENYING DEFENDANT GLAXOSMITHKILINE LLC'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND FAILURE TO STATE A CLAIM

…

…

On February 25, 2022, Defendant GlaxoSmithKline LLC ("GSK"), filed *Defendant GlaxoSmithKline LLC's Motion to Dimiss for Lack of Personal Jurisdiction and Failure to State a Claim*. On March 25, 2022, Plaintiffs Sara Elabbassy, as Special Administrator of the Estate Of Decedent Husrom, deceased Jamil Husrom, individually and as the legal guardian for Khulod Husrom, a minor, Salih Husrom, a minor, Fatima Husrom, a minor, and Mohammed Husrom, a minor (collectively, the "Plaintiffs"), filed *Plaintiffs' Opposition to Defendant GlaxoSmithKline LLC's Motion to Dismiss*. On April 13, 2022, GSK filed *Defendant GlaxoSmithKline LLC's Reply in Support of Motion to Dismiss for Lack of Personal Jurisdiction and Failure to State a Claim*. On April 20, 2022, the Court heard argument at the hearing on this Motion. The Court, having heard oral arguments and after review of the points and authorities and the pleadings, hereby DENIES GSK's motion to dismiss without prejudice.

I. BACKGROUND.

According to Plaintiffs' Second Amended Complaint, ranitidine, better known as Zantac, was developed by GSK and approved for prescription use in 1983. In their Complaint and briefing, Plaintiffs assert that Zantac was a "wildly successful" drug. They further assert that, due to GSK's marketing strategy, 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 GSK's sales of $3.98 billion. According to the pleadings, even as late as 2016, Zantac was the 50th most prescribed drug in the United States with over 15 million prescriptions.

Plaintiffs contend that the marketing strategy that led to Zantac's success for over 30 years emphasized the purported safety of the drug. They assert that Zantac has been marketed as a safe and effective treatment for infants, children, and adults; that GSK, through its constant television campaigns, marketed Zantac as safe to use when consuming foods containing high levels of nitrates, such as tacos and pizza; and that because GSK promoted the drug as being safe, Zantac became available without a prescription in 1996. Generic versions of the drug (ranitidine) became available the following year. In their Second Amended Complaint, Plaintiffs contend that GSK knew from the beginning that ranitidine has the potential to cause cancer. They reference studies purportedly conducted by GSK in 1981 and 1987 that, they allege, were purposefully distorted to

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mask any potential cancer risk.

Plaintiffs are a Nevada family suing over the death of a loved one. According to the Second Amended Complaint, the decedent contracted esophageal cancer and died after taking both the branded and the generic versions of Zantac—a drug that was marketed by GSK as a method for treating gastroesophageal reflux disease—from November 2016 to September 2019. Plaintiffs allege that GSK cultivated a market in Nevada for the product and derived substantial revenue from this state. In their argument in opposition to GSK's motion to dismiss, Plaintiffs assert that the decedent lived in Nevada, was subjected to GSK's marketing in Nevada, presumably believed GSK's alleged representations that the drug was safe in Nevada, took both the branded and generic Zantac drugs bearing GSK's warning label in Nevada, and died in Nevada. At oral argument, the Court questioned GSK's counsel as to whether, at the pleading stage, the Court should assume that GSK did market and sell Zantac in Nevada. (Hr'g Tr. 29:24-30:2.) GSK's counsel conceded this point. (*Id.* at 30:3.)

II. THIS COURT HAS SPECIFIC PERSONAL JURISDICTION OVER GSK.

GSK first argues that this Court lacks personal jurisdiction over it. The parties agree that GSK is not headquartered or incorporated in Nevada, and therefore there is no general jurisdiction over it. Rather, the question is whether "specific" jurisdiction exists over GSK in this state.

In *Ford*, the Supreme Court clarified that there are two different ways that a plaintiff may establish specific jurisdiction. First, the plaintiff may show that the claims "arise out of" the defendant's contacts with the forum—an inquiry that "asks about causation." *Id.* But if the plaintiff cannot make a "causal showing," he can still satisfy the requirements of specific jurisdiction by showing that his claims "relate to" the defendant's contacts with the forum. *Id.* It is this second test—the "relate to" test—that Plaintiffs in this case have satisfied.

This second test "contemplates that some relationships will support jurisdiction without a causal showing." *Id.*; *Ayla, Ltd. Liab. Co. v. Alya Skin Pty. Ltd.*, No. 20-16214, 2021 U.S. App. LEXIS 25921, at *18 n.5 (9th Cir. Aug. 27, 2021) ("We clarify that our precedents permit but do not require a showing of but-for causation to satisfy the nexus requirement."). Rather, the "relate to" inquiry focuses on whether there is a "strong relationship among the defendant, the forum, and

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the litigation." *Ford*, 141 S. Ct. at 1028. The relatedness requirement "incorporates real limits." *Id.* at 1026. Nevertheless, "regularly marketing" a product in a state puts a defendant on "clear notice" that it will be "subject to jurisdiction in the State's courts when the product malfunctions there." *Id.* at 1030.

GSK argues that because Plaintiffs seek to hold GSK liable based on the theory of "innovator liability," under which the sole basis for Plaintiffs' cause of action is GSK's alleged failure to update and maintain the warning label for brand-name Zantac, the only relevant jurisdictional facts are those that pertain to GSK's labeling decisions. Plaintiffs do not contest that those labeling decisions took place out of state. In support of its position, GSK relies on the decision of the MDL Court in the Zantac litigation, *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 2021 WL 2682602, at *14 (S.D. Fla. June 30, 2021). The MDL Court concluded that "[t]he nature of an innovator-liability claim … compels" the conclusion that "only those activities that relate to the brand-name manufacturers' labeling decisions" could support specific jurisdiction. *Id.*

By contrast, Plaintiffs rely directly on the Supreme Court's analysis in *Ford* and on an analogous case within the Ninth Circuit. Plaintiffs argue that in the innovator liability case *Quinn-White v. Novartis Pharm. Corp.*, the court found specific personal jurisdiction because "[a]lthough Plaintiff Quinn-White did not ingest Defendant's drug, Plaintiff alleges that her California-based physician reviewed and relied on Novartis's label and its warnings in California, where Novartis marketed its drugs." No. CV 16-4300 PSG (AGRx), 2016 U.S. Dist. LEXIS 201328, at *7 (C.D. Cal. Oct. 7, 2016). GSK, in its reply brief, asserts that *Quinn-White* was wrongly decided.

After careful consideration and a thorough reading of many of the relevant opinions, and with all due respect to the MDL Court, this Court concludes that, at this early stage, GSK's motion to dismiss for lack of personal jurisdiction should be denied. Plaintiffs' arguments and authorities better harmonize with the Supreme Court's reasoning in *Ford*. In *Ford*, the Supreme Court did not first winnow down the relevant jurisdictional facts to only those aspects of the defendant's conduct that were allegedly tortious. Rather, the Court asked whether there was "'an affiliation between the forum and the underlying controversy,' without demanding that the inquiry focus on cause." *Ford*, 141 S. Ct. at 1026. An "affiliation" may occur where the plaintiff is injured by a product in

a state and the defendant has made "efforts" to "serve, directly or indirectly, the market" in that state. *Id.* at 1027 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

Thus, so long as there is at least some "affiliation between the forum and the underlying controversy," a defendant cannot complain that the exercise of personal jurisdiction "offend[s] traditional notions of fair play and substantial justice." *Id.* If a defendant does not wish to be sued in a certain state, it can "structure [its] primary conduct to lessen or avoid exposure to a given State's courts," for example by declining to do any business in that state. *Id.* at 1025. But when a company "exercises the privilege of conducting activities within a state—thus enjoy[ing] the benefits and protection of [its] laws—the State may hold the company to account for related misconduct." *Id.*

GSK poses a hypothetical that it argues defeats Plaintiffs' position. GSK argues that even if it had *never* marketed or sold Zantac in Nevada, then under Plaintiffs' theory of jurisdiction, Plaintiffs could still seek to hold GSK liable under a theory of innovator liability in Nevada—and that this would be, it contends, an absurd result. As GSK's counsel conceded at oral argument, however, this hypothetical is not the case here. At this stage, the Court must assume that GSK did, through its marketing, cultivate a market for Zantac in Nevada. If GSK had never marketed Zantac in Nevada, then it would be unclear that Plaintiffs' claims would sufficiently "relate to" the forum for GSK to be hailed into a Nevada Court. Because GSK actively cultivated a market for ranitidine in this State, however, under *Ford*, its regular marketing put it on "clear notice" that it could be "subject to jurisdiction in the State's courts when the product malfunctions there." *Id.* at 1030. Here, unlike in GSK's hypothetical, there is a sufficient "affiliation" between the parties, the product, and the forum state.

GSK further argues that finding specific personal jurisdiction would violate Due Process because, with respect to other companies' products, it has not received the benefits and protections of Nevada law. At least at the pleading stage, however, the Court assumes that by "conducting so much business in" Nevada and reaping the financial rewards of successfully marketing ranitidine in this State, GSK has "enjoy[ed] the benefits and protection of" Nevada's laws—"the enforcement of contracts, the defense of property, the resulting formation of effective markets." *Id.* at 1030.

Those benefits give rise to "reciprocal obligations for the Defendants under state law," notably the obligation not to make negligent misrepresentations; and breaching those obligations "relates to" the negligent misrepresentation claims, allowing Nevada courts to hold GSK accountable consistent with the Constitution and Due Process. *Id.* Having addressed the threshold jurisdictional issue, the Court now turns to GSK's motion to dismiss for failure to state a claim.

III. PLAINTIFFS HAVE STATED A CLAIM FOR INNOVATOR LIABILITY.

Nevada is a notice pleading state. *McGowen v. Second Judicial Dist. Court of Nev.*, 432 P.3d 220, 225 (Nev. 2018) ("Nevada has not adopted the federal 'plausibility' pleading standard."). Thus, to succeed on a motion to dismiss for failure to state a claim, the defendant must show that, after every reasonable inference is drawn in the plaintiff's favor, "it appears beyond a doubt that the plaintiff could prove no set of facts that would entitle him to relief." *Munda v. Summerlin Life & Health Ins. Co.*, 127 Nev. 918, 923, 267 P.3d 771, 774 (2011) (cleaned up). With this in mind, the Court turns to Plaintiffs' theory of "innovator liability."

Under the theory of "innovator liability," a brand-name manufacturer of a drug may be held responsible for the contents of a generic manufacturer's warning label because, under federal law, the generic manufacturer is *required* by to copy the brand-name manufacturer's label. *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1210 (Mass. 2018) (citing 21 U.S.C. § 355(j)(2)(A)(v) & (j)(4)(G)). Because federal law only requires the generic manufacturer to copy the brand-name manufacturer's label, many of Plaintiffs' state law failure-to-warn claims against the generic manufacturer are impliedly preempted by federal law. *PLIVA, Inc., v. Mensing*, 564 U.S. 604 (2011).

Courts have recognized that this is fundamentally unfair to the plaintiff. For instance, in *Franzman v. Wyeth, Inc.*, a Missouri court acknowledged (in applying Kentucky law to the case before it) that there was "inherent unfairness [in] first substantially preempting a consumer's tort claims against the generic manufacturer, and next concluding that the same consumer's tort claims are also barred against the brand-name manufacturer responsible for the product design, formula, dosage, labeling and warning that are at the core of the consumer's claims." 451 S.W.3d 676, 691 (Mo. Ct. App. 2014). The Sixth Circuit has also recognized the "basic unfairness" of the "classic

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'Catch 22'" that occurs where the plaintiff cannot sue the *generic* manufacturer for failure to warn because that company didn't design the label, but also can't sue the *brand-name* manufacturer because it didn't make the product the plaintiff consumed. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013) (applying Tennessee law).

In *Franzman* and *Strayhorn*, however, state law products liability statutes prevented the Courts from adopting the "innovator liability" theory. *See Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1221 (Mass. 2018) (distinguishing cases finding no duty because those were "resolved under the products liability statutes of other States"). The federal case law presented by GSK is not persuasive, as those decisions were "issued by Federal courts that are constrained in their interpretation of State law in the absence of clear guidance from State appellate courts." *Id.* This Court must, relying on Nevada tort principles, reach its own conclusion.

Where, as here, no legislative scheme bars application of the theory, judges have applied traditional tort law principles to properly allocate the risk of loss onto the party in the best position to prevent the harm (the brand-name manufacturer). *See, e.g.*, *Rafferty*, 92 N.E.3d at 1221; *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18 (Cal. 2017); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014), *superseded by statute*, Ala. Code § 6-5-530(a); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010). While the name GSK uses for Plaintiffs' theory—"innovator liability"—may be relatively recent, the principles underpinning it are well-established.

So-called "innovator liability" is based on the commonsense principle that liability for injuries should be assigned those parties who are in the best position to avoid them. *Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (The "responsibility for injuries caused by defective products is properly fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market.").

In *Allison*, the Nevada Supreme Court explained that when considering whether to permit the plaintiff's theory of liability, the Court should consider "public interest" principles. *Id.* at 953. The Court reasoned that these "public policy considerations . . . were put well by Professor Prosser in the noted law review article, 'The Fall of the Citadel':

> The public interest in human safety requires the maximum possible protection for the user of the product, and those best able to afford it are the suppliers of the chattel. By placing their goods upon the market, the suppliers represent to the public that they are suitable and safe for use; and by packaging, advertising and otherwise, they do everything they can to induce that belief . . . .

Id. (citing 50 Minn. L. Rev. 791, 799 (1966)).

The Court further endorsed this vision of Nevada's common law tort principles, explaining that "[t]his concept of 'public interest' is the guiding principle of our present opinion." *Id.* Indeed, Nevada law has viewed products liability law in this light for over fifty years. *See Stackiewicz v. Nissan Motor Corp.*, 686 P.2d 925, 926–27 (Nev. 1984) (providing an overview of the evolution of products liability law in Nevada); *Shoshone Coca-Cola Bottling Co. v. Dolinski*, 420 P.2d 855, 857 (Nev. 1966) (adopting the California Supreme Court's expansion of strict liability doctrines).

Recently, Nevada has reaffirmed its commitment to providing the "maximum possible protection" for consumers and has rejected attempts to narrow liability. *Ford Motor Co. v. Trejo*, 402 P.3d 649, 655 (2017) (not requiring the plaintiff to proffer evidence of an alternative feasible design). In *Trejo*, the Court recognized the "unique position of manufacturers" in "establishing the reasonable expectations of a product that in turn cause consumers to demand that product." *Id.* at 529–30. Moreover, the Court has not shied away from following California's lead in products liability cases. *Shoshone*, 420 P.2d at 857. There is, accordingly, no reason for this Court to reject Plaintiffs' "innovator liability" theory.

Rather, following the principle laid out in *Allison*, this Court should assign responsibility for injuries "*wherever* it will most effectively reduce the hazards to life and health inherent in defective products that reach the market." *Allison*, 878 P.2d at 952 (emphasis added). The best, and likely only, way to "effectively reduce the hazards to life and health" arising from inadequate or otherwise defective generic drug labels is to hold the brand-name manufacturer (who exercises complete control over the contents of the drug label) liable for injury resulting from its failure to properly warn of known risks. Indeed, this is the same logic that California relied on when it found a brand-name manufacturer liable for an inadequate drug label included with a generic drug. *See T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 32 (Cal. 2017) ("The brand-name drug manufacturer is the only entity with the unilateral ability to strengthen the warning label. So a duty of care on

behalf of all those who consume the brand-name drug or its bioequivalent ensures that the brand-name manufacturer has sufficient incentive to prevent a known or reasonably knowable harm.").

GSK relies on the unpublished decision *Moretti v. Wyeth, Inc.*, where the federal court read *Allison* to hold that only the manufacturer of a product could be liable to a consumer. No. 2:08-cv-00396-JCM-(GWF), 2009 U.S. Dist. LEXIS 29550, at *9–10 (D. Nev. Mar. 20, 2009). With all respect to the Court in that case, this Court does not read *Allison* for this proposition. Rather, in *Allison*, the Nevada Supreme Court stated that under general tort principles, liability should be assigned "*wherever* it will most effectively reduce the hazards to life and health inherent in defective products that reach the market." *Allison*, 878 P.2d at 952 (emphasis added). Under the facts of that *particular* case, the risk of loss was most appropriately allocated to the manufacturer. *Allison* never held, however, that only the manufacturer of a specific item could be liable for damages. Further, because the MDL Court relied on *Moretti* to predict that the Nevada Supreme Court would reject "innovator liability," but does not address the guiding principles outlined in *Allison*, the MDL Court's opinion is not persuasive. *In re Zantac*, 510 F. Supp. at 1219.

GSK also cites to *Dow Chem. Co. v. Mahlum*, where the Nevada Supreme Court stated that "[t]he duty to disclose requires, at a minimum, some form of relationship between the parties." 114 Nev. 1468, 1486 (1998). The Court in *Dow Chemical*, however, was not faced with the unique federal regulatory scheme in place in this situation. Moreover, GSK had a duty created by federal law to disclose to the public any defects in its drug. *Rafferty*, 92 N.E.3d at 1209 ("the manufacturer must also show that the proposed warning label for the drug is accurate and adequate." (citing 21 U.S.C. § 355(b)(1). And once GSK "assumed the duty to supervise and exert control" over the New Drug Application ("NDA"), "it had to do so in a reasonably prudent manner." *Wright v. Schum*, 781 P.2d 1142, 1146 (Nev. 1989). The Court therefore holds that, under the facts as alleged in the Second Amended Complaint, GSK did owe a duty to Plaintiffs under Nevada law.

Lastly, GSK urges this Court to reject what it styles "predecessor liability," which it defines in its brief as the theory "according to which a brand-name company can be held liable even after it transfer the NDA to a different company, if it was foreseeable that the successor would rely on the predecessor's labeling decisions." The Court agrees with the Supreme Court of California,

however, that a brand-name manufacturer's sale of the rights to a drug does not, as a matter of law, terminate its liability for injuries foreseeably and proximately caused by deficiencies present in the warning label prior to the sale. *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017). This is because "significant moral blame attaches to the failure to warn about a drug's risks when the brand-name drug manufacturer knew or should have known about those risks. The fact that the brand-name manufacturer has since exited the market does not alter the calculus." *Id.* at 46–47.

Moreover, as argued by counsel for Plaintiffs at oral argument, even if GSK lost the ability to alter or change the warning label when it sold its rights in the NDA, it still allegedly had knowledge about the risk of cancer associated with ranitidine and still had the ability to alert the public or the FDA. Lastly, GSK's theory—that the sale of a New Drug Application prospectively cuts off a manufacturer's liability moving forward—creates a perverse incentive for brand-name manufacturers to conceal defects in their drugs and then sell them off to limit their liability.

Lastly, GSK argues that Nevada law precludes Plaintiff from recovering for personal injury for a negligent misrepresentation. According to GSK, Plaintiff's damages for negligent misrepresentation are limited to pecuniary or "out-of-pocket" loss only. For instance, Plaintiffs would be limited to their special damages and, as alleged in the Complaint in Plaintiffs' prayer for relief, funeral expenses. Plaintiffs' counsel moved orally at the hearing for leave to file a surreply addressing these arguments. Plaintiffs' motion for leave to file a surreply is denied without prejudice, and the Court takes the matter regarding whether Plaintiffs damages are limited to their out-of-pocket expenses under advisement.

THEREFORE, the Motion is DENIED WITHOUT PREJUDICE.

~~IT IS SO ORDERED this _____ day of _____ 2022.~~

Dated this 9th day of September, 2022

DISTRICT COURT JUDGE

4D9 CF5 DCF8 0DB7
Joe Hardy
District Court Judge

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Respectfully submitted:

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From:	Justin Hepworth
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Cc:	Mike Kane; Amber Casteel; adam@krauseandkinsman.com; Jonathan Hilton
Subject:	RE: Husrom v. Las Vegas Medical Group (A-21-835385-C) Orders on Brand Defendants Motion to Sever and Glaxosmithkline MTD
Date:	Monday, May 23, 2022 7:10:52 AM
Attachments:	image001.png image002.png Order Denying Defendant Glaxosmithkline LLC Motion to Dismiss for Lack Personal Jurisidiction and Failure to State a Claim - Defense Edits58.docx

Once you make Erika's changes, you may also affix my electronic signature to the order the motion to sever.

As for the order on GSK's motion to dismiss, attached you will find our proposed changes. Please let me know if we need to discuss.

From: Erika Turner <eturner@Gtg.legal>
Sent: Wednesday, May 18, 2022 8:53 AM
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Subject: RE: Husrom v. Las Vegas Medical Group (A-21-835385-C) Orders on Brand Defendants Motion to Sever and Glaxosmithkline MTD

Brandon,

With the attached minor comments, you have permission to affix my e-signature.

Erika

Erika Pike Turner
Partner

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From: Brandon Born <Brandon@the702firm.com>
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Subject: RE: Husrom v. Las Vegas Medical Group (A-21-835385-C) Orders on Brand Defendants Motion to Sever and Glaxosmithkline MTD

Counsel,

Attached are our proposed Order Denying Brand Defendants' Motion to Sever and Order Denying Defendant GlaxoSmithKline LLC's Motion to Dismiss for Lack of Personal Jurisdiction and Failure to State a Claim. Please let me know if you have any proposed revisions or if we have permission to affix your e-signature for submission.

Best,

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CSERV

DISTRICT COURT
CLARK COUNTY, NEVADA

Yasmin Husrom, Plaintiff(s) vs. Las Vegas Medical Group LLC, Defendant(s)	CASE NO: A-21-835385-C DEPT. NO. Department 15

AUTOMATED CERTIFICATE OF SERVICE

This automated certificate of service was generated by the Eighth Judicial District Court. The foregoing Order Denying was served via the court's electronic eFile system to all recipients registered for e-Service on the above entitled case as listed below:

Service Date: 9/9/2022

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